

**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, 2020

OR

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

Commission File Number 001-39539

**PMV PHARMACEUTICALS, INC.**

(Exact name of Registrant as specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**8 Clarke Drive, Suite 3**  
**Cranbury, NJ**  
(Address of principal executive offices)

**46-3218129**  
(I.R.S. Employer  
Identification No.)

**08512**  
(Zip Code)

Registrant's telephone number, including area code: (609) 642-6670

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.00001	PMVP	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the 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 15(d) of the 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, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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 voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on December 31, 2020, was \$1,920,312,921. The Registrant has elected to use December 31, 2020, which was the last business day of the Registrant's most recently completed fiscal year, as the calculation date because on June 30, 2020 (the last business day of the Registrant's most recently completed second fiscal quarter), the Registrant was a privately-held company. Shares of the Registrant's common stock held by each executive officer, director and holder of 10% or more of the outstanding common stock have been excluded because such persons may be deemed affiliates. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose.

The number of shares of Registrant's Common Stock outstanding as of February 28, 2021 was 44,782,566.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement relating to the 2021 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. The proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2020.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, development plans, planned preclinical studies and clinical trials, future results of clinical trials, expected research and development costs, regulatory strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements

In some cases, you can identify forward-looking statements by terms such as “may”, “will”, “should”, “would”, “expect”, “plans”, “anticipate”, “could”, “intend”, “target”, “project”, “contemplate”, “believe”, “estimate”, “predict”, “potential” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- our financial performance;
  - the sufficiency of our existing cash, cash equivalents and short-term marketable securities to fund our future operating expenses and capital expenditure requirements;
  - our need to raise additional funding before we can expect to generate any revenues from product sales;
  - our ability to obtain additional funding for our operations, when needed, including funding necessary to complete further development and commercialization of our product candidates, if approved;
  - the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
  - the implementation of our strategic plans for our business and product candidates;
  - the size of the market opportunity for our product candidates and our ability to maximize those opportunities;
  - the initiation, timing, progress and results of our research and development programs, preclinical studies, any clinical trials and investigational new drug applications, or IND, and other regulatory submissions;
  - the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
  - our estimates of the number of patients expected to have certain p53 mutants and the number of patients that will enroll in our clinical trials;
  - the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other favorable results;
  - our plans relating to the clinical development of our product candidates, including the disease areas to be evaluated;
  - the timing, progress and focus of our clinical trials, and the reporting of data from those trials;
  - our ability to obtain and maintain regulatory approval of our product candidates;
  - our plans relating to commercializing our product candidates, if approved;
  - the expected benefits of potential future strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise;
  - the success of competing therapies that are or may become available;
  - the timing or likelihood of regulatory filings and approvals, including our expectation to seek accelerated reviews or special designations, such as breakthrough therapy and orphan drug designation, for our product candidates;
  - our plans relating to the further development and manufacturing of our product candidates, including for additional indications that we may pursue;
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- existing regulations and regulatory developments in the United States and other jurisdictions;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- our plan to rely on third parties to conduct and support preclinical and clinical development;
- our ability to retain the continued service of our key personnel and to identify, hire and then retain additional qualified personnel;
- the impact of the ongoing COVID-19 pandemic or other related disruptions on our business; and
- our expectation regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions described in the section titled “Item 1A. Risk Factors” and elsewhere in this Annual Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

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## PART I

### Item 1. Business.

We are a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53 mutations. p53 is a well-defined tumor suppressor protein known as the “guardian of the genome,” and normal, or wild-type, p53 has the ability to eliminate cancer cells. However, mutant p53 proteins can be misfolded and lose their wild-type tumor suppressing function. These p53 mutations are found in approximately half of all cancers. The field of p53 biology was established by our co-founder Dr. Arnold Levine when he discovered the p53 protein in 1979. We have leveraged more than four decades of research experience and developed unique insights into p53 to create a precision oncology platform designed to generate selective, small molecule, tumor-agnostic therapies that structurally correct specific mutant p53 proteins to restore their wild-type function. We are deploying our precision oncology platform to target the top ten most frequent, or hotspot, p53 mutations that are collectively associated with approximately 10-15% of all cancers.

Our lead product candidate, PC14586, is an orally available small molecule designed to potently and selectively correct p53 misfolding caused by a specific p53 mutation, Y220C, while sparing wild-type p53. The Y220C mutation is associated with 1.0-1.5% of all cancers, including breast, non-small cell lung cancer, or NSCLC, colorectal, pancreatic and ovarian cancers. PC14586 is designed to restore the wild-type conformation by occupying the crevice created by the tyrosine to cysteine mutation in amino acid position 220. While we are in the early stages of discovery and development of our product candidates and our novel approach is unproven, we are initially pursuing a tumor-agnostic development strategy and initiated a Phase 1/2 clinical trial in October 2020. Our strategy is to seek approval under an accelerated pathway, and we believe our Phase 1/2 clinical trial has the potential to serve as a pivotal study. In October 2020, we were granted U.S. Food and Drug Administration, or the FDA, Fast Track designation of PC14586 for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation. We dosed our first patient in this clinical trial in the fourth quarter of 2020. We cannot guarantee that the FDA will agree with this strategy of utilizing the Phase 1/2 clinical trial as a pivotal study, which could require us to conduct additional clinical trials prior to seeking FDA approval. In addition, we are leveraging our precision oncology platform to develop a pipeline of oral small molecule product candidates that structurally correct other p53 hotspot mutations to restore their wild-type function.

A better understanding of mutations that drive cancers have facilitated the development of precise, gene- and protein-specific drugs known as targeted therapies. Targeted therapies have the potential to transform treatment of some cancers by providing robust clinical benefit to patients. In many cases, clinical responses can be dramatic enough to support expedited regulatory approval of these therapies. Further, recent advancements in next-generation-sequencing, or NGS, have accelerated the development of targeted therapies. A recent study found that 75% of oncologists in the United States employ genetic sequencing. We believe p53 mutations are particularly well-suited for the evolving precision oncology paradigm, as a single mutation can cause p53 malfunction, and p53 is one of the genes commonly sequenced, to our knowledge, in NGS panels. We believe that our precision oncology platform offers a substantial opportunity to expand the number of patients who will benefit from targeted therapies.

Our innovation engine consists of three complementary drivers:

- deep understanding of, and leadership in, p53 biology that enable unique insights into targeting individual mutations;
- ability to design structure-based oral small molecule product candidates that selectively target and correct specific p53 mutants; and
- assays, screens, preclinical model systems and biomarkers that enable us to assess and optimize selective small molecule product candidates for specific p53 mutants.

## PC14586 and Pipeline

We are leveraging our precision oncology platform to develop a pipeline of orally available, potent and highly selective small molecule product candidates that are designed to structurally correct specific mutant p53 proteins to restore their wild-type function. An overview of our development pipeline is shown in the table below.



- (1) In Discovery, we screen compounds against biological assays to identify lead compounds with selective activity to our specific mutant p53 target of interest.
- (2) In Lead Optimization, we modify the lead compound to improve potency, selectivity, pharmacokinetic and toxicity parameters and physical chemical properties important for clinical development.
- (3) In IND-Enabling Studies, we conduct preclinical studies, in accordance with Good Laboratory Practice, or GLP, required for an IND submission to the FDA.

Our lead product candidate, PC14586, is designed to be an orally available small molecule that structurally corrects the mutant p53 protein with the Y220C mutation. The Y220C mutation results from tyrosine being substituted by a cysteine at amino acid position 220 and is associated with 1.0-1.5% of all cancers, including breast, NSCLC, colorectal, pancreatic and ovarian cancers. There are currently no products approved by the FDA, and we are not aware of any other products in clinical development, that selectively target the p53 Y220C mutation.

PC14586 is designed to bind to the mutation site and structurally correct the misfolded p53 protein, while sparing wild-type p53. Our approach has yielded a highly selective product candidate, which we believe can maximize the potential therapeutic potency and minimize risk to normal functioning cells. In preclinical studies, PC14586 has shown selective on-target activity (*i.e.*, primarily functions in cells with the p53 Y220C mutation) and exhibited robust anti-tumor activity evidenced by potent tumor growth inhibition, or TGI, and strong tumor regression as a single agent. In these studies, PC14586 also induced the expression of Macrophage Inhibitory Cytokine-1, or MIC-1, which is an established biomarker for wild-type p53 activity that can be measured non-invasively in the blood in animal models as well as in humans. Further, preclinical studies have demonstrated significant synergistic effects in combination with anti-PD-1 therapy.

We initiated a Phase 1/2 clinical trial for PC14586 in October 2020. In addition, we were granted FDA Fast Track designation of PC14586 for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation in October 2020. We dosed our first patient in this clinical trial in the fourth quarter of 2020. The Phase 1 portion of the trial is designed to evaluate escalating doses of PC14586 to determine the maximum tolerated dose, or MTD, and recommended Phase 2 dose of PC14586 when administered orally to patients on a once daily dosing schedule. Safety, tolerability and effects on biomarkers such as MIC-1 will also be assessed. The Phase 1 portion is also designed to assess preliminary anti-tumor efficacy in patients with advanced solid tumors that have the p53 Y220C mutation. In the Phase 2 portion, we plan to evaluate the objective response rate, or ORR, and duration of response, or DoR, in patients with advanced solid tumors that have the p53 Y220C mutation. We initially intend to pursue an accelerated approval on the basis of this Phase 1/2 clinical trial for a tumor-agnostic indication for PC14586, subject to discussions with FDA and other health authorities.

We believe the mechanism of action employed by PC14586 to structurally correct a specific p53 mutant and restore wild-type p53 activity could offer a unique value proposition in oncology, and is a strategy that can be pursued broadly across other p53 mutations. To that point, we are developing a pipeline of candidates targeting other p53 hotspot mutations. We have other preclinical programs that have demonstrated biochemical validation, for which we are leveraging knowledge from our PC14586 Y220C program. We believe we can scale our discovery and development principles across all p53 hotspot mutations to streamline the process of further developing our pipeline.

### Our Strategy

Our vision is to become a leading precision oncology company by designing, developing and commercializing novel precision medicines for every patient with a tumor containing a p53 mutation. We believe we are well positioned to leverage our deep experience in p53 biology, precision oncology platform and foundational knowledge acquired through our lead program to bring these therapies to patients. The critical components of our strategy include:

- **Advancing our lead product candidate, PC14586, as a tumor-agnostic, oral small molecule single-agent therapy for cancer patients.** We have designed PC14586 to be an orally available, tumor-agnostic therapeutic and, if approved, we believe it could become the first agent to address the p53 Y220C mutation-defined patient population. In October 2020, we initiated a Phase 1/2 clinical trial for PC14586 in multiple solid tumors with the p53 Y220C mutation. We plan to conduct our clinical trials in this genetically-defined patient population and leverage learnings from recently approved tumor-agnostic drugs to inform the clinical and regulatory pathways for PC14586. If successful in achieving clinically meaningful anti-tumor efficacy in patients with p53 Y220C mutations across a range of solid tumor types, we plan to meet with regulatory authorities to discuss the potential to pursue approval for a tumor-agnostic label under the FDA's accelerated approval pathway. In addition to the recent Fast Track designation by the FDA, we also plan to explore pursuing other expedited regulatory pathways, such as breakthrough therapy designation and orphan drug designation for PC14586.
- **Harnessing the power of our precision oncology platform to discover and develop additional differentiated product candidates that are designed to precisely target p53 mutations in cancer.** We believe that the general principles for our PC14586 Y220C program can be applied to other p53 hotspot mutations. Using our extensive in-house expertise, deep understanding of chemistry and decades of experience researching the p53 protein, we believe that we will be able to leverage and apply foundational knowledge from the advancement of PC14586 to the discovery and development of small molecules targeting other p53 mutations. We are advancing several early-stage programs focused on targeting the p53 hotspot mutations, including our R273H program. In an ongoing effort to bring forward new product candidates, we plan to continue to invest in our precision oncology platform, including our high-throughput screens that allow for quantitative visualization of the conversion from mutant to wild-type p53 in a dose-dependent manner.
- **Leveraging the advantages of precision medicine and our expertise in p53 biology to pursue accelerated approval of our product candidates.** For our lead product candidate, PC14586, we are actively working with physicians and leading academic centers to enroll patients with the p53 Y220C mutation identified through NGS in our Phase 1/2 clinical trial. In order to rapidly confirm mechanistic and clinical proof of concept, we utilize assays to measure target engagement and biomarkers, as well as assess clinical responses in patients. We expect this strategy, which we also plan to replicate for our other future product candidates, will enable a rapid determination of target engagement and has potential to serve as a predictive marker of efficacy, thereby providing clear decision points for clinical development and efficient advancement of our product candidates towards approval. If we obtain early and encouraging clinical results, we may seek breakthrough therapy designation from the FDA, which, if granted, is intended to expedite clinical development and regulatory review. We intend to maximize the benefit of our product candidates by pursuing a tumor-agnostic approach.
- **Identifying and exploring combination therapy approaches for our product candidates.** Though PC14586 has demonstrated clear and robust tumor regression as a single agent in preclinical animal models, we believe that the mechanism of correcting the structure of mutant p53 can be complementary to

other oncology therapies. Leveraging our expertise in p53 biology, chemistry and cancer pharmacology, we plan to identify and explore combination strategies with multiple cancer therapies. For example, chemotherapy and radiation therapy, approaches that result in DNA damage, upregulate p53 and are natural candidates for combining with our product candidates. In addition, we believe that p53 plays a role in influencing the tumor microenvironment. Therefore, immune checkpoint inhibitors, such as anti-PD-1 and anti-CTLA-4 agents, could also be considered as potential combination agents for use with our product candidates. We believe that our unique expertise will enable us to prioritize therapeutic strategies and optimize outcomes for clinical studies.

### **Our History and Team**

We believe we have established a leadership position in the discovery and development of oral small molecule therapies targeting mutant p53. Founded in 2013 by David Mack, Ph.D., Arnold Levine, Ph.D. and Thomas Shenk, Ph.D., we have built a precision oncology platform and chemistry discovery engine that leverages more than four decades of research experience and unique insights into the p53 protein. Dr. Levine is widely recognized for his seminal contributions to the field of p53 biology, having discovered p53 in 1979.

We have assembled a team with significant experience in drug discovery and development, with particular expertise in the discovery of small molecule oncology programs. Dr. Mack, our President and Chief Executive Officer, was previously General Partner at Alta Partners and co-founder and Vice President of Genomic Research at Eos Biotechnology, where he led the advancement of multiple product candidates prior to the company's sale to Protein Design Labs. Winston Kung, our Chief Operating Officer and Chief Financial Officer, was previously Vice President of Business Development and Global Alliances at Celgene and Chief Business Officer of Celgene Cellular Therapeutics. Leila Alland, M.D., our Chief Medical Officer, is an oncologist with 20 years of experience developing oncology products in the biopharmaceutical industry, most recently as Chief Medical Officer of Affimed. Deepika Jalota, Pharm.D., our Chief Regulatory and Quality Assurance Officer, was previously Vice President in Oncology Regulatory Affairs at Bayer and led the tumor-agnostic regulatory strategy for larotrectinib (Vitrakvi) in collaboration with Loxo Oncology.

Our company was founded and continues to be supported by world-class scientific advisors, including our scientific advisory board, or SAB:

- Scott Lowe, Ph.D.—Chair, Cancer Biology and Genetics Program, Sloan Kettering Institute, Chair, Geoffrey Beene Cancer Research Center, Memorial Sloan Kettering and co-founder of ORIC Pharmaceuticals (Nasdaq: ORIC);
- Richard Heyman, Ph.D.—Vice Chair of the Board of Trustees at the Salk Institute, former Chief Executive Officer of Aragon Pharmaceuticals (acquired by Johnson & Johnson (NYSE: JNJ)), co-founder and former Chief Executive Officer of Seragon Pharmaceuticals (acquired by Roche Genentech), and co-founder, Chairman and former Chief Executive Officer of ORIC Pharmaceuticals (Nasdaq: ORIC);
- Michael Jung, Ph.D.—Distinguished Professor of Chemistry and Biochemistry at University of California, Los Angeles, and co-founder of Aragon Pharmaceuticals (acquired by Johnson & Johnson (NYSE: JNJ)) and Seragon Pharmaceuticals (acquired by Roche Genentech), and co-discovered Xtandi, an FDA-approved prostate cancer drug licensed to Medivation (acquired by Pfizer (NYSE: PFE)), and Erleada, an FDA-approved prostate cancer drug developed by Aragon Pharmaceuticals and acquired by Johnson & Johnson;
- Arnold Levine, Ph.D.—Professor Emeritus, School of Natural Sciences Biology, Institute of Advanced Studies;
- Guillermina Lozano, Ph.D. —Chair, Department of Genetics, The University of Texas MD Anderson Cancer Center;
- Frank McCormick, Ph.D., F.R.S.—Professor at the UCSF Helen Diller Comprehensive Cancer Center, co-founder of Bridge Bio and Onyx Pharmaceuticals and initiated and led drug discovery efforts that led to approval of Nexavar, an FDA-approved drug for liver, thyroid and kidney cancer;



- Charles Sawyers, M.D.—Marie-Josée and Henry R. Kravis Chair in Human Oncology and Pathogenesis, Memorial Sloan Kettering, co-founder of Aragon Pharmaceuticals (acquired by Johnson & Johnson (NYSE: JNJ)), Seragon Pharmaceuticals (acquired by Roche Genentech), and ORIC Pharmaceuticals (Nasdaq: ORIC), and member of the board of directors of Novartis (NYSE: NVS), and co-discovered Xtandi, an FDA-approved prostate cancer drug licensed to Medivation and Erleada, an FDA-approved prostate cancer drug developed by Aragon Pharmaceuticals and acquired by Johnson & Johnson;
- Thomas Shenk, Ph.D.—James A. Elkins Professor of Life Sciences in the Department of Molecular Biology at Princeton University; and
- Karen Vousden, Ph.D.—Chief Scientist at Cancer Research UK (CRUK), Group Leader at the Francis Crick Institute and member of the board of directors of Bristol-Myers Squibb (NYSE: BMY).

### **Background on Targeted Therapies**

Cancer is a genetic disease that results from changes in a person's DNA that causes cells to grow and divide uncontrollably. Genes are the distinct segments in a cell's DNA that can encode proteins with structural or functional roles in the body. Alterations in some genes can lead to the expression of mutant proteins with impaired or abnormal functions that can cause cancer. Cancer has historically been both diagnosed and treated based on a tumor's organ site, such as the breast, lung, ovary, brain, pancreas, skin, bone or blood.

Recent advances in genetic sequencing and a better understanding of the genetic alterations that drive tumor development and growth have facilitated precise, gene and protein-specific drug development, known as targeted therapies. Targeted therapies have the potential to transform treatment of some cancers by providing robust clinical benefit to patients. In notable cases, the clinical outcomes have been dramatic enough to support expedited regulatory approval of these therapies. For example, Retevmo in RET-altered NSCLC and thyroid cancers (Lilly/Loxo); Ayvakit, in platelet-derived growth factor receptor alpha exon 18 mutated advanced gastrointestinal stromal tumor, or GIST (Blueprint); Rozlytrek, in solid tumors with a neurotrophic tropomyosin receptor kinase, or NTRK, gene fusion (Roche); Vitrakvi, in solid tumors with an NTRK gene fusion (Loxo/Bayer); Zykadia, in anaplastic lymphoma kinase-positive, or ALK+, advanced NSCLC (Novartis); Zelboraf, in advanced melanoma with a BRAF V600E mutation (Roche Genentech); Xalkori, in ALK+ advanced NSCLC (Pfizer); Tagrisso, in epidermal growth factor receptor mutation-positive, or EGFR+, advanced NSCLC (AstraZeneca); and Qinlock, in GIST (Deciphera), all received approvals within five years of first dosing in humans. This time period is significantly reduced compared to conventional drug development timelines. Despite this progress, a recent analysis found that only 8% of patients with metastatic cancer have tumors with genetic profiles eligible for treatment with an approved targeted agent, which leaves a large opportunity for precision oncology.

There is an emerging change in the development of targeted therapies, in that cancer is increasingly being targeted through a tumor-agnostic approach with a focus on selectively targeting a genetic or protein mutation irrespective of tumor type. For example, there are now multiple tumor-agnostic product approvals that are based on a genetic mutation that defines the disease, as opposed to the tumor type. These include the aforementioned Vitrakvi and Rozlytrek approvals as well as the pembrolizumab, or Keytruda, approval in metastatic microsatellite instability-high, or MSI-high, or deficient mismatch repair, or dMMR, solid tumors. We believe that these approvals represent a fundamental shift in the development of targeted therapies and will increasingly lead to cancer being characterized for treatment in a genetic, rather than in a tumor-specific, manner.

The widespread recognition that cancer is a genetic disease, as much as it is a disease defined by histology or anatomical location, has driven the increased use of genetic sequencing, which is now employed by 75% of oncologists in the United States. As technology advances in DNA sequencing, the availability of well-defined genetic sequencing tests increases. With the increasing number of approved targeted therapies, we believe that physicians will seek a better understanding of the underlying genetic and protein abnormalities associated with a specific type of cancer in order to determine the optimal course of treatment. Advances in genetic sequencing are leading to transformations in the discovery and development of new targeted oncology drugs.

We believe p53 mutations are prime targets for precision oncology, as more than 50% of all human cancers contain a p53 mutation. Identifying the specific p53 gene mutation and structurally correcting the corresponding mutant p53 protein can potentially serve as a basis of treatment for these cancers. Diagnostic tests are currently used by physicians in their practice to identify patients with p53 mutations. Given the high prevalence of p53 mutations in cancers, we believe that the best way to address p53-driven cancers is by targeting individual p53 mutations using a precision oncology approach and significantly expand the scope of patients who can benefit from targeted therapies.

### **Background on p53, the Most Frequently Mutated Gene in Human Cancer**

The p53 gene provides instructions for the production of tumor suppression protein p53 and is the most widely mutated gene in human cancers. Since its discovery in 1979 by our co-founder Dr. Arnold Levine, p53 has been extensively studied by researchers and the pharmaceutical industry due to its central role in preventing the initiation and proliferation of liquid and solid tumors. p53 has long been referred to as the “guardian of the genome” because it regulates expression of a number of genes that comprise the body’s first line of cellular defense against cancers. Among its multiple biologic functions, p53 regulates a variety of tumor suppressive responses including cell cycle arrest, DNA repair, senescence and apoptosis.

p53 is a transcriptional factor, which binds to the promoters of its target genes in a sequence-specific manner and regulates their expression, thereby controlling cell cycle and cell death. p53 is activated when DNA damage is detected and when oxidative or other cellular stresses exceed thresholds for normal cellular function. p53 activation facilitates the repair of the cell’s damaged DNA or triggers the killing of the damaged cell through a process known as programmed cell death, or apoptosis, before the cell can become cancerous and proliferate.

Under normal cellular conditions, p53 is kept at low levels by expression of murine double minute 2, or MDM2, a ubiquitin ligase that promotes the degradation of p53. Upon p53 activation by damaged DNA, and other types of stresses, p53 is upregulated and blocks the proliferation of pre-malignant and malignant cells or eliminates them by inducing apoptosis. Mutant p53 loses the ability to eliminate the proliferation of pre-malignant and malignant cells. Given that the mutational status of p53 in a tumor has a strong impact on sensitivity to commonly used anti-cancer drugs and radiotherapy, p53 is important both as a biomarker and as a novel therapeutic target.

A key challenge in the development of p53-targeted therapies is the vast number of p53 mutants that lose tumor suppression activity. To date, more than 25,000 unique p53 mutations have been discovered. The p53 hotspot mutations occur as a result of site-specific substitution of one amino acid for another and lead to loss of tumor suppression function for the p53 protein. Strategies that attempt to restore wild-type p53 activity in a non-selective manner (*i.e.*, regardless of which p53 mutation the tumor is harboring) are likely to face significant challenges, as a “one size fits all” drug is unlikely to address all p53 mutants and could have the potential for off-target toxicities. We are initially focusing on targeting the p53 hotspot mutations.

## Our Focus: Top Ten Most Frequent p53 Mutations

p53 Hotspot Mutation	Frequency Among p53 Mutations
R175H	5.6%
R248Q	4.4%
R273H	4.0%
R248W	3.5%
R273C	3.3%
R282W	2.8%
G245S	2.1%
R249S	2.0%
Y220C	1.8%
V157F	1.0%

### Our Approach to Targeting p53

Our goal is to bring precision oncology therapies to a greater number of patients. Decades of research on p53 has unveiled its potential as a precision oncology target, but prior drug development efforts have been unsuccessful. Mutant p53 historically has been classified as “undruggable” due to the difficulty of restoring wild-type p53 function. Mutations in p53 can give rise to mutant p53 proteins with different conformational structures. As a result, we are designing oral small molecule therapies that selectively target a specific p53 mutation while not binding to wild-type p53. We believe our novel approach designed to reactivate p53 function through the structural correction of mutant p53 protein to wild-type p53 represents a therapeutic strategy to target p53.

Our drug development efforts leverage our understanding that:

- mutations throughout the p53 protein can drive tumor formation and growth;
- a mutant p53 protein resulting from a specific mutation can potentially be structurally corrected by a selective small molecule, thereby reactivating wild-type p53 activity; and
- the p53 hotspot mutations comprise approximately 30% of all p53 mutations and each p53 hotspot mutation represents an individual therapeutic target for drug discovery and development.

We believe we can address certain key limitations of current-generation precision oncology therapies by applying our platform to identify and generate therapies that address functional deficiencies associated with specific p53 mutations. We believe this will allow us to design and develop potential therapies for patients for whom there are currently no targeted treatment options.

### Our Innovation Engine

We have built an innovation engine that allows us to discover and develop potential targeted therapies for mutant p53-driven cancers. This engine consists of three complementary drivers:

- **Deep understanding of, and leadership in, p53 biology that enable unique insights into targeting individual mutations.** We have leveraged more than four decades of research experience and developed unique insights into p53 biology, a field that was discovered and established by our co-founder Dr. Arnold Levine. Additionally, our SAB consists of some of the most prominent thought leaders in p53 biology. p53 is a highly complex gene, and thousands of distinct p53 mutations have been identified. A blanket approach to targeting mutant p53 has significant challenges, as a “one size fits all” drug is

unlikely to address all p53 mutants. Based on our experience and expertise, we are developing oral small molecules that each selectively target a specific p53 hotspot mutation.

- Ability to design structure-based oral small molecule product candidates that selectively target and correct specific p53 mutants.** Designing molecules for p53 mutants requires an intricate understanding of the p53 protein structure and the associated biology. We leverage structure-based technologies to give our oral small molecule product candidates access to challenging binding sites that are generally not accessible using conventional small molecule drug discovery approaches. For each target, we take detailed data from structural and functional studies of mutated p53 proteins to design development candidates against the challenging binding sites. Our design techniques help us to identify potential product candidates that can selectively target a single p53 mutant, while sparing wild-type p53.
- Assays, screens, preclinical model systems and biomarkers that enable us to assess and optimize selective small molecule product candidates for specific p53 mutants.** We test our product candidates across a diverse set of human cancer cells based on research and understanding of bioinformatics and functional genomics. We also identify and monitor pharmacodynamic biomarkers and surrogates of clinical activity to help measure target engagement, including MIC-1, a serum-based biomarker. The biological insights we generate help us to better target various p53 mutants based on their structure and biology. We develop innovative preclinical *in vitro* and *in vivo* models to advance potential therapeutic programs for translation to the clinic.

### Our Product Candidate and Development Programs

We are leveraging our precision oncology platform to develop a pipeline of oral small molecule product candidates that structurally correct other p53 hotspot mutations to restore their wild-type function. We own worldwide commercial rights to all of our programs. An overview of our development pipeline is shown in the table below.

Target	Program	Diseases	Discovery <sup>1</sup>	Lead Optimization <sup>2</sup>	IND-Enabling Studies <sup>3</sup>	Phase 1	Phase 2	Phase 3
p53 Y220C	PC14586	Tumor Agnostic						
p53 R273H	Undisclosed	Tumor Agnostic						

- In Discovery, we screen compounds against biological assays to identify lead compounds with selective activity to our specific mutant p53 target of interest.
- In Lead Optimization, we modify the lead compound to improve potency, selectivity, pharmacokinetic and toxicity parameters and physical chemical properties important for clinical development.
- In IND-Enabling Studies, we conduct preclinical studies, in accordance with GLP required for an IND submission to the FDA.

We expect to initially seek approval of our product candidates in most instances, including with PC14586, at least as a second line therapy or for the patients with no satisfactory alternative treatments or where the cancer has progressed following other treatment. Subsequently, depending on the nature of the clinical data and experience with any approved products or product candidates, if any, we may pursue approval as an earlier line therapy and potentially as a first line therapy. Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA customarily approves new therapies for a second line or later lines of use. When cancer is detected

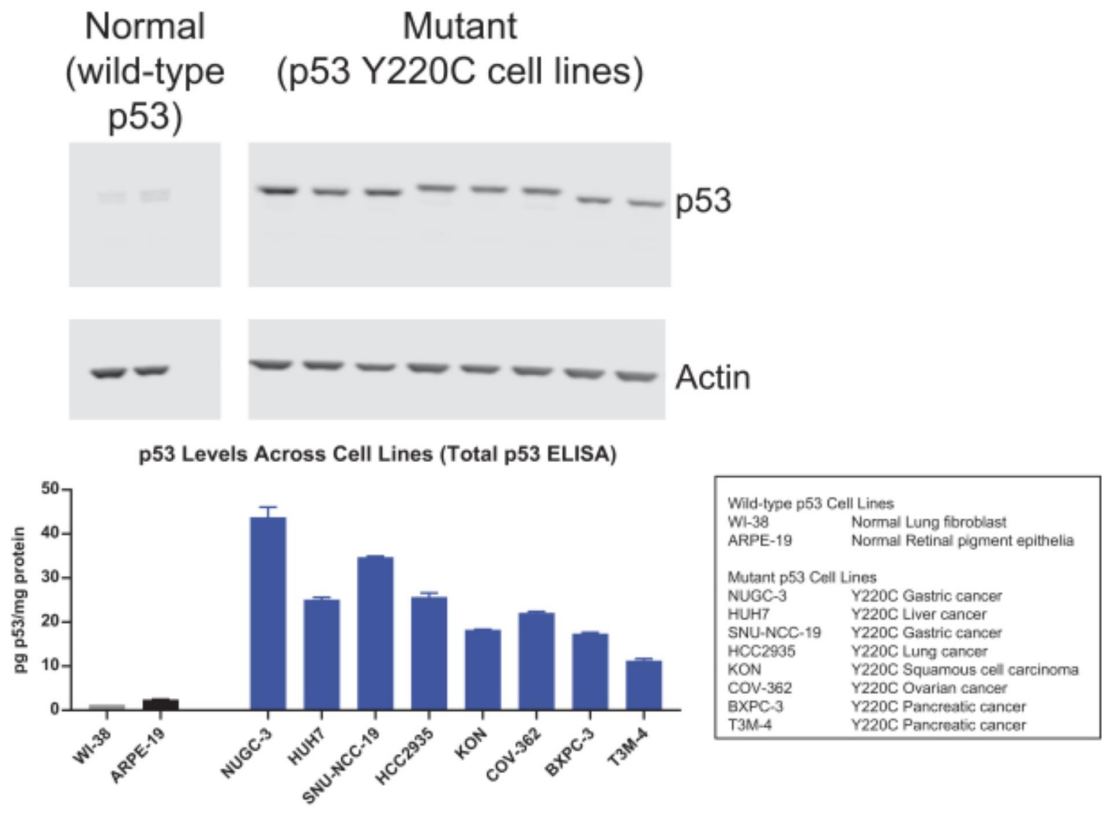
early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapies, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery or a combination of these, proves unsuccessful, second line therapies may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies.

***PC14586: A Selective Structural Corrector of p53 Y220C Mutations***

p53 is the most widely mutated gene in human cancers. The vast majority of these mutations occur as a result of missense mutations that are found in the DNA binding domain. p53 Y220C mutations are found in approximately 1.0-1.5% of all cancers. This particular mutation is expressed in a large variety of solid tumors, including breast, NSCLC, colorectal, pancreatic and ovarian cancers. Our lead product candidate, PC14586, is designed to be an orally available small molecule that structurally corrects a p53 protein containing the Y220C mutation and restores wild-type p53 function.

Wild-type p53 in a normal cell is at low to undetectable levels, but an external insult such as UV radiation or exposure to a carcinogen results in activation and upregulation of the protein. In these instances, wild-type p53 pauses the cell-cycle to survey the integrity of the genome, and if the damage to the genome cannot be repaired, wild-type p53 induces a potent program of cell suicide or programmed cell death. Given wild-type p53's profound ability to induce cell death, it is tightly regulated in normal biology by an auto-regulatory loop with MDM2, a downstream induced target of wild-type p53 transcriptional activation. MDM2 production results in degradation of the wild-type p53 protein and re-sets the cell to normal function.

In the case of a mutant p53, there is a loss of p53 wild-type tumor suppression function due to a loss of downstream wild-type p53 transcriptional activation, including MDM2 induction. A consequence of this dysregulation is the inability of the cancer cell to degrade mutant forms of p53, resulting in a profound accumulation of mutant p53 protein in the cancer cell as shown below for the Y220C mutation.

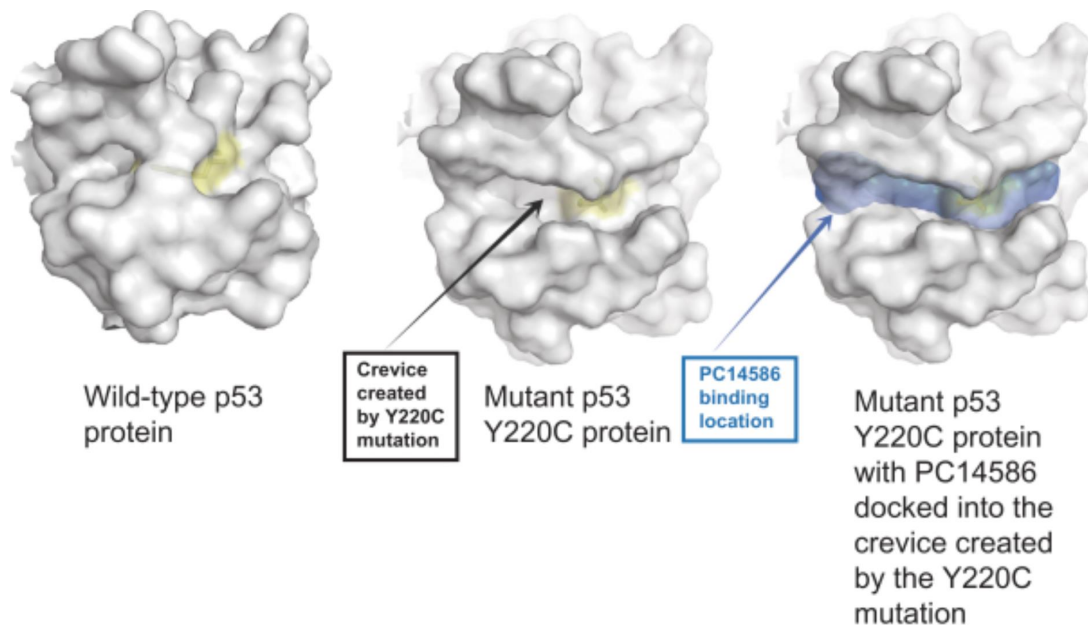


While treatment options such as surgery, chemotherapy, radiotherapy and immuno-therapy are available for breast, NSCLC, colorectal, pancreatic and ovarian cancer, there are no approved precision oncology therapies for the subset of patients with the p53 Y220C mutation. The availability of an oral small molecule selective for the p53 Y220C mutation may offer a novel precision therapy for this population, which we believe could potentially change the treatment paradigm for such patients.

**Mechanism of Action**

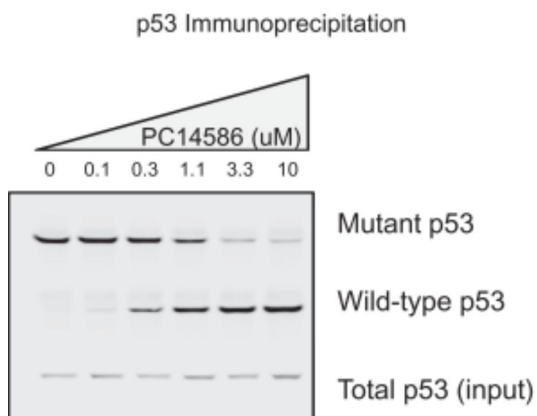
PC14586 is an orally available small molecule candidate that is designed to selectively bind to the crevice created by the p53 Y220C mutation, and thereby restore the wild-type p53 protein structure and tumor suppressing function. In the diagram below, wild-type p53 protein is compared with a mutant p53 Y220C protein and a mutant

p53 Y220C protein with PC14586 bound in the crevice created by the Y220C mutation. By docking into the crevice created by the Y220C mutation, PC14586 is designed to restore the wild-type p53 conformation and function.



In preclinical studies, we have demonstrated that PC14586 rapidly converts the large protein pool of mutant p53 Y220C protein to wild-type structure. As seen in the graphic below, in an *in vitro* study, PC14586 induced conversion of p53 protein from mutant to wild-type conformation in a dose-dependent manner as evidenced by a decrease in mutant p53 and an increase in wild-type p53, while total p53 remains relatively unchanged.

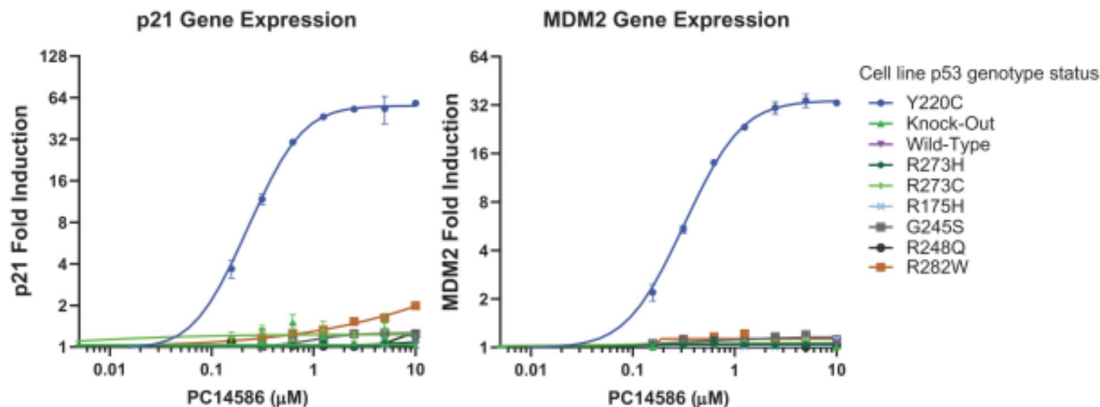
#### PC14586 Demonstrated Structural Conversion from Mutant p53 to Wild-type p53 *in vitro*



PC14586 selectively binds to the crevice created by the Y220C mutation as this molecule does not bind to wild-type p53 or other p53 mutations, including R273H, R273C, R175H, G245S, R248Q and R282W, as demonstrated by the lack of activity (as measured by p21 and MDM2 gene expression seen in the below diagrams). PC14586 only binds to the crevice created by the Y220C mutation, and none of the other tested p53 hotspot mutations, as illustrated by gene expression changes in the Y220C cell line when PC14586 is added in increasing concentrations.

Additionally, structural correction from a mutant p53 Y220C conformation to a wild-type p53 conformation by PC14586 restored p53-dependent transcription of downstream targets, which is indicative of wild-type p53 biological activity. For example, as shown in the figures below, p21 and MDM2, two of the downstream targets of p53, were selectively upregulated by PC14586 in a dose-dependent manner in cells where the p53 Y220C mutation was present. Since PC14586 is highly selective for the p53 Y220C mutation, it did not affect expression levels of p21 and MDM2 in tumor cell lines containing wild-type p53, p53 knock-out or other p53 hotspot mutations as noted in the figures below.

#### PC14586 Induced Transcription of p21 and MDM2 Only in Cell Lines with the p53 Y220C Mutation

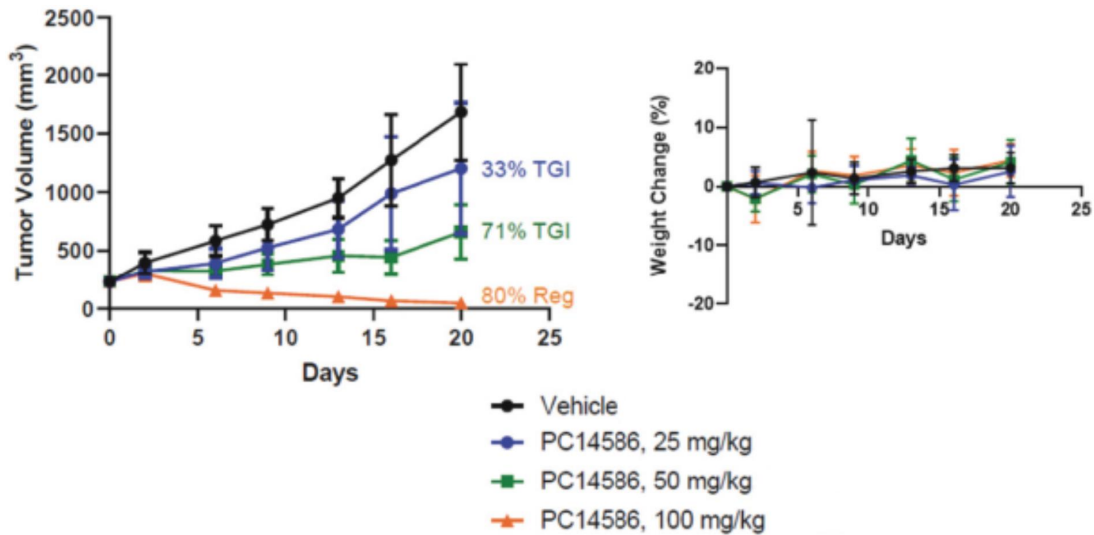


#### Preclinical In Vivo Data

PC14586 exhibited single-agent anti-tumor activity in a dose-dependent manner against mutant p53 Y220C tumors, evidenced by both potent TGI and tumor regression. Oral once-daily dosing over 21 days of PC14586 was well tolerated in nude mice (ten mice per dosing group) bearing p53 Y220C NUGC3 xenograft tumors up to 100 mg/kg, as evidenced by the lack of body weight loss, which is the generally accepted surrogate for toxicity in mice. PC14586 demonstrated dose-dependent TGI at daily doses ranging from 25 mg/kg to 50 mg/kg and robust tumor regression at 100 mg/kg daily.



## PC14586 Single-Agent Administration in NUGC3 Xenograft Model Resulted in Tumor Regression and was Well Tolerated



In preclinical animal studies, PC14586 exhibited fast absorption and a durable plasma exposure, which resulted in robust target engagement that correlated with compound exposure levels. Target engagement was demonstrated by the decrease in mutant p53 Y220C and the increase in the wild-type conformation.

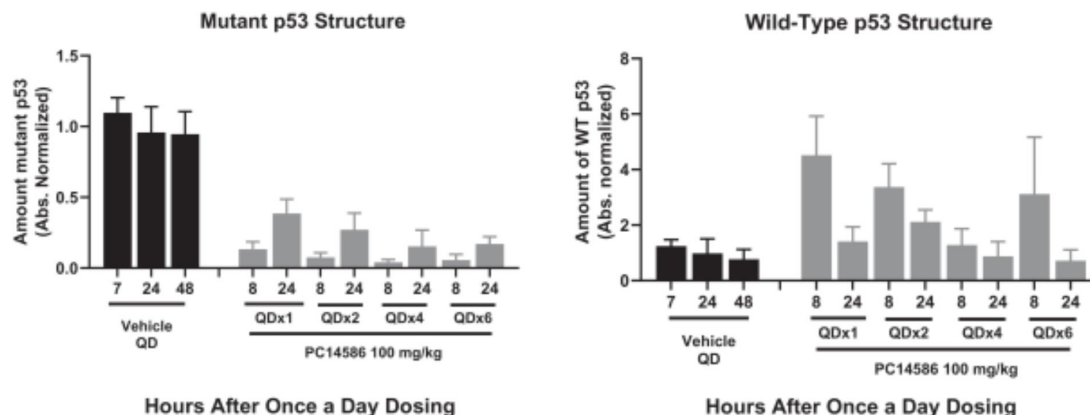
Along with tumor regression, in acute dose pharmacokinetic/pharmacodynamic, or PK/PD, studies, oral administration of PC14586 to xenograft mice bearing the NUGC3 (p53 Y220C) tumors resulted in conversion of mutant p53 protein to a wild-type p53 structure as illustrated in the figure below.

In the mutant p53 structure chart below, the amount of mutant p53 decreased at 8 hours after PC14586 administration on day 1 (QDx1), and the amount of mutant p53 rose by the 24 hour time point compared to the 8 hour time point in the QDx1 portion of the x-axis. When another dose of PC14586 was administered on day 2 (QDx2), the amount of mutant p53 decreased at the 8 hour time point and rose again by the 24 hour time point. The pattern was repeated on the fourth (QDx4) and sixth day (QDx6) of dosing. In all the PC14586 datapoints, the amount of mutant p53 was less than in the vehicle dosing.

In the wild-type p53 structure chart below, the amount of wild-type p53 increased at 8 hours after PC14586 administration on day 1 (QDx1) and the amount of wild-type p53 decreased by the 24 hour time point compared to the 8 hour time point in the QDx1 portion of the x-axis. The pattern was repeated over the second (QDx2), fourth (QDx4) and sixth (QDx6) days of dosing. In all the PC14586 datapoints, the amount of wild-type p53 was greater than in the vehicle dosing.

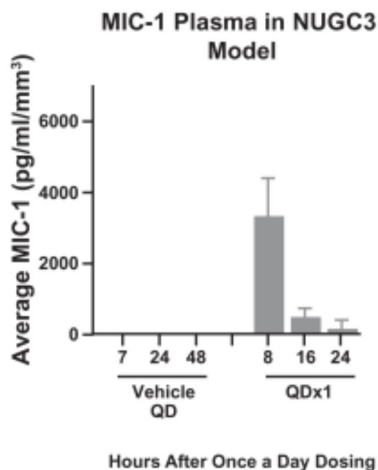
When viewed together, the two charts below show an increase in wild-type p53 corresponding to a decrease in mutant p53 at each of the PC14586 administration time points, which indicate the conversion of mutant p53 to wild-type p53 with the administration of PC14586.

### In vivo Studies, PC14586 Converted Mutant p53 Protein to a Wild-type p53 Structure



Additionally, functional p53 activity in the tumor tissue was also demonstrated (*i.e.*, the induction of wild-type p53 downstream targets). As illustrated in the figure below, PC14586 was observed to induce the expression of the p53 downstream target MIC-1, a clinically validated secreted biomarker of wild-type p53 activity. The administration of PC14586 was associated with an increase in MIC-1 plasma concentration in comparison to the vehicle dosing.

### PC14586 Increased Plasma Concentration of MIC-1, a Clinically Validated Secreted Biomarker of Wild-type p53 Activity

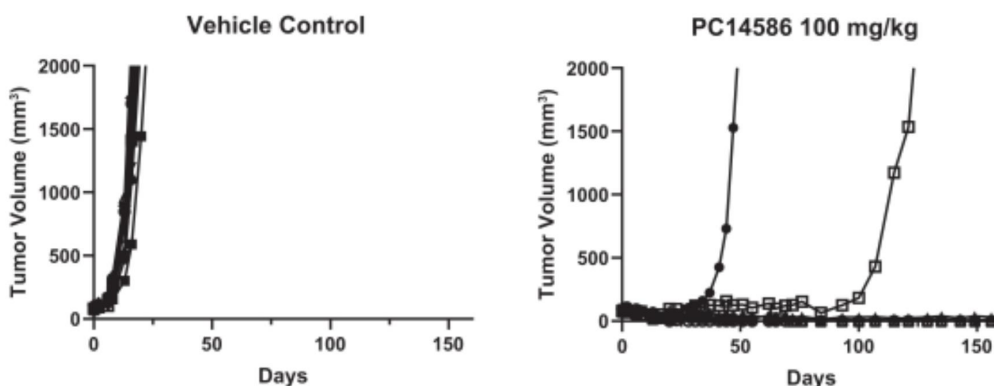


We also created a human p53 knock-in, or HUPKI, mouse that expresses a p53 protein with the human p53 DNA binding domain and the p53 Y220C mutation. The HUPKI mouse presents spontaneously with sarcomas at six to eight months of age, which we can harvest and re-implant in a wild-type mouse to create a mouse tumor model that has an intact immune system harboring a human p53 Y220C mutation. We believe this syngeneic mouse model better represents the patient population that we expect to see in the clinic, as compared to mouse xenograft models

that incorporate human tumors in mice with no immune system. While some patients with cancer may have weakened immune systems, we believe that few patients have severely or fully dysfunctional immunocompromised systems, and therefore a syngeneic model may better represent the patient population than an immunocompromised mouse model. In addition, with an intact immune system, this model allows us to test anti-tumor activity of PC14586 in combination with immune checkpoint inhibitors.

As illustrated by the table below, PC14586, administered as a single-agent at a daily oral dose of 100 mg/kg for 70 days, demonstrated regression in tumors that express the p53 Y220C mutation in the syngeneic mouse model. The durability of the response was measured by median survival, where median survival for a 100 mg/kg dose of PC14586 exceeded 156 days, even though drug treatment was discontinued on day 70. This compared with median survival of only 17 days for the vehicle.

#### PC14586 Tumor Regression and Durable Responses in Syngeneic Mouse Model



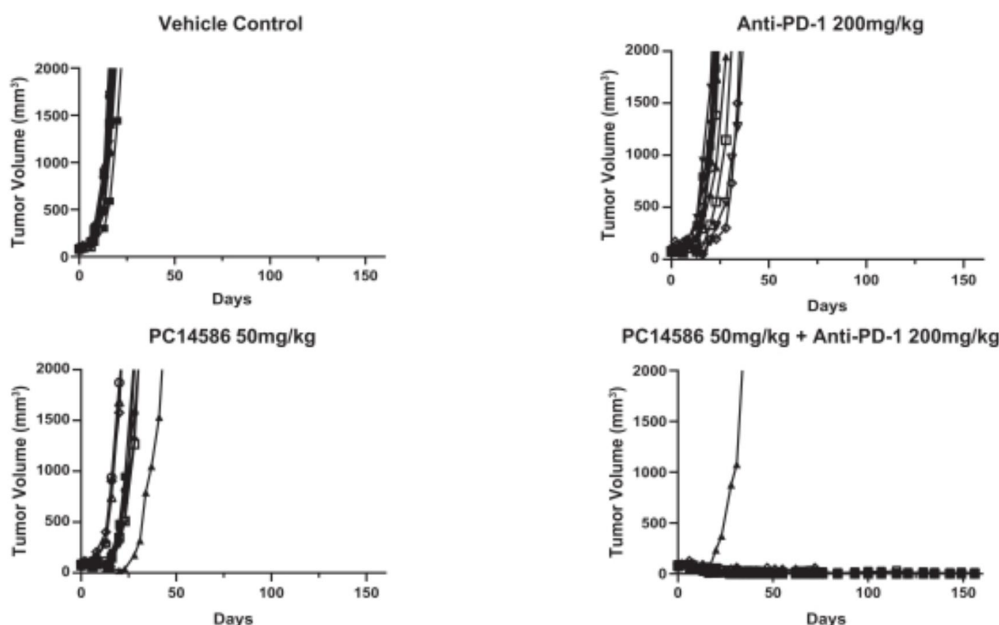
*Note: Each line represents each mouse where each group has 10 mice*

Group	Median Survival Time (Days)
Vehicle	17
PC14586 100 mg/kg	>156

*Note: Dosing ceased on day 70 in the PC14586 arm.*

PC14586 also exhibited anti-tumor activity in combination with anti-PD-1 therapy in syngeneic mouse models with the human p53 Y220C mutation. The scientific rationale for such a combination comes from the emerging literature suggesting an interplay between p53 and the immune system, which is the key mechanism of action of cancer immunotherapies such as anti-PD-1 antibodies. When PC14586 was administered at a sub-therapeutic daily oral dose of 50 mg/kg for 70 days in combination with a therapeutic dose of a PD-1 antibody, regression of tumors that express the p53 Y220C mutation was observed. As illustrated by the table below, median survival for a sub-therapeutic dose of PC14586 combined with anti-PD-1 treatment exceeded 156 days, even though drug treatment was discontinued on day 70, compared with median survival of only 24 days for anti-PD-1 treatment alone.

## PC14586 + Anti-PD-1 Combination Showed Regression of Tumor Growth in Syngeneic Mouse Model



Note: Each line represents each mouse where each group has 10 mice

Group	Median Survival Time (Days)
Vehicle	17
Anti-PD-1 200 mg/kg	24
PC14586 50 mg/kg	28
PC14586 50 mg/kg + Anti-PD-1 200 mg/kg	>156

Note: Dosing ceased on day 70 in the PC14586 + Anti-PD-1 arm.

### Clinical Development Plan

We initiated a Phase 1/2 clinical trial for PC14586 in October 2020. In addition, we were granted FDA Fast Track designation of PC14586 for the treatment of patients with locally advanced or metastatic solid tumors with a p53 Y220C mutation in October 2020. We dosed our first patient in this clinical trial in the fourth quarter of 2020. While we are in the early stages of discovery and development of our product candidates and our novel approach is unproven, we are initially pursuing a tumor-agnostic development strategy. Our strategy is to seek approval under an accelerated pathway, and we believe our Phase 1/2 clinical trial has the potential to serve as a pivotal study. We cannot guarantee that the FDA will agree with this strategy of utilizing the Phase 1/2 clinical trial as a pivotal study, which could require us to conduct additional clinical trials prior to seeking FDA approval. However, based on the pivotal studies conducted by other companies to support the approval of other products, such as studies conducted by Agios (Idhifa) and Blueprint Medicines (Ayvakit), as well as the pivotal studies announced by other companies for their product candidates, including Amgen (sotorasib), Mirati (adagrasib) and Black Diamond Therapeutics (BDTX-189), we believe our Phase 1/2 clinical trial has the potential to serve as a pivotal study. In our Phase 1/2 clinical trial, we plan to enroll patients with advanced solid tumors that harbor the p53 Y220C mutation, characterized by NGS of either a solid or blood-based (circulating tumor DNA) biopsy.

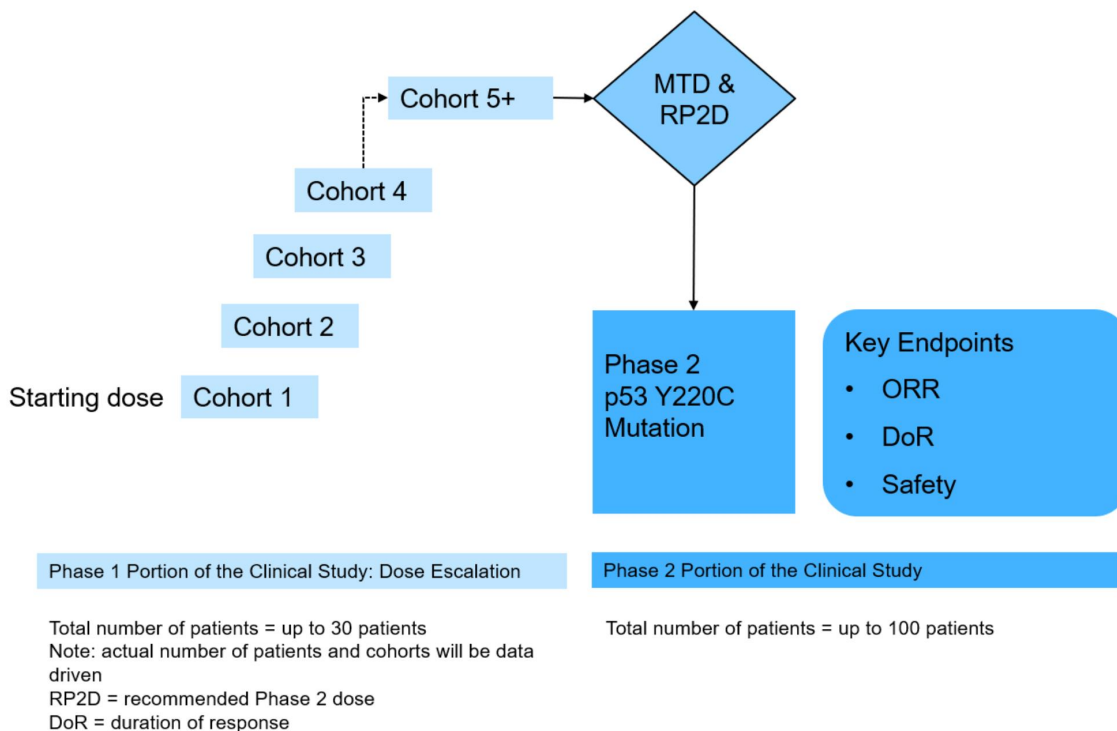
The Phase 1 portion is designed to evaluate escalating oral doses of PC14586 to determine the MTD and recommended Phase 2 dose of PC14586 when administered orally to patients on a once daily dosing schedule, as

well as to assess safety, tolerability and effects on biomarkers such as MIC-1. The Phase 1 portion is also designed to assess preliminary anti-tumor efficacy in patients with advanced solid tumors that have the p53 Y220C mutation. The trial is planned to primarily evaluate once daily dosing, but may also assess more frequent dosing schedules, such as twice daily, if the drug pharmacology or patient tolerability suggest this could be a more efficacious approach. In the Phase 1 portion, we plan to enroll up to 30 patients with locally advanced or metastatic solid tumors that have the p53 Y220C mutation determined using NGS, whose disease has progressed during or after prior standard of care therapy. Multiple biomarker assays will be used in the trial to assess on target and on mechanism activity, and preliminary clinical efficacy in patients will also be assessed.

The Phase 2 portion of the Phase 1/2 clinical trial is expected to enroll up to 100 patients. We expect to enroll a population with a variety of locally advanced or metastatic cancers including breast, NSCLC, colorectal, pancreatic and ovarian cancer. The planned primary objective of the Phase 2 portion is to evaluate the anti-tumor efficacy of PC14586 in patients with the p53 Y220C mutation, as shown by objective response rate. Other secondary endpoints planned to be assessed include the duration of response, progression free survival, overall survival and endpoints to evaluate the safety and tolerability of PC14586.

Patient blood and tumor samples will be collected prior to the start of study treatment for retrospective, confirmatory mutation testing using a central clinical trial assay. In addition, blood and tumor samples will be collected and stored to facilitate future development of a companion diagnostic test.

### PC14586 Phase 1/2 Clinical Trial Design

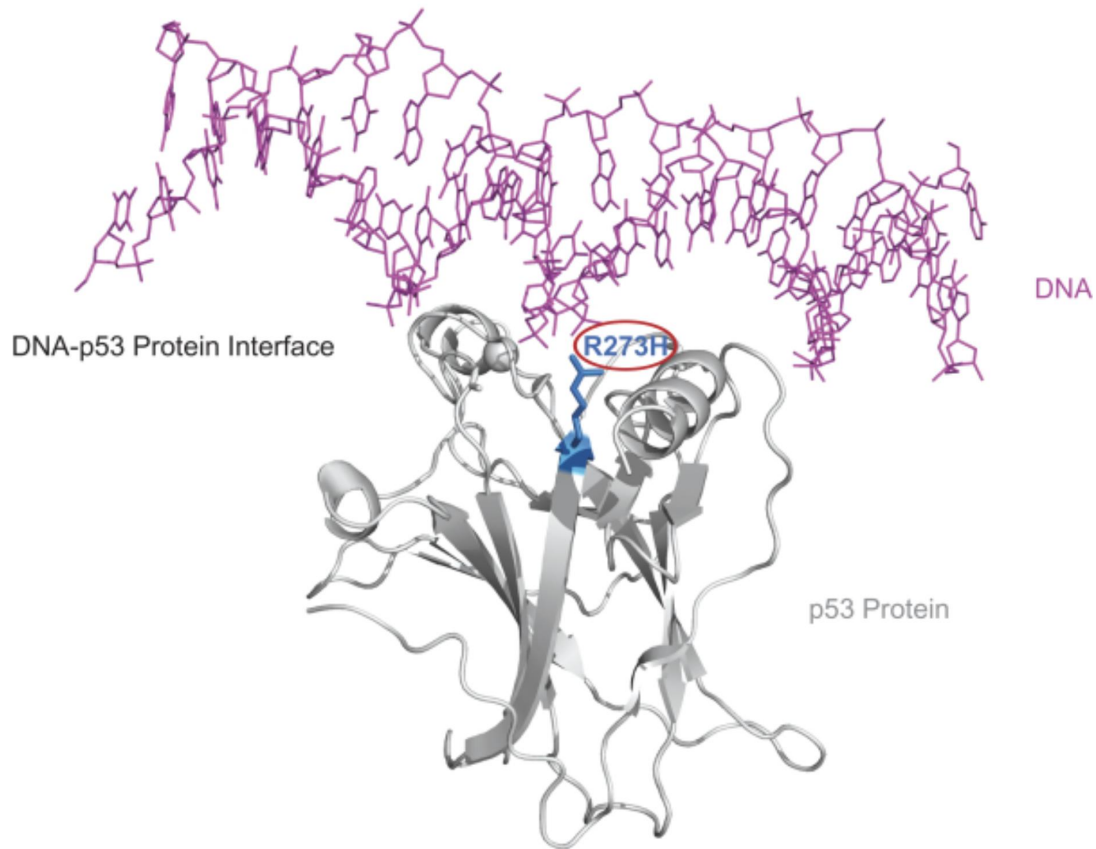


If the data from our Phase 1/2 clinical trial show robust activity across the tumor types, we initially intend to pursue an approval from the FDA under the accelerated approval pathway for a tumor-agnostic indication. This strategy is based on approval pathways utilized by pembrolizumab (Keytruda) in MSI-high/dMMR cancers and larotrectinib (Vitrakvi) and entrectinib (Rozlytrek) in NTRK gene fusion cancers. If we observe clinical benefit in certain tumor or cancer types but do not have sufficient data or powering to support a tumor-agnostic indication from the Phase 1/2 clinical trial, we may seek a tumor or cancer specific label and evaluate additional trials to pursue a broader labeling for PC14586. We believe that the results of the Phase 1/2 clinical trial in PC14586 with respect to the endpoints of ORR and DoR, along with the safety data from the clinical trial, have the potential to support approval of a new drug application, or NDA, subject to discussions with FDA and provided we can obtain data from a sufficient sample size across the tumor types. While accelerated approval cannot be guaranteed, if we obtain accelerated approval, we anticipate that the FDA will require the conduct of a post-approval commitment to confirm clinical benefit.

We may also seek orphan drug or breakthrough therapy designation from the FDA. In addition, we may engage in health authority interactions with agencies outside the United States such as in Europe and Japan, for example. We plan to collaborate with a partner to develop a companion diagnostic test. Further, we expect to initially seek approval of our product candidates, in most instances, including with PC14586, at least as a second line therapy. Subsequently, depending on the nature of the clinical data and experience with any approved products or product candidates, if any, we may pursue approval as an earlier line therapy and potentially as a first line therapy.

### ***R273H: Our Second Program***

R273H is the third most frequent p53 mutation and is found in approximately 4% of all p53 mutations. The R273H mutation results from arginine being substituted by a histidine at amino acid position 273 and is considered a DNA contact mutation. DNA contact mutations affect residues involved directly in DNA-p53 binding but do not alter the p53 protein structure. R273 is one of the most frequently altered residues in human cancer (6.4% of all somatic mutations), with the alteration to a histidine (R273H) being the most common of the R273 mutations.



The R273H mutation causes a decrease in binding between the p53 protein and DNA, resulting in its inability to activate transcription of p53 target genes. We are generating molecules designed to enhance and restore the binding of the p53 protein and DNA. Our R273H program continues to progress towards lead optimization, as we have identified potential candidates from our screening campaigns.

### **Other Pipeline Programs**

In addition to our PC14586 Y220C and R273H programs, we are focused on developing a pipeline of product candidates targeting other p53 hotspot mutations. These programs have been developed internally using our precision oncology platform and expertise.

We are able to utilize the same general principles and similar drug discovery methods developed from our PC14586 Y220C program across other p53 hotspot mutations to facilitate the discovery of additional new product candidates. We study the structural and functional properties of the target. We use assays, screens, preclinical model

systems and biomarkers to assess and optimize selective small molecules for specific p53 mutants. Specifically, many of the efficiencies from assays and model systems developed for our PC14586 Y220C program are being applied to other p53 hotspot mutations. In addition, the key insights gained from the medicinal chemistry campaigns are being leveraged across other p53 hotspot mutations. By leveraging our team's depth of expertise around p53, we are positioned to accelerate our efforts to expand the pipeline of therapies that selectively target p53 hotspot mutations.

### **Competition**

Our industry is intensely competitive and subject to rapid and significant technological change, as well as strong defense of intellectual property. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face substantial competition from major pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

We are a precision oncology company pioneering the discovery and development of small molecule therapies targeting p53 mutations. We are aware of other product candidates that are in clinical development as potential treatments of various cancers through the modulation of p53. There are many product candidates that may affect the p53 pathway, such as through MDM2 inhibition. We are aware of molecules in development that also are being explored for p53 upregulation/activation in various stages of preclinical or clinical development being tested by Actavalon, Aprea Therapeutics, CDG Therapeutics, Cotinga Pharmaceuticals, Innovation Pharmaceuticals and Senhwa Biosciences, among others. We are also aware of selective small molecule inhibitors that are designed to target wild-type p53 containing tumors through the p53-MDM2 interaction, which are in various stages of clinical development being tested by Aileron Therapeutics, Ascentage Pharma, Boehringer Ingelheim, Daiichi Sankyo (out-licensed worldwide rights to Rain Therapeutics), Kartos Therapeutics, Novartis and Roche, including testing MDM2 inhibitors in combination with a variety of other anti-cancer agents.

We face competition with respect to our current product candidates and will face competition with respect to future product candidates, from segments of the pharmaceutical, biotechnology and other related markets that pursue targeted therapies for patients with genetically-defined cancers. If PC14586 or our future product candidates do not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

In addition, we will likely need to develop our product candidates in collaboration with companion diagnostic companies, and we will face competition from other companies in establishing these collaborations. Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy or a combination of such methods. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drug and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Some of these drugs are branded and subject to



patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our product candidates that we successfully introduce to the market will pose challenges. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

### **Manufacturing**

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates undergoing preclinical testing, as well as for clinical testing and commercial manufacture if our product candidates receive marketing approval.

All of our product candidates are small molecules and are manufactured in synthetic processes from available starting materials. The chemistry appears amenable to scale up and does not currently require unusual equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

We generally expect to rely on third parties for the manufacture of companion diagnostics for our products, which are assays or tests to identify an appropriate patient population. Depending on the technology solutions we choose, we may rely on multiple third parties to manufacture and sell a single test.

Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with current Good Manufacturing Practice, or cGMP, requirements which impose certain production, manufacturing, procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP requirements and other aspects of regulatory compliance.

### **Commercialization**

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization to sell our products. We believe that such an organization will be able to address the community of oncologists who are the key specialists in treating the patient populations for which our product candidates are being developed.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

### **Intellectual Property**

We strive to protect the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining and defending patent rights. We also rely on know-how relating to our proprietary technology and product candidates and continuing innovation to develop, strengthen and maintain our proprietary position. We also plan to rely on data exclusivity, market exclusivity and patent term extensions

when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to defend and enforce our proprietary rights, including any patents that we may own in the future; and to operate without infringing the valid and enforceable patents and other proprietary rights of third parties. Intellectual property rights may not address all potential threats to our competitive advantage.

With respect to our existing and future product candidates and processes we intend to develop and commercialize in the normal course of business, we intend to pursue further patent protection covering, when possible, compositions, methods of use, dosing and formulations. We also may pursue patent protection with respect to manufacturing and drug development processes and technologies. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies. We may not be able to obtain patent protections for our compositions, methods of use, dosing and formulations, manufacturing and drug development processes and technologies throughout the world. Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued U.S. patent that is directed to or claims an FDA-approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. This process is called “patent term extension.” The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of biopharmaceuticals has emerged in the United States. The relevant patent laws and their interpretation outside of the United States are also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have, or may obtain, blocking patents of which we are currently unaware that could be used to prevent us from developing or commercializing our product candidates and practicing our proprietary technology. Further, defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, pay royalties or redesign our products. Doing so may be impossible or require substantial time and monetary expenditure. We may also elect to enter into a license agreement to settle litigation or to resolve disputes prior to litigation. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. Should a license to a third party patent become necessary, we cannot predict whether we would be able to obtain a license, or if a license were available, whether it would be available on commercially reasonable terms. If such a license is necessary and a license under the applicable patent is unavailable on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed. This scenario could materially adversely affect our business. Even if we obtain a license to third party intellectual property, we may later

decide, or it may later become necessary, to terminate the license. If we do so, we may no longer be free to use the technology protected by the patents no longer under license. Also, if a competitor developed the technology protected by the patents no longer under license, we would not be able to block the competitor's progress. If the competitor's product was competitive with ours, then we may suffer economic harm from the competitive product.

The issuance of a patent is not conclusive as to its scope, validity or enforceability and our issued patents may be challenged, invalidated, deemed unenforceable or circumvented. These scenarios could limit our ability to stop competitors from marketing-related products or could limit the term of patent protection that otherwise may exist for our product candidates. 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 do not know whether any of our product candidates will be protectable or remain protected by enforceable patents. 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. Moreover, any efforts to enforce our intellectual property rights are likely to be costly and may divert the efforts of our scientific and management personnel. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may also be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent directed to such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

We generally file a provisional patent application with the U.S. Patent and Trademark Office, or USPTO, first and then subsequently file a corresponding non-provisional patent application. This process enables us to establish an earlier effective filing date in the subsequently filed non-provisional patent application. To benefit from the earlier effective filing date, we must file a corresponding non-provisional patent application, such as a utility application in the United States or an international application under the Patent Cooperation Treaty, or PCT, within 12 months of the date of the provisional patent application filing. Based on a PCT filing, we may file national and regional patent applications in the United States or foreign jurisdictions, such as the European Union, China, Japan and possibly others. To date, we have not filed for patent protection in all national and regional jurisdictions where such protection may be available, and we may decide to abandon national and regional patent applications before a patent is granted. In addition, the patent grant proceeding for each national or regional patent application that we file is an independent proceeding. As a result, it is possible for a patent application to be granted in one jurisdiction and denied in another jurisdiction, and depending on the jurisdiction, the scope of patent protection may vary. As of February 28, 2021, we owned two issued US patents relating to methods of use and composition of matter of PMV compounds, including PC14586, at least 11 pending US patent applications, and at least ten pending foreign patent applications, each of which relates to methods of use and composition of matter of PMV compounds, including PC14586. The two issued US patents are expected to expire in 2037, without taking into account any possible patent term adjustment or extensions.

### **Government Regulation and Product Approval**

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, preclinical and clinical testing, manufacture,

quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. Generally, before a new drug can be marketed, considerable data must be generated, which demonstrates the drug's quality, safety and efficacy. Such data must then be organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

### ***U.S. Drug Development Process***

In the United States, the FDA regulates drugs under the Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA after completion of all pivotal trials;
- determination by the FDA within 60 days of its receipt of an NDA to accept the filing for substantive review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and of selected clinical investigation sites to assess compliance with GCP requirements; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB or ethics committee for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial

begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, FDA may require, or sponsors may voluntarily pursue, post-approval trials, sometimes referred to as Phase 4 studies, that are conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, such as with accelerated approval drugs, the FDA may mandate the performance of post-approval clinical trials as a condition of approval of an NDA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 1 and Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

If the coronavirus disease 2019, or COVID-19, pandemic continues, our clinical trial plans and future planned clinical trials may be adversely affected, delayed or interrupted. We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects participating in clinical trials during the COVID-19 pandemic. For example, the FDA issued guidance in March 2020, which the FDA subsequently updated, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic. In June 2020, the FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs. Additional COVID-19 related guidance released by the FDA includes guidance addressing resuming normal drug and biologics manufacturing operations; manufacturing, supply chain, and inspections; and statistical considerations for clinical trials during the COVID-19 public health emergency.

### ***NDA Review and Approval Process***

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing complies with cGMP requirements to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any

requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA to address all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and 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 or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

### ***Expedited Development and Review Programs***

The FDA has various programs, including Fast Track designation, breakthrough therapy designation, accelerated approval and priority review, that are intended to expedite the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions. For example, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a Fast Track product has opportunities for frequent interactions with the review team during product development and, once a NDA is submitted, the product may be eligible for priority review. With regard to a Fast Track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a Fast Track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review, accelerated approval and breakthrough therapy designation. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

The Food and Drug Administration Safety and Innovation Act established a category of drugs referred to as “breakthrough therapies” that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a “breakthrough therapy” if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

Fast Track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

#### ***Post-approval Requirements***

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements, which impose certain production, manufacturing, procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.



The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

### ***Orphan Drugs***

Under the Orphan Drug Act, the FDA may grant orphan drug designation, or ODD, to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with either a patient population of fewer than 200,000 individuals in the United States, or a patient population greater of than 200,000 individuals in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States of that drug or biologic. ODD must

be requested before submitting an NDA. After the FDA grants ODD, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has received ODD and subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same biologic for the same indication for seven years from the approval of the NDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of ODD are tax credits for certain research and a waiver of the NDA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received ODD. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

### ***Marketing Exclusivity***

Market exclusivity provisions authorized under the FDCA can delay the submission and approval of certain marketing applications for products containing the same active ingredient. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from accepting ANDAs or 505(b)(2) NDAs for drugs referencing the approved application for review. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

## ***Other Healthcare Laws***

Pharmaceutical manufacturers are subject to additional healthcare fraud and abuse laws, regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal anti-kickback, false claims, civil monetary penalty, consumer fraud, pricing reporting, data privacy and security and physician payment transparency laws and regulations as well as similar foreign laws in the jurisdictions outside the U.S. Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information; state and local laws which require tracking gifts and other remuneration and transfer of value provided to physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by the Health Insurance Portability and Accountability Act of 1996, thus complicating compliance efforts.

The risk of our being found in violation of these or other laws and regulations is increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts and their provisions are open to various interpretations. These laws and regulations are subject to change, which can increase the resources needed for compliance and delay drug approval or commercialization. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Also, we may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments. Violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in government healthcare programs and imprisonment.

## ***Coverage and Reimbursement***

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufacturers to provide scientific, cost-effectiveness and clinical support for the use of a product to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests that are used with applicable pharmaceutical products require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical products, will apply to companion diagnostics.

Moreover, third-party payors are increasingly reducing coverage and reimbursement for pharmaceutical products and related services. The U.S. government and state legislatures have continued implementing cost-

containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. 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. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products.

### ***Healthcare Reform***

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Affordable Care Act, or ACA, was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; creates a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, in 2017, Congress enacted the Tax Cut and Jobs Act, or Tax Act, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case, although it is unclear when a decision will be made or how the Supreme Court will rule. In November 2020, the United States Supreme Court held oral arguments on this case. It is uncertain how the United States Supreme Court will rule on this case or how healthcare measures of the Biden administration will impact the ACA and our business. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. For example, at the federal level, the Trump administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the other of pocket costs of drug products paid by consumers. In July and September 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration’s proposals. The FDA also released a final rule in September 2020 providing guidance for states to build and submit importation plans for drugs from Canada. Further, in November 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The Centers for Medicare & Medicaid Services, or CMS, also issued an interim final rule implementing President Trump’s Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. It is unclear to what extent these new regulations and any future regulations and legislation by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability. In addition, individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

#### ***FDA Approval and Regulation of Companion Diagnostics***

We expect that our product candidates may require use of a diagnostic to identify appropriate patient populations for our products. These diagnostics, often referred to as companion diagnostics, are medical devices, often in vitro devices, which provide information that is essential for the safe and effective use of a corresponding drug. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval. We expect that any companion diagnostic developed for our product candidates will utilize the PMA pathway.

The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device’s safety and effectiveness and information

about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, a PMA application typically requires data regarding analytical and clinical validation studies. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards are not maintained, or problems are identified following initial marketing.

In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, if FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic device is not approved or cleared for that indication at the same time. The review of *in vitro* companion diagnostics in conjunction with the review of our therapeutic treatments for cancer will, therefore, likely involve coordination of review by the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health Office of In Vitro Diagnostics. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption, or IDE, regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE. After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

## Employees

As of February 28, 2021, we had 44 full-time employees, including 15 employees with Ph.D., M.D. or Pharm.D. degrees. Of these full-time employees, 32 employees are engaged in research and development activities.

None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

## Corporate Information

We were incorporated in Delaware in March 2013 under the name “PJ Pharmaceuticals, Inc.” In July 2013, we changed our name to “PMV Pharmaceuticals, Inc.” Our principal executive offices are located at 8 Clarke Drive, Suite 3, Cranbury, New Jersey 08512. Our telephone number is (609) 642-6670. Our website address is [www.pmvpharma.com](http://www.pmvpharma.com). Information contained on, or that can be accessible through, our website is not a part of this Annual Report on Form 10-K and the inclusion of our website address in this Annual Report on Form 10-K is an inactive textual reference only.

On September 25, 2020, we completed our initial public offering, or IPO, pursuant to which we issued and sold, 13,529,750 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to 1,764,750 additional shares of common stock, at a public offering price of \$18.00 per share. The gross proceeds from the IPO were approximately \$243.5 million and the net proceeds were approximately \$223.2 million, after deducting underwriting discounts and commissions and other offering expenses.

We use the name “PMV Pharma,” the “PMV Pharma” logo and other marks as unregistered trademarks in the United States and other countries. This Annual Report on Form 10-K contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we or their owners will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable owner to these trademarks and trade names. We do not intend our use or display of other entities’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

## Available Information

Our Internet address is [www.pmvpharma.com](http://www.pmvpharma.com). Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K (and amendments to those reports), proxy and information statements and other information filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available through the “Investors” portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our filings with the SEC may be accessed through the SEC at <http://www.sec.gov>. The information contained on the websites referenced in this Annual Report on Form 10-K is not incorporated by reference into this filing. Further, our references to website URLs are intended to be inactive textual references only. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

## Item 1A. Risk Factors

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission, or SEC, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Many of the following risks and uncertainties are, and will be, exacerbated by the coronavirus disease 2019, or COVID-19, pandemic and any worsening of the global business and economic environment as a result. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.*

### Risk Factors Summary

***Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as fully described below. The principal factors and uncertainties that make investing in our common stock risky include, among others:***

- we have a limited operating history, have not completed any clinical trials, and have no products approved for commercial sale;
- we have incurred significant losses since our inception, and we expect to incur significant net losses for the foreseeable future and may not be able to achieve or sustain revenue or profitability in the future;
- we have not generated any revenue from our product candidates and may never generate revenue or be profitable and our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates;
- we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success;
- we will require substantial additional capital to finance our operations;
- our discovery and preclinical and clinical development is focused on the development of precision medicines for patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs targeting p53 hotspot mutations is novel, may never lead to marketable products and may not ultimately represent a significant market;
- we are very early in our development efforts and are substantially dependent on our lead product candidate, PC14586. If we are unable to advance, obtain regulatory approval for and commercialize PC14586, our business, financial condition and results of operations will be materially adversely affected;
- interim “top-line” and preliminary data that we announce for our initial open-label Phase 1/2 clinical trial for PC14586 may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. If the interim, top-line or preliminary data that we report differ from actual results, our ability to obtain approval for our product candidates may be adversely affected, which could materially adversely affect our business, financial condition and results of operations;
- the subset of cancer patients that we are targeting are expected to have certain p53 mutations and we may not be able to identify a sufficient number of patients whom we can recruit and retain for our clinical trials to obtain approval for our current or future product candidates;
- our novel approach to the discovery and development of our current and future product candidates is unproven, and we may not be successful in our efforts to use and expand our platform to build a pipeline of product candidates with commercial value;



- the regulatory approval processes of the U.S. Food and Drug Administration, or FDA, and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approvals for our product candidates, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired;
- we currently rely, and plan to rely in the future, on third parties to conduct and support preclinical and clinical development, and these third parties may not meet expectations;
- if we are unable to obtain and maintain sufficient patent and other intellectual property protection for our product candidates and technology, our competitors could develop and commercialize products and technology similar or identical to ours;
- our success depends in part on our ability to protect our intellectual property; and
- our ability to develop companion diagnostics with third party collaborators, which must also separately be approved as medical devices by the FDA.

**Risks Related to Our Limited Operating History, Business, Financial Condition, Results of Operations and Need for Additional Capital**

***We have a limited operating history, have not completed any clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.***

We are a clinical stage biotechnology company with a limited operating history. We commenced operations in March 2013, and our operations to date have been primarily limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and, more recently, clinical studies, and establishing arrangements with third parties for the manufacture of initial quantities of product candidates. In September 2020, our lead product candidate, PC14586, received authorization to proceed under an investigational new drug application, or IND, with the FDA. Then, in October 2020, we received Fast Track designation for PC14586, from the FDA, and in the fourth quarter of 2020, we initiated patient dosing in our Phase 1/2 clinical trial of PC14586. We have not demonstrated an ability to successfully conduct or complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a company with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and results of operations to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

***We have incurred significant losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain revenue or profitability in the future.***

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We are still in the early stages of development of our product candidates. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We have financed our operations primarily through private placements of our preferred stock and our initial public offering.

We have incurred significant net losses in each period since we commenced operations in March 2013. Our net losses were \$34.4 million and \$25.4 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of \$109.9 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Additionally, the net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indicator of our future performance.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- continue our research and development efforts and submit investigational new drug, or IND, applications for our product candidates;
- conduct preclinical studies and clinical trials;
- fail to demonstrate adequate efficacy or an acceptable safety profile in our clinical trials;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities, whether alone or with third parties, to commercialize any product candidates for which we may obtain regulatory approval, if any;
- obtain, expand, maintain, enforce and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel; and
- operate as a public company.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek regulatory approval for and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

***We have not generated any revenue from our product candidates and may never generate revenue or be profitable. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates.***

Our ability to become profitable depends upon our ability to generate revenue. We have not received marketing approval for any product candidate, and we have not generated any revenue from any product sales. We do not expect to generate revenue unless or until we successfully complete preclinical and clinical development and obtain regulatory approval of, and then successfully commercialize, at least one product candidate. We dosed our first patient in our Phase 1/2 clinical trial of our lead product candidate, PC14586, in the fourth quarter of 2020, and we have not yet reported any clinical data. We will need to transition from a company with a research focus to a company capable of supporting clinical development and commercial activities. We have not yet demonstrated our ability to successfully complete large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. In addition, all of our other product candidates are still in preclinical development and have not been evaluated in humans. We face significant translational risk as our

product candidates advance to the clinical stage, and promising results in preclinical studies may not be replicated in clinical trials. All of our current and future product candidates will require preclinical and clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- successful enrollment and timely completion of our clinical trials for our lead product candidate, PC14586, and timely initiation and completion of our preclinical studies for our future product candidates, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development of PC14586 and our future product candidates;
- our ability to complete IND-enabling studies and successfully submit and receive authorization to proceed under INDs or comparable applications;
- whether we are required by the FDA or other comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA and comparable foreign regulatory authorities the safety, efficacy, consistent manufacturing quality and acceptable risk-benefit profile of our small molecule product candidates or any future product candidates, and such regulatory authorities' acceptance of our tumor-agnostic development strategy;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA and comparable foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates over alternative or more conventional therapies, such as chemotherapy, to treat solid tumors;
- the actual and perceived availability, cost, risk profile and side effects and efficacy of our product candidates, if approved, relative to existing and future alternative cancer therapies and competitive product candidates and technologies;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- patient demand for our product candidates and any future product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercializing our product candidates. Successful completion of preclinical studies and clinical trials does not mean that any of our current or future product candidates will receive regulatory approval. Even if regulatory approvals are obtained, we could experience significant delays or an inability to successfully commercialize our current and any future product candidates, which would materially harm our business. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

***Due to the significant resources required for the development of our product candidates, we must prioritize development of certain product candidates and/or certain indications. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

We are currently focused on developing orally available small molecule, tumor-agnostic therapies targeting p53 mutants. We seek to maintain a process of prioritization and resource allocation among our programs to maintain a balance between advancing our lead product candidate, PC14586, as well as developing our other and any future product candidates.

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. In addition, if we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the cancer or pharmaceutical, biopharmaceutical or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected.

***We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and product development programs or future commercialization efforts.***

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, PC14586, and advance our future product candidates. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. We also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of December 31, 2020, we had \$361.4 million in cash and cash equivalents. On September 29, 2020, we completed our IPO, selling 13,529,750 shares of common stock at a public offering price of \$18.00 per share, which includes 1,764,750 shares sold upon full exercise of the underwriters' option to purchase additional shares of common stock. The aggregate proceeds from the offering, net of underwriting discounts and commissions and other offering expenses, were approximately \$223.2 million. Although we believe that our available cash and cash

equivalents will be sufficient to fund our planned operations through 2023, this belief is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates or any future product candidates we choose to pursue, and conducting preclinical studies and clinical trials, including our clinical trials of PC14586;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing and amount of any milestone, royalty and/or other payments we are required to make pursuant to any future license or collaboration agreements;
- the cost of manufacturing our product candidates or any future product candidates and any products we successfully commercialize;
- the cost of building a sales force in anticipation of product commercialization;
- the cost of commercialization activities of our product candidates, if approved for sale, including marketing, sales and distribution costs;
- our ability to establish future collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio;
- the timing, receipt and amount of sales of any future approved products; and
- the impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

We do not have any committed external source of funds and adequate additional financing may not be available to us on acceptable terms, or at all. In addition, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

#### **Risks Related to Product Development**

*Our discovery and product development is focused on the development of precision medicines for patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs targeting p53 hotspot mutations is novel, may never lead to marketable products and may not ultimately represent a significant market.*

The discovery and development of precision medicines for patients with genetically defined cancers is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Further, despite decades of research on p53 as a target for precision medicines, prior product development efforts have been unsuccessful. Although we believe, based on our preclinical work and p53 research generally, that the top ten most frequent, or hotspot, p53 mutations have potential as precision oncology targets, clinical results may not confirm this hypothesis or may only confirm it for certain mutations or certain tumor types.

Further, even if our approach is successful in showing clinical benefit for tumors harboring the p53 mutation targeted by our lead product candidate, PC14586, we may never successfully identify additional product candidates for targeting other p53 mutants through our platform. Therefore, we do not know if our approach of treating patients with genetically defined cancers will be successful, and if our approach is unsuccessful, our business will be materially adversely affected.

In addition, because our approach targets genetically defined cancer patients and not specific tumors based on tumor or cancer types, we are initially pursuing a tumor-agnostic development strategy (*i.e.*, pursuing approval for a potential indication based on a specific genetic mutation rather than a specific type of tissue). There is currently a limited number of approved tumor-agnostic therapies and we may not receive approval for a broad tumor-agnostic indication or may be delayed in receiving broad tumor-agnostic approval. If our Phase 1/2 trial for PC14586 does not support a tumor-agnostic indication, but we observe clinical benefit in certain tumor or cancer types, we may decide to pursue a tumor- or cancer-specific indication which may require additional clinical trials. Further, even if our Phase 1/2 trial for PC14586 is successful, the FDA may not agree that such study can serve as a pivotal study, which would require us to conduct additional clinical trials prior to approval.

***We are very early in our development efforts and are substantially dependent on our lead product candidate, PC14586. If we are unable to advance PC14586 or any of our future product candidates through clinical development, obtain regulatory approval and ultimately commercialize PC14586 or any of our future product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.***

We are very early in our development efforts. We dosed our first patient in our Phase 1/2 clinical trial of our lead product candidate, PC14586, in the fourth quarter of 2020, and we have not yet reported any clinical data. All of our other product candidates are still in preclinical development and have never been tested in human subjects. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of PC14586 and one or more of our future product candidates. In addition, our product development programs contemplate the development with third party collaborators of companion diagnostics, which are assays or tests used to identify an appropriate patient population for our product candidates. Companion diagnostics are subject to regulation as medical devices and must themselves be approved for marketing by the FDA and comparable foreign regulatory agencies before we may commercialize such companion diagnostics with our product candidates. The success of our product candidates will depend on several factors, including the following:

- our ability to continue our business operations and product candidate research and development, and adapt to any changes in the regulatory approval process, manufacturing supply or clinical trial requirements and timing due to the ongoing COVID-19 pandemic and otherwise, including complying with new regulatory guidance or requirements on conducting clinical trials during the COVID-19 pandemic;
- timely and successful completion of preclinical studies and clinical trials;
- receipt of authorization to proceed under INDs for our planned clinical trials or future clinical trials;
- FDA acceptance of our tumor-agnostic development strategy;
- successful patient enrollment in and completion of clinical trials, which may be impacted by the COVID-19 pandemic;

- successful development with third party collaborators of companion diagnostics for use with our product candidates;
- safety, tolerability and efficacy profiles for our product candidates that are satisfactory to the FDA or any foreign regulatory authority for marketing approval;
- receipt of marketing approvals for our product candidates and any companion diagnostics from applicable regulatory authorities, which must be approved contemporaneously;
- completion of any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates, if any product candidates are approved;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other cancer therapies;
- obtaining and maintaining third-party coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of our products following approval.

Many of these factors are beyond our control, and it is possible that we may never obtain regulatory approval for our product candidates even if we expend substantial time and resources seeking their development and approval. If we do not achieve regulatory approval in a timely manner or at all, we could experience significant delays or an inability to commercialize our current or future product candidates, which would materially adversely affect our business. If we do not receive regulatory approvals for our current or future product candidates, we will not be able to continue our operations.

The success of our business, including our ability to finance our company and generate revenue from products in the future, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the product candidates we develop, which may never occur. Our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating cost-effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production in accordance with cGMP, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenue from product sales. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. Changes in the manufacturing process or facilities will require further comparability analysis and approval by FDA before implementation, which could delay our clinical trials and product candidate development, and could require additional clinical trials, including bridging studies, to demonstrate consistent and continued safety and efficacy.

We have not previously submitted a new drug application, or NDA, to the FDA or similar approval filings to a comparable foreign regulatory authority, for any product candidate. An NDA or other relevant regulatory filing must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. We cannot be certain that our current or future product candidates will be successful in clinical trials or receive regulatory approval. Further, even if they are successful in clinical trials, our product candidates or any future product candidates may not

receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights for each product candidate, as well as the availability of competitive products, whether there is sufficient third-party reimbursement and adoption by physicians.

***The subset of cancer patients that we are targeting are expected to have certain p53 mutants and we may not be able to identify a sufficient number of patients whom we can recruit and retain for our clinical trials to obtain approval for our current or future product candidates.***

The patient populations for our current product candidates are limited to those with specific p53 mutations, which represents a substantially smaller subset of the generally treated cancer patient population. We expect our future product candidates to be similarly limited. We will need to screen and identify patients with these targeted mutations. Further, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations with each p53 hotspot mutation will be large enough to allow us to successfully conduct the requisite clinical trials necessary to obtain marketing approval for each mutation-specific product candidate before we can commercialize our products, if approved, and achieve profitability.

***Our novel approach to the discovery and development of our current and future product candidates is unproven, and we may not be successful in our efforts to use and expand our platform to build a pipeline of product candidates with commercial value.***

A key element of our strategy is to use and expand our platform to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of various cancers. Although our research and development efforts to date have resulted in our discovery and development of PC14586 and future product candidates, PC14586 and future product candidates may not be safe or effective as a cancer treatment, and we may not be able to further develop PC14586 and develop any future product candidates. Our platform is evolving and may not reach a state at which building a pipeline of product candidates is possible. For example, we may not be successful in identifying additional p53 hotspot mutations for which our platform can develop safe and effective product candidates. There can be no assurance that any development problems we experience in the future related to our platform will not cause significant delays or unanticipated costs or that such development problems can be solved. Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance.

Furthermore, even if our product candidates are successful in correcting structural deficiencies associated with p53 mutants, such success would not provide a guarantee of the effectiveness of such product candidate in total tumor regression *in vivo*. There can be no assurances that one or more of our future product candidates would succeed in correcting or restoring function of specific p53 mutants *in vivo* and that such mutation would be the only genetic mutation resulting in a patient's cancer. In the event that a patient's cancer is the result of other mutations or factors in addition to a p53 mutation, even if we correct or restore the p53 functionality, the patient's cancer may persist.

If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue which materially adversely affect our business, financial condition and results of operations.

***Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our clinical development and ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which could have an adverse effect on our business.***

In order to obtain FDA approval to market a new small molecule product, we must demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the FDA. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product



candidate, we must complete extensive preclinical studies that support our planned INDs in the United States. We dosed our first patient in our Phase 1/2 clinical trial of our lead product candidate, PC14586, in the fourth quarter of 2020, and we have not yet reported any clinical data. All of our other product candidates are in preclinical development. We cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical studies will ultimately support further development of our programs. While we have received authorization to proceed under an IND for our lead product candidate, PC14586, we cannot be sure that we will be able to submit and receive authorizations to proceed under additional INDs or similar applications with respect to our other product candidates on the timelines we expect, if at all, and we cannot be sure that submission of IND or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical studies may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- timely completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- timely submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board, or IRB, ethics committee at each clinical site before each trial may be initiated;
- delays in reaching a consensus with regulatory agencies on study design and obtaining regulatory authorization to commence clinical trials; and
- obtaining sufficient quantities of our product candidates for use in preclinical studies and clinical trials from third-party suppliers on a timely basis.

Moreover, even if clinical trials do begin for our preclinical programs, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety or efficacy to obtain the requisite regulatory approvals for any product candidates we develop. Even if we obtain positive results from preclinical studies or initial clinical trials, we may not achieve the same success in future trials.

***The results of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities. Successful preclinical studies and clinical trials cannot provide assurance of successful commercialization.***

We are required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective before we can seek marketing approvals for their commercial sale. Success in preclinical studies does not mean that future clinical trials will be successful. For instance, we do not know whether PC14586 will perform in its clinical trials as PC14586 has performed in preclinical studies, nor can we predict how our future product candidates will perform in future preclinical studies or clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates or prevent regulatory approval. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations,

differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates.

Even if we succeed in developing and commercializing our product candidates, we may never generate sufficient or sustainable revenue to enable us to be profitable.

***We have limited experience as a company in conducting clinical trials.***

We have limited experience as a company in conducting clinical trials with the initiation of our Phase 1/2 clinical trial for PC14586 in October 2020. In part because of this lack of experience, we cannot be certain that our clinical trials of PC14586 and ongoing preclinical studies of our other product candidates will be completed on time or if the planned preclinical studies and clinical trials will begin or be completed on time, if at all. Large-scale clinical trials require significant additional financial and management resources and reliance on third-party clinical investigators, CROs and consultants. Relying on third-party clinical investigators, CROs and consultants may force us to encounter delays that are outside of our control. We may be unable to identify and contract with sufficient investigators, CROs and consultants on a timely basis or at all. For our lead product candidate, PC14586, we entered into a master services agreement with a CRO to lead our first-in-human open label Phase 1/2 clinical trial. There can be no assurance that we will be able to negotiate and enter into any additional master services agreement with other CROs, as necessary, on terms that are acceptable to us on a timely basis or at all.

***We may need to use existing commercial diagnostic tests or develop, or enter into a collaboration or partnership in the future to develop, novel companion diagnostics for some of our current or future product candidates. If we or our future partners are unable to successfully develop, validate and obtain approval for such companion diagnostics, or experience significant delays in doing so, we may not realize the full commercial potential of our future product candidates.***

As one of the key elements of our product development strategy, we seek to identify cancer patient populations that may derive meaningful benefit from our current or future product candidates. Because specific genetic mutations will be used to identify the appropriate patients for our programs and our current or future product candidates, we believe that our success may depend, in part, on our ability to use existing diagnostic tests and genetic sequencing, or to develop novel companion diagnostics in collaboration with partners.

Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of our product candidates. In our Phase 1/2 clinical trial, we are working with physicians and leading academic centers to enroll patients with the p53 Y220C mutation identified through next generation sequencing, or NGS. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges.

We have little experience as a company in the development of diagnostics. As such, we expect to rely on future partners for the design, development and manufacture of appropriate diagnostics to pair with our current or future product candidates. We have not yet begun discussions with any potential partners with respect to the development of companion diagnostics and may be unsuccessful in entering into collaborations for the development of companion diagnostics for our programs and our current or future product candidates. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early

clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities outside the United States as medical devices and require separate regulatory approval or clearance prior to commercialization. Moreover, the FDA generally requires the contemporaneous approval of companion diagnostics and the associated therapeutic.

We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we, our partners, or any third parties that we engage to assist us, are unable to successfully develop and supply companion diagnostics for our current product candidates and any future product candidates, or experience delays in doing so:

- the development of our current product candidates and any future product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials; and
- we may not be able to obtain approval of our current product candidates and any future product candidates that require companion diagnostics on a timely basis or at all.

If any of these events were to occur, our business would be adversely impacted.

***The outbreak of the novel coronavirus disease, COVID-19, could materially adversely impact our business, results of operations and financial condition, including our preclinical studies and clinical trials.***

In January 2020, the World Health Organization declared the outbreak of COVID-19 as a “Public Health Emergency of International Concern,” which continues to spread throughout the world and has adversely impacted global commercial activity and contributed to significant declines and volatility in financial markets. The COVID-19 outbreak and government responses are creating disruption in global supply chains and adversely impacting many industries. The outbreak could have a continued material adverse impact on economic and market conditions and trigger a period of global economic slowdown. We continue to monitor the impact of the COVID-19 outbreak closely. The extent to which the COVID-19 outbreak will impact its operations or financial results is uncertain.

The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have our administrative employees continuing their work outside of our offices and limited the number of staff in any given research and development laboratory. Our research and development teams are currently operating under heightened protective COVID-19 protocols, which has altered our operations and processes. While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material adverse effect on our business, financial condition and results of operations. As a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of

clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;

- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption or delays to our sourced discovery and clinical activities; and
- changes in clinical site procedures and requirements as well as regulatory requirements for conducting clinical trials during the pandemic.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued a guidance, which FDA subsequently updated, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report contingency measures implemented to manage the trial, and any disruption of the trial as a result of the COVID-19 pandemic; a list of all subjects affected by the COVID-19 pandemic related study disruption by unique subject identifier and by investigational site and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the trial.

The COVID-19 pandemic continues to revolve rapidly, with the status of operations and government restrictions evolving weekly. The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The trading prices for shares of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic and the trading prices for shares of our common stock could also experience high volatility. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the COVID-19 could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the COVID-19 pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, the ultimate geographic spread of the disease, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and the actions taken to contain COVID-19 or address its impact in the short and long term, among others. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy. We will continue to monitor the situation closely.

In addition, our business could be materially adversely affected by other business disruptions to us or our third-party providers that could materially adversely affect our potential future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CROs, contract manufacturing organizations, or CMOs, and other contractors, consultants and third parties could be subject to other global pandemics, earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather

conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could materially adversely affect our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

***If we experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials on a timely basis or at all for our product candidates if we are unable to recruit and enroll a sufficient number of eligible patients to participate in these trials through completion of such trials as required by the FDA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. For example, our enrollment for clinical trials of PC14586 will require patients to have the specific p53 Y220C mutation. If we are unable to locate a sufficient number of such patients, our clinical trial and development plans could be delayed.

Enrollment of patients in our clinical trials may be delayed or limited as our clinical trial sites limit their onsite staff or temporarily close as a result of the COVID-19 pandemic. In addition, patients may not be able to visit clinical trial sites for dosing or data collection purposes due to limitations on travel and physical distancing imposed or recommended by federal or state governments or patients' reluctance to visit the clinical trial sites during the pandemic. The drop-out rates in our clinical trials may be increased during the pandemic. Clinical trial patients who become infected with the COVID-19 virus may complicate the clinical trial data, procedures and analysis. These factors resulting from the COVID-19 pandemic could delay the anticipated readouts from our PC14586 clinical trials and our regulatory submissions, and increase the costs associated of the clinical trials.

Patient enrollment may also be affected if our competitors have ongoing clinical trials for programs that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' programs. Patient enrollment for our current or any future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or future product candidates being investigated for the indications we are investigating;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- delays in or temporary suspension of the enrollment of patients in our clinical trials due to the COVID-19 pandemic;
- ability to obtain and maintain patient consents;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and

- the risk that patients enrolled in clinical trials will drop out of the trials before completion, including as a result of contracting COVID-19 or other health conditions or being forced to quarantine, or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, we may introduce an alternative formulation of PC14586 into the dose expansion phases of our future clinical trials. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

***The market opportunities for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.***

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA customarily approves new therapies only for a second line or later lines of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapies, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect to initially seek approval of our product candidates in most instances at least as a second line therapy. Subsequently, depending on the nature of the clinical data and experience with any approved products or product candidates, if any, we may pursue approval as an earlier line therapy and potentially as a first line therapy. But there is no guarantee that our product candidates, even if approved as a second or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have the p53 hotspot mutations we are targeting, who may have their tumors genetically sequenced, as well as the subset of people with these mutations in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our assumptions and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved for a second or third line of therapy, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type.

***A variety of risks associated with marketing our product candidates internationally may materially adversely affect our business.***

We plan to eventually seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or our interpretation of data from preclinical studies or clinical trials;
- approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- impact of the COVID-19 pandemic on our ability to produce our product candidates and conduct clinical trials in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our business, financial condition and results of operations.

***We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.***

Our industry is intensely competitive and subject to rapid and significant technological change as well as strong defense of intellectual property. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face substantial competition from major pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

In particular, we are aware of molecules in development that also are being explored for p53 upregulation/activation in various stages of preclinical or clinical development being tested by Actavalon, Aprea Therapeutics, CDG Therapeutics, Cotinga Pharmaceuticals, Innovation Pharmaceuticals and Senhwa Biosciences, among others. We are also aware of selective small molecule inhibitors that are designed to target wild-type p53 containing tumors through the p53-murine double minute 2, or MDM2, interaction, which are in various stages of clinical development being tested by Aileron Therapeutics, Ascentage Pharma, Boehringer Ingelheim, Daiichi Sankyo (out-licensed worldwide rights to Rain Therapeutics), Kartos Therapeutics, Novartis and Roche, including testing MDM2 inhibitors in combination with a variety of other anti-cancer agents.

We face competition with respect to our current product candidates and will face competition with respect to future product candidates, from segments of the pharmaceutical, biotechnology and other related markets that pursue targeted therapies for patients with genetically-defined cancers. If PC14586 or our future product candidates do not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

In addition, we will likely need to develop our product candidates in collaboration with companion diagnostic companies, and we will face competition from other companies in establishing these future collaborations. Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy or a combination of such methods. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drug and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our product candidates that we successfully introduce to the market will pose challenges. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

Product candidates that we may successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products.

***Our long-term prospects depend in part upon discovering, developing and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.***

Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates beyond our lead product candidate, PC14586, and those we currently have in preclinical development. A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from



preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of future product candidates we may develop will depend on many factors, including the following and the other factors relating to product development described elsewhere in this “Risk Factors” section:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of the product candidate for use in clinical trials; and
- adverse events in the clinical trials.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize additional product candidates, which would materially adversely affect our business, financial condition and results of operations.

Even if we successfully advance any future product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from our future product candidates.

***Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.***

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may adversely affect our business, financial condition and prospects significantly.

While we have only recently initiated a clinical trial for our lead product candidate, PC14586, as is the case with all oncology drugs, it is likely that there may be significant side effects associated with its use. PC14586 or future product candidates may be used in populations for which safety concerns may be reviewed by regulatory agencies. In addition, we expect that PC14586 will be studied in combination with other therapies, which may exacerbate adverse events associated with the therapy. Further, our product candidates will be used in patients that have weakened immune systems, which may exacerbate any potential side effects associated with their use. Patients treated with PC14586 or any of our future product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients’ illnesses. For example, it is expected that some of the patients enrolled in our PC14586 clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such trials. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects.

If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may

be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially adversely affect our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early stage clinical trials.

***We expect to develop our current or future product candidates in combination with other therapies, which exposes us to additional risks.***

We intend to develop our current or future product candidates in combination with one or more currently approved cancer therapies or therapies in development. For example, our preclinical studies have demonstrated robust tumor regression when sub-therapeutic doses of PC14586 were used in combination with anti-PD-1 therapy. Patients may not be able to tolerate PC14586 or any of our future product candidates in combination with other therapies or dosing of PC14586 or any of our future product candidates in combination with other therapies may have unexpected consequences. Even if any of our current or future product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

We may also evaluate our current or future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with PC14586 or any future product candidate, we may be unable to obtain approval of or successfully market any one or all of the current or future product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

***Interim, initial, “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data,

and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could materially adversely affect our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be adversely affected, which could materially adversely affect our business, financial condition and results of operations.

***Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.***

The use of precision medicines as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other cancer medicines;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for other precision medicines and public perception of other precision medicines;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;

- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates receive regulatory approval but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

In addition, although our product candidates differ in certain ways from other precision medicine approaches, serious adverse events or deaths in other clinical trials involving precision medicines, even if not ultimately attributable to our product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates and a decrease in demand for any such product candidates.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

***The insurance coverage and reimbursement status of newly-approved products is uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would adversely affect our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.***

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may materially change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or future product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return

on our investment. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our business, financial condition and results of operations, our ability to raise capital needed to commercialize product candidates and our overall financial condition.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our business, financial condition and results of operations, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we

obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Additionally, we may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. Even if we obtain regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Medicare reimbursement methodologies, whether under Part A, Part B or clinical laboratory fee schedule may be amended from time to time, and we cannot predict what effect any change to these methodologies would have on any product candidate or companion diagnostic for which we receive approval. Our inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the companion diagnostic tests that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants
- initiation of investigations by regulators;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also have various

exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

***Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.***

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA or other comparable foreign regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA or other comparable foreign regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

***We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.***

We have never commercialized a product candidate and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for the product candidates which we may license to others, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our product candidates, ensuring regulatory compliance of our company, employees and third parties under applicable healthcare laws and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenue from them or be able to reach or sustain profitability.

***We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.***

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third-party sales, marketing and distribution collaborators regarding the sales and

marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or if at all, or if we are able to do so, that these third-party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

### **Risks Related to Regulatory Process and Other Legal Compliance Matters**

***The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.***

We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including our lead product candidate PC14586, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for each targeted indication.

Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval.

The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted IND, NDA or equivalent application types, may cause delays in the approval or rejection of an application. For example, FDA has recently issued guidance on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the COVID-19 pandemic, including recordkeeping and implementation of contingency measures in response to the ongoing pandemic. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including our Phase 1/2 clinical trial design for PC14586, or require us to modify the design of our clinical trials, including additional procedures and contingency measures in response to the COVID-19 pandemic or as required by clinical sites, IRBs, FDA or other regulatory authorities;
- the FDA or comparable foreign regulatory authorities may disagree with our tumor-agnostic development strategy;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;



- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication, or a related companion diagnostic is suitable to identify appropriate patient populations;
- the FDA or other comparable regulatory authorities may fail to approve companion diagnostic tests that may be required for our product candidates;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks, or that a product candidate has an acceptable benefit-risk ratio for its proposed indication;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures, specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- our third-party contractors may fail to comply with regulatory requirements or otherwise fail or be unable to adequately perform their obligations to allow for the conduct of our planned or future clinical studies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would materially adversely affect our business, results of operations and prospects.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

***We may not be able to obtain orphan drug designation or obtain or maintain the benefits associated with orphan drug designation, such as orphan drug exclusivity and, even if we do, that exclusivity may not prevent the FDA or other comparable foreign regulatory authorities, from approving competing products.***

As part of our business strategy, we may seek orphan drug designation, or ODD, for any eligible product candidates we develop, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing and making available the drug will be recovered from sales in the United States. Our target indications may include diseases with large patient populations or may include orphan indications. However, there can be no assurances that we will be able to obtain orphan designations for our product candidates.

In the United States, ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has ODD subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the product was designated. The applicable exclusivity period is 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for ODD or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain ODD for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained ODD for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process.

***We may seek and fail to obtain breakthrough therapy designations for our current or Fast Track and breakthrough therapy designations for future product candidates. Even if we are successful, such programs may not lead to a faster development or regulatory review process, and they do not guarantee we will receive approval for any product candidate. We may also seek to obtain accelerated approval for one or more of our product candidates but the FDA may disagree that we have met the requirements for such approval.***

If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track designation. In October 2020, we received Fast Track designation for PC14586 from the FDA. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular future product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Further, even though we have received Fast Track designation for PC14586, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may also seek breakthrough therapy designation for any product candidate that we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Like Fast Track designation, breakthrough therapy designation is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition,

even if a product candidate we develop qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Separately from Fast Track or breakthrough therapy designation, we may seek accelerated approval for one or more of our product candidates. A product candidate intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval if it is determined to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-approval clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires pre-approval of promotional materials for accelerated approval products, once approved. We cannot guarantee that the FDA will agree any of our product candidates has met the criteria to receive accelerated approval, which would require us to conduct additional clinical testing prior to seeking FDA approval. Even if any of our product candidates received approval through this pathway, the required post-approval confirmatory clinical trials may fail to verify the predicted clinical benefit of the product, and we may be required to remove the product from the market or amend the product label in a way that adversely impacts its marketing.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be adversely affected.

***Preclinical and clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.***

Our lead product candidate, PC14586, is in early clinical development and all of our other product candidates are in discovery or preclinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product

candidates in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and a failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Our preclinical studies and clinical trials may not be successful.

We cannot be certain that our preclinical study and clinical trial results will be sufficient to support regulatory approval of our product candidates, or that FDA or other comparable regulatory authorities will find our planned clinical strategy to be acceptable. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Failure or delay can occur at any time during the clinical trial process. In addition, the COVID-19 pandemic is still evolving as of this time and much of its impact remains unknown, and it is impossible to predict the impact the COVID-19 pandemic may have on the development of our product candidates, our preclinical studies and clinical trials and our business.

Additionally, our PC14586 Phase 1/2 clinical trial is, and other clinical trials we conduct in the future may be, open-label in study design and conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

We may experience delays in obtaining the FDA’s authorization to initiate clinical trials, completing ongoing clinical trials of PC14586 and preclinical studies of our other product candidates and initiating our planned preclinical studies and clinical trials. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will begin on time, not require redesign, enroll an adequate number of research subjects or patients on time, or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the availability of financial resources to commence and complete clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing with our tumor-agnostic development strategy;
- delays in obtaining regulatory approval or authorization to commence a clinical trial, including delays or issues relating to any future companion diagnostics which we may develop;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB or ethics committee approval at each clinical trial site;
- recruiting an adequate number of suitable patients to participate in a clinical trial;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate, for example, if we experience delays or challenges in identifying patients with the mutations required for our clinical trials, we may have to reimburse sites for genetic sequencing costs in order to encourage sequencing of additional patients;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- having third-party contractors fail to complete their obligations in a timely manner or failing to comply with applicable regulatory requirements;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidate for use in preclinical studies or clinical trials from third-party suppliers.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for our future clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion, or termination, of any preclinical study or clinical trial of our product candidates, the commercial prospects of our product candidates may be adversely affected, and our ability to generate revenue from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our preclinical studies or clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may materially adversely affect our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If one or more of our product candidates generally prove to be ineffective, unsafe or commercially unviable, our entire pipeline and platform would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Changes in funding or disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including for 35 days beginning on December 22, 2018, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. In May 2020, FDA announced that it will continue to postpone domestic and foreign routine surveillance inspections due to COVID-19. While FDA indicated that it will consider alternative methods for inspections and could exercise discretion on a case-by-case basis to approve products based on a desk review, if a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***Even if we receive regulatory approval of our product candidates, we will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries.

Following potential approval of any of our current or future product candidates, the FDA or other comparable regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA may also require a risk evaluation and mitigation strategy, or REMS, in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements, GLP requirements and good clinical practice, or GCP, requirements, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product

candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, certain policies and regulations promulgated during the Trump administration as well as those implemented by the Biden administration may impact our business and industry. To the extent any current or future executive or legislative actions impose significant changes in or burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities, such as implementing regulations through rulemaking, issuance of guidance, and agency review and approval of marketing applications on a timely basis, our business and clinical development plans could be negatively impacted. It remains to be seen how the Biden administration and new leadership at the HHS and FDA will impact our business. If we, as well as our contractors, are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or are not able to maintain regulatory compliance, we may be delayed in obtaining regulatory approval, lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue.

***Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.***

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act, or ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the

Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

There have been legislative and judicial efforts to repeal, replace, or change some or all of the ACA, including measures taken during the Trump administration. While Congress has not passed repeal legislation to date, the Tax Cuts and Jobs Act, or Tax Act, repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. In November 2020, the United States Supreme Court held oral arguments on this case. It is unclear how the United States Supreme Court will rule on this case, or how other future judicial and legislative efforts, including healthcare measures of the Biden administration, will impact the ACA or our business. We will continue to evaluate the effect that the ACA has on our business. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices; however on December 20, 2019, President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax and the health insurance provider tax. It is impossible to determine whether similar taxes could be instated in the future. CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS has recently published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Other legislative changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget for fiscal year 2021 includes allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to



lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. In July and September 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. The FDA also released a final rule in September 2020 providing guidance for states to build and submit importation plans for drugs from Canada. Further, in November 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The CMS also issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. In December 2020, CMS also issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. The Biden administration, including new leadership at the HHS, may halt, amend, or revoke certain actions implemented during the Trump administration. It is unclear to what extent these new regulations and any future regulations and legislation by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability.

Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations

and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

***The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.***

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

***Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care 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. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and material adversely affect to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

***Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.***

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment and exclusion from government healthcare programs. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- federal civil and criminal false claims laws, including the False Claims Act, or FCA, which can be enforced through civil “qui tam” or “whistleblower” actions, and civil monetary penalty laws, impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payment Sunshine Act, created under the ACA and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to HHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include payments and transfers of

value made during the previous year to certain non-physician providers, such as physician assistants and nurse practitioners;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock or stock options for services provided to us and may be in the position to influence the ordering of or use of our product candidates, if approved, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

***Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.***

In connection with our clinical trials or enrollment or continued enrollment of patients in any future clinical trials, we will be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional

mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European activities. Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated.

In the United States, most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations. HIPAA impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. Even when HIPAA does not apply, according to the Federal Trade Commission, or FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain states have enacted additional laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA was amended on September 23, 2018. In November 2020, California passed the California Privacy Rights Act, or CPRA, which amends and expands the CCPA. Although the CCPA includes exemptions for certain clinical trial data, the law may increase our compliance costs and potential liability with respect to other personal information. The CCPA and CPRA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could materially adversely affect our business, financial condition and results of operations. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could adversely affect our business.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations may also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.***

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

***We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.***

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

#### **Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business**

***We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.***

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly

dependent on our management, scientific and medical personnel, including our Chief Executive Officer and President, our Chief Operating Officer and Chief Financial Officer and our Chief Medical Officer. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could materially adversely affect our business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be adversely affected.

Additionally, we rely on our founders and other scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. These advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting relationships with our scientific founders or if they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be materially adversely affected.

***In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.***

As of February 28, 2021, we had 44 full-time employees, including 32 employees engaged in research and development activities. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and other comparable foreign regulatory agencies' review process for PC14586 and any future product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize PC14586 and future product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of PC14586 and any future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage

our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize PC14586 and future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.***

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems, and those of our third-party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. For example, companies have experienced an increase in phishing and social engineering attacks from third parties in connection with the COVID-19 pandemic. To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. We cannot assure you that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties, will prevent significant breakdowns or breaches in systems or other cyber incidents that cause loss, destruction, unavailability, alteration or dissemination of, or damage to, our data that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information and personal information), which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Notifications and follow-up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security incident were to result in a loss, destruction or alteration of, or damage to,



our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in or, failure or security breach of our systems or third-party systems where information important to our business operations or commercial development is stored. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

***Business disruptions could materially adversely affect our future revenue and financial condition and increase our costs and expenses.***

Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, pandemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously adversely affect our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

***Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited.***

Our net operating loss, or NOL, carryforwards may be unavailable to offset future taxable income because of restrictions under U.S. tax law. Our federal NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years, and therefore could expire unused. Under the Tax Act, as amended by the CARES Act, our federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but for taxable years beginning after December 31, 2020, the deductibility of federal NOLs generated in tax years beginning after December 31, 2017 is limited to 80% of current year taxable income.

As of December 31, 2020 and 2019, we had federal NOL carryforwards of \$97.7 million and \$66.4 million, respectively. As of December 31, 2020, we had state NOL carryforwards for New Jersey, California and Massachusetts of approximately \$92.8 million, \$4.9 million and \$0.9 million, respectively. As of December 31, 2019, we had state NOL carryforwards for New Jersey, California and Massachusetts of approximately \$61.5 million, \$4.9 million and \$0.9 million, respectively. Some of the federal and state NOL carryforwards expire beginning in the year 2033. We also had federal and state research and development credit carryforwards of approximately \$3.5 million and \$2.2 million, respectively, as of December 31, 2020 and 2019. The federal credits will begin to expire in 2034 if not utilized. The California state credits carryforward indefinitely and the New Jersey state credits expire starting in 2021.

In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an “ownership change” (generally defined as a cumulative change (by value) in the corporation’s ownership by “5-percent shareholders” that exceeds 50 percentage points over a rolling three-year period), the corporation’s ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change taxable income or tax liabilities may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine whether we have experienced an ownership change or the annual limitations, if any, that could result from such an ownership change. Our ability to utilize our NOLs and certain other tax attributes could be limited by an ownership change as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations. There is also a risk that due to

federal or state regulatory changes, such as suspensions on the use of NOLs, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

***A portion of our chemistry-based product development and sourcing of certain manufacturing raw materials for our product candidates takes place in China through third-party manufacturers. A significant disruption in the operation of those manufacturers, a trade war or political unrest in China could materially adversely affect our business, financial condition and results of operations.***

We currently contract certain product development and manufacturing operations to third parties outside the United States, including in China, and we expect to continue to use such third-party manufacturers for such product candidates. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates. Furthermore, since these manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. For example, a trade war could lead to tariffs on the chemical intermediates we use that are manufactured in China. Any of these matters could materially adversely affect our business, financial condition and results of operations. Any recall of the manufacturing lots or similar action regarding our product candidates used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in China.

### **Risks Related to Reliance on Third Parties**

***We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.***

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners to conduct and support our preclinical studies and clinical trials under agreements with us. We are continuing to build our internal chemistry, manufacturing and controls, biology and preclinical development capabilities to supplement activities conducted by third parties on our behalf. As part of this personnel build out, we may incur additional costs or experience delays in engaging directly with other third-party CROs and CMOs.

We expect to have to negotiate budgets and contracts with CROs, trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before

approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with pharmaceutical product produced under cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our product candidates. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be adversely affected, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

***We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture our product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.***

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture our product candidates. We have not yet caused our product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates. We will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates and we may not be able to do so on favorable terms. We have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other comparable foreign regulatory authorities following inspections that will be conducted after we submit an application to the FDA or other comparable foreign regulatory authorities. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially adversely affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, if any third-party manufacturers on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected.

Our anticipated reliance on a limited number of third-party manufacturers exposes us to a number of risks, including the following:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must inspect any manufacturers for cGMP compliance as part of our marketing application;
- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates;
- our third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards and we have no control over third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel.

Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our company until deficiencies are remedied.

***We currently, and may in the future, depend on single-source suppliers for some of the ingredients, components and materials used in, and the manufacturing processes required to develop, our product candidates.***

We currently, and may in the future, depend on single-source suppliers for some of the ingredients, components and materials used in, and manufacturing processes required to develop, our product candidates. There are, for certain of these components, relatively few alternative sources of supply and there is limited need for multiple suppliers at this stage of our business. We cannot ensure that these suppliers or service providers will remain in business, have sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of raw materials, ingredients, components, key processes and finished goods exposes us to several risks,

including disruptions in supply, price increases or late deliveries. These suppliers may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or service provider could lead to supply delays or interruptions which would materially adversely affect our business, financial condition and results of operations.

If we have to switch to a replacement supplier, the manufacture and delivery of our product candidates may be interrupted for an extended period, which could materially adversely affect our business. Establishing additional or replacement suppliers for any of the components or processes used in or for our product candidates, if required, may not be accomplished quickly and would create increased cost. If we are able to find a replacement supplier, the replacement supplier would need to be qualified, would need to process our technology transfer and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single-source ingredients, components and materials used in our products, any interruption or delay in the supply of ingredients, components or materials or our inability to obtain ingredients, components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our product candidates.

***If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

***Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure by us or our third-party manufacturers to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.***

In order to commercially produce our products either at our own facility or at a third party's facility, we will need to comply with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our precision medicines as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our precision medicines for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

*We may, in the future, form or seek collaborations or strategic alliances or enter into licensing arrangements, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.*

We may, in the future, form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into future collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into future collaborations or

strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

***If we decide to establish collaborations, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.***

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek, in the future, to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We would face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations in the future, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

***If conflicts arise between us and our future collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.***

If conflicts arise between our future corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Future collaborators or strategic partners may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our current or future product candidates. Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the

development and commercialization of products. Any of these developments could adversely affect our product development efforts.

***If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.***

From time to time, we evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and/or acquire intangible assets that could result in significant future amortization expense.

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

***If we are unable to obtain and maintain sufficient patent and other intellectual property protection for our product candidates and technology, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any product candidates we may develop.***

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. We will only be able to protect our product candidates, proprietary technologies and their uses from unauthorized use by third parties to the extent that valid and enforceable patents or trade secret protections cover them. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Composition-of-matter patents on the active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our products for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.



The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own may fail to result in issued patents in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability, inventorship or scope thereof. Such a challenge may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. This will require us to be cognizant of the time from invention to filing of a patent application.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know-how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially-viable terms, then we may not be able to launch our product. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition and results of operations.

***Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to protect our intellectual property rights throughout the world.***

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates. These candidates include PC14586 and others, their respective components, formulations, methods used to manufacture them and methods of treatment. Our commercial success will also depend on successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our pending and future patent applications may not result in issued patents that protect our technology or products, in whole or in part. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies.

If we delay in filing a patent application, and a competitor files a patent application on the same or a similar technology before we do, we may face a limited ability to secure patent rights. We may not be able to patent the technology at all. Even if we can patent the technology, we may be able to patent only a limited scope of the technology, and the limited scope may be inadequate to protect our products, or to block competitor products that are similar or adjacent to ours. Our earliest patent filings have been published. A competitor may review our published patents and arrive at the same or similar technology advances for our products as we developed. If the competitor files a patent application on such an advance before we do, then we may no longer be able to protect the technology, we may require a license from the competitor, and if the license is not available on commercially-viable terms, then we may not be able to launch our product.

In the future we may in-license intellectual property from licensors. We may rely on these licensors to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be in-licensed. For example, we cannot be certain that such activities by licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. For example, our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. These pharmaceutical compounds may be covered by intellectual property rights held by others. We may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates. These diagnostic test or tests may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would adversely affect our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, and may allow our competitors access to the same technologies licensed to us.

Additionally, we may sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive for commercializing our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

During the course of business we have decided not to pursue certain products or processes and have terminated certain corresponding intellectual property license agreements, and we may do so again in the future. If it is later determined that our activities or product candidates infringe this intellectual property we may be liable for damages, enhanced damages or subjected to an injunction, any of which could have a material adverse effect on our business.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the U.S. Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, we may become involved in opposition, interference, derivation, *inter partes* review or other proceedings challenging our patent rights, and the outcome of any proceedings are highly uncertain. Such challenges may result in the patent claims of our owned or in-licensed patents being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors or use such information to compete with us. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be adversely affected and this would have a material adverse effect on our business.

If any of our patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates. Likewise, our current patents covering our proprietary technologies and our product candidates are expected to expire through 2037, without taking into account any possible patent term adjustments or extensions. Upon the expiration of our current patents, we may lose the right to exclude others

from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other countries. Competitors may use our technologies in countries where we have not obtained patent protection to develop their own products and further, may infringe our patents in territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain countries. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement or protection of patents, trade secrets and other intellectual property, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign countries could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. We have contract research and manufacturing relationships with contract organizations that operate in certain countries that are at heightened risk of theft of technology, data and intellectual property through direct intrusion by private parties or foreign actors, including those affiliated with or controlled by state actors. Accordingly, our efforts to protect or enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.***

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment (such as annuities) and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

***Any issued patents we may own covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO.***

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the U.S. and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an

unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

***We may become involved in lawsuits or litigation at the USPTO to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our future licensors is threatened, it could dissuade other companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

We may be required to protect our patents through procedures created to attack the validity of a patent at the USPTO. The USPTO hears post-grant proceedings, including PGR, IPR and derivation proceedings. An adverse

determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours for a meaningful amount of time, or at all.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union and certain other countries. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be expected, and our competitive position, business, financial condition, results of operations and prospects could be materially adversely affected.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate. Any of the foregoing could adversely affect our competitive position, business, financial condition, results of operations and prospects.

***Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. United States Congress has in recent years considered legislation to reduce the term of certain drug patents in order to ease generic entry and increase competition. Evolving judicial interpretation of patent law could also adversely affect our business. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

***We may be subject to claims challenging the inventorship of our patents and other intellectual property.***

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Also, former employees may become employed by competitors who develop similar technology, and could assist the competitor in designing around our patents. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

We use and will continue to use registered and/or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or

protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

***Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain. Defending against such lawsuits will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.***

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our product candidates infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to: infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business; substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees; a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us; however, the third party is not required to grant the license; if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and redesigning our product candidates or processes so they do not infringe; redesign may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third



party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

***Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common stock to decline.***

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors or their former employers.***

As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

***If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.***

We may in the future enter into license agreements with third parties under which we receive rights to intellectual property that are important to our business. These intellectual property license agreements may impose on us various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

We may also in the future enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all,

which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property.

We may need to obtain licenses in the future from third parties to advance our research or allow commercialization of our product candidates, and we cannot provide any assurances that there are no third-party patents which might be enforced against our product candidates in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place.

#### **Risks Related to Ownership of Our Common Stock**

##### ***The price of our stock may be volatile, and you could lose all or part of your investment.***

The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors include:

- the results of our ongoing, planned or any future preclinical studies, clinical trials or clinical development programs;
- the commencement, enrollment, or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in preclinical studies and clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial, including due to the suspension of a clinical trial by the FDA or other regulatory authorities;

- any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- expiration of lock-up agreements;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or stockholder litigation;
- the impact of any natural disasters or public health emergencies, such as the COVID-19 pandemic;
- general economic, political, industry and market conditions, including the new presidential administration in the United States; and
- other events or factors, many of which are beyond our control.

The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and adverse impact on the market price of our common stock.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In particular, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies have been highly volatile as a result of the COVID-19 pandemic. In addition, broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management’s attention and resources, which would materially adversely affect our business, financial condition and results of operation.

***An active trading market for our common stock may not continue to develop or be sustained.***

Prior to the closing of our IPO in September 2020, there was no public trading market for our common stock. Although our common stock is listed on the Nasdaq Global Select Market, the market for our shares has demonstrated varying levels of trading activity. We cannot predict the prices at which our common stock will trade or whether an active trading market will be sustained in the future. The lack of an active market may impair investors’ ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable may reduce the market value of their shares and may impair our ability to raise capital.

***If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. If no or few securities or industry analysts commence coverage of us, our stock price would be negatively impacted. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

***Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships, alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

***Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

As of December 31, 2020, we had 44,777,818 shares of common stock outstanding. Of these shares, approximately 13,529,750 shares are freely tradable and substantially all of the remaining shares of common stock

will be available for sale in the public market beginning in March 2021 following the scheduled expiration of lock-up agreements that certain of our stockholders and the underwriters entered into in connection with our IPO. Goldman Sachs & Co. LLC, BofA Securities, Inc., Cowen and Company, LLC and Evercore Group L.L.C. may release these stockholders from their lock-up agreements with the underwriters at any time and without notice, which would allow for earlier sales of such shares in the public market.

Moreover, holders of an aggregate of 28,197,798 shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market beginning in March 2021 following the scheduled expiration of lock-up agreements that certain of our stockholders and the underwriters entered into in connection with our IPO. If these additional shares are, or if it is perceived that they will be, sold in the public market, the trading price of our common stock could decline.

In addition, on September 28, 2020, we filed a registration statement on Form S-8 registering 8,879,210 shares of common stock that we may issue under our equity incentive plans. As a result, shares registered under this registration statement on Form S-8 can be freely sold in the public market subject to the satisfaction of vesting arrangements and the exercise of such options, volume limitations applicable to affiliates and the lock-up agreements described above.

Sales of a substantial number of such shares upon expiration of the lock-up agreements, the perception that such sales may occur, or early release of these agreements, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval.***

As of December 31, 2020, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 55.6% of our voting stock. Certain of our directors are affiliated with the holders of 5% or more of our capital stock. In particular, Peter Thompson, M.D. is an affiliate of OrbiMed Private Investments V LP and Thilo Schroeder, Ph.D. is an affiliate Nextech V Oncology S.C.S., SIACAV-SIF. As a result, this group of stockholders may be able to impact matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

***We are an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2020, as amended, or JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (2) the date we qualify as a “large accelerated filer,” with at least \$700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our IPO.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company,” which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

***We will incur significant increased costs as a result of operating as a public company, and our management has devoted and will continue to devote substantial time to new compliance initiatives.***

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have and will continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these

requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

***We do not intend to pay dividends on our capital stock, so any returns will be limited to the value of our stock.***

We have never declared or paid any cash dividends on our capital stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our capital stock. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

***Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed “for cause” and only with the approval of two-thirds of our stockholders;
- authorize the issuance of “blank check” preferred stock that our board could use to implement a stockholder rights plan (also known as a “poison pill”);
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware, or DGCL, prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

***Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, or Securities Act, the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find these types of provisions to be inapplicable or unenforceable, and if a court were to find the exclusive forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could materially adversely affect our business.

***Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person



reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;

- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we are not obligated, pursuant to our amended and restated bylaws, to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

While we maintain a directors' and officers' insurance policy, such insurance may not be adequate to cover all liabilities that we may incur, which may reduce our available funds to satisfy third-party claims and may materially adversely affect our cash position.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would materially adversely affect our business and the trading price of our common stock.***

We are subject to Section 404 of the Sarbanes-Oxley Act and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. We will also be required to disclose changes made in our internal controls and procedures on a quarterly basis. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. In addition, undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the trading price of our stock.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

***We are subject to increased risk of securities class action litigation, which is expensive and could divert management attention.***

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could materially adversely affect our business.

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.***

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current product candidates and any future product candidates and research-stage programs, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;

- the timing and outcomes of clinical trials for our future product candidates, or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- competition from existing and potential future products that compete with our product candidates and any of our future product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of our product candidates;
- the level of demand for our future product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with our product candidates;
- our ability to commercialize our product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain future collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic and political environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

Our corporate headquarters is located at 8 Clarke Drive, Cranbury, New Jersey 08512, where we lease a facility containing 18,446 square feet of office and laboratory space pursuant to a lease agreement that expires in June 2022. We also lease 6,297 square feet of laboratory space at 3000 Eastpark, South Brunswick, New Jersey 08512 pursuant to a lease that expires in July 2022. In January 2021, we signed a lease for 50,581 square feet of office and laboratory space at One Research Way in Princeton, New Jersey 08540. That lease term extends through 2032, has a five-year extension option, and is intended to replace our two existing facilities. Finally, we lease 3,292 square feet of office space at 420 Bedford Drive, Lexington, Massachusetts 02420 pursuant to a lease that expires in August 2023, with an option to extend for an additional three years.

We believe that our current facilities are adequate for our current and near term needs and that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

**Item 3. Legal Proceedings.**

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. As of February 28, 2021, we were not a party to any material legal matters or claims. In the future, we may become party to legal matters and claims in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.****Market Price of Common Stock**

Our common stock has been listed on the Nasdaq Global Select Market under the symbol “PMVP” since September 25, 2020. Prior to that date there was no public trading market for our common stock.

**Holders of Common Stock**

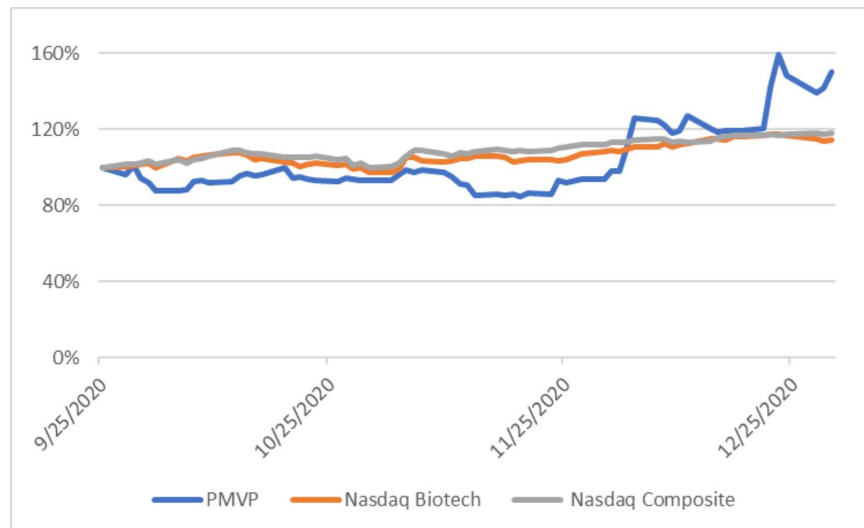
As of January 31, 2021, there were approximately 43 holders of record of our common stock. We believe actual number of stockholders is greater than this number of record holders. The approximate number of holders includes holders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose share may be held in trust by other entities.

**Performance Graph**

*This graph below is not “soliciting material” or deemed “filed” with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to liabilities under that Section, and shall not be deemed incorporated by reference into this Annual Report on Form 10-K or into any other filing of PMV Pharma. under the Securities Act, as amended, except to the extent that we specifically incorporate this information by reference therein, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.*

The following graph compares the cumulative total return to stockholder return on our common stock relative to the cumulative total returns of the Nasdaq Composite Index and the Nasdaq Biotechnology Index. An investment of \$100 is assumed to have been made in our common stock and each index on September 25, 2020 (the first day of trading of our common stock) and its relative performance is tracked through December 31, 2020. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. The stockholder returns shown on the graph below are based on historical results and are not indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

**COMPARISON OF CUMULATIVE TOTAL RETURN**  
among PMV Pharma, the NASDAQ Composite Index and the NASDAQ Biotechnology Index



**Dividend Policy**

We have never declared or paid cash dividends on our common stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors might deem relevant.

**Recent Sales of Unregistered Securities**

From January 1, 2020 through December 31, 2020, we sold and issued the following unregistered securities, which share numbers have been adjusted, as appropriate, to reflect the 5.2651-for-one reverse stock split which became effective on September 24, 2020:

- (1) We granted stock options to employees, directors and consultants covering an aggregate of 1,375,196 shares of common stock, at a weighted-average exercise price of \$5.23 per share.
- (2) We sold an aggregate of 4,070 shares of common stock to employees for cash consideration in the aggregate amount of \$6 thousand pursuant to stock option exercises.
- (3) We sold an aggregate of 9,688 shares of common stock to a warrant holder pursuant to exercise of the warrant. Cash consideration for this transaction was \$194 thousand.
- (4) In July 2020, we issued an aggregate of 5,321,864 shares of Series D preferred stock to six accredited investors at a price per share of \$13.1533, for total gross proceeds of \$70.0 million. In connection with the completion of our IPO, all shares of Series D preferred stock automatically converted into an equivalent number of shares of our common stock.

The offers, sales and issuances of the securities described in this Item 5 were deemed to be exempt from registration under the Securities Act under either (i) Rule 701 promulgated under the Securities Act as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in

compliance with Rule 701 or (ii) Section 4(a)(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) as transactions by an issuer not involving any public offering. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the stock certificates and instruments issued in such transactions.

#### **Use of Proceeds from our Public Offering of Common Stock**

On September 24, 2020, our registration statement on Form S-1 (File No. 333-248627) relating to our IPO of common stock was declared effective by the SEC. The IPO closed on September 25, 2020 at which time we issued 13,529,750 shares of common stock (including the exercise in full by the underwriters of their option to purchase an additional 1,764,750 shares of common stock) at a public offering price of \$18.00 per share. We received net proceeds from the IPO of approximately \$223.2 million, after deducting the underwriting discounts and commissions of approximately \$17.0 million and estimated offering related expenses of approximately \$3.3 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates. Goldman Sachs & Co. LLC, BofA Securities, Cowen, and Evercore IS acted as joint book-running managers for the offering.

There has been no material change in the planned use of proceeds from the IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on September 24, 2020.

#### **Purchases of Equity Securities by the Issuer and Affiliated Purchases**

None.

#### **Item 6. Selected Financial Data.**

You should read the selected historical financial data below in conjunction with the section titled “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the audited financial statements included elsewhere in this report. The selected financial data included in this section are not intended to replace the financial statements included elsewhere in this Annual Report on Form 10-K. We derived the selected statements of operations data for the years ended December 31, 2020, 2019 and 2018 and the selected balance sheet data at December 31, 2020 and 2019 from our audited consolidated financial statements included elsewhere in this

report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Year Ended		
	December 31, 2020	December 31, 2019	December 31, 2018
<b>Operating Expenses:</b>			
Research and development	\$ 23,933	\$ 20,759	\$ 13,853
General and administrative	11,009	5,878	5,039
Total operating expenses	34,942	26,637	18,892
Loss from operations	(34,942)	(26,637)	(18,892)
Other income:			
Interest income, net	651	1,301	1,341
Other expense	(143)	(8)	16
Total other income	508	1,293	1,357
Loss before provision for income taxes	(34,434)	(25,344)	(17,535)
Provision for income taxes	6	8	3
Net loss	(34,440)	(25,352)	(17,538)
Unrealized gains on marketable securities, net of tax	3	10	52
Comprehensive loss	\$ (34,437)	\$ (25,342)	\$ (17,486)
Net loss per share—basic and diluted	\$ (2.40)	\$ (8.35)	\$ (5.82)
Weighted-average common shares outstanding	14,364,475	3,035,243	3,012,284

	December 31, 2020	December 31, 2019
Cash, cash equivalents, and short-term marketable securities	\$ 361,422	\$ 101,486
Working capital (1)	358,351	97,570
Property and equipment, net	569	739
Total assets	\$ 365,531	\$ 103,033
Total current liabilities	6,410	4,523
Convertible preferred stock	—	168,933
Accumulated deficit	(109,880)	(75,440)
Total stockholders' equity (deficit)	\$ 359,121	\$ (70,474)

(1) Working capital is defined as current assets minus current liabilities.



## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*You should read the following discussion and analysis of our financial condition and results of operations together with "Selected Financial Data" and the financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed in "Part I, Item 1A. Risk Factors" and in other parts of this Annual Report on Form 10-K.*

A discussion of our financial performance for the year ended December 31, 2020 as compared to the year ended December 31, 2019 appears below under the captions "Results of Operations" and "Liquidity and Capital Resources." A discussion of our financial performance for the year ended December 31, 2019 compared to the year ended December 31, 2018 can be found in our Registration Statement filed on Form S-1/A, in the "Management Discussion And Analysis Of Financial Condition And Results Of Operations" section, under the same captions, filed with the SEC on September 24, 2020, which is available free of charge on the SEC's website at [www.sec.gov](http://www.sec.gov) and our Investor Relations website at [ir.pmvpharma.com/financial-information/sec-filings](http://ir.pmvpharma.com/financial-information/sec-filings). These website addresses are intended to be inactive, textual references only. None of the materials on, or accessible through, these websites are part of this report or are incorporated by reference herein.

### Overview

We are a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53 mutations. p53 is a well-defined tumor suppressor protein known as the "guardian of the genome," and normal, or wild-type, p53 has the ability to eliminate cancer cells. However, mutant p53 proteins can be misfolded and lose their wild-type tumor suppressing function. These p53 mutations are found in approximately half of all cancers. The field of p53 biology was established by our co-founder Dr. Arnold Levine when he discovered the p53 protein in 1979. We have leveraged more than four decades of research experience and developed unique insights into p53 to create a precision oncology platform designed to generate selective, small molecule, tumor-agnostic therapies that structurally correct specific mutant p53 proteins to restore their wild-type function. We are deploying our precision oncology platform to target the top ten most frequent, or hotspot, p53 mutations that are collectively associated with approximately 10-15% of all cancers.

Since our formation in March 2013, we have devoted substantially all of our time and efforts to performing research and development activities and raising capital. We are not profitable and have incurred losses in each year since our inception. Our net losses were \$34.4 million, \$25.4 million, and \$17.5 million for the years ended December 31, 2020, 2019, and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of \$109.9 million. We do not currently have any product candidates approved for sale, and we continue to incur significant research and development and general administrative expenses related to our operations. We initiated a Phase 1/2 clinical trial in October 2020 for our lead product candidate, PC14586. In October 2020, we were granted FDA Fast Track Designation of PC14586 for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation. We dosed our first patient in this clinical trial in the fourth quarter of 2020. We expect that our operating expenses will increase significantly as we advance our product candidates through preclinical and clinical development, seek regulatory approval and prepare for and, if approved, proceed to commercialization; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel. Furthermore, we have incurred and will continue to incur additional costs associated with operating as a public company that we did not experience as a private company. We expect to continue to incur significant losses for the foreseeable future.

Prior to our initial public offering, or IPO, we funded our operations primarily from the issuance and sale of convertible preferred stock. As of December 31, 2020, we had \$361.4 million in cash and cash equivalents. We believe that our existing capital resources will be sufficient to fund our planned operations at least through 2023.

Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing.

Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

We plan to continue to use third-party service providers, including clinical research organizations, or CROs, and contract manufacturing organization, or CMOs, to carry out our preclinical and clinical development and to manufacture and supply the materials to be used during the development and commercialization of our product candidates. We do not currently have a sales force.

## **Components of Results of Operations**

### ***Revenue***

To date, we have not generated any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all.

### ***Operating Expenses***

#### ***Research and Development Expenses***

Our research and development expenses consist primarily of costs incurred to conduct research, such as the discovery and development of our product candidates as well as the development of future product candidates. Research and development expenses include personnel costs, including stock-based compensation expense, third-party contractor services, laboratory materials and supplies, and depreciation and maintenance of research equipment. We expense research and development costs as they are incurred.

As we are at a very early stage of development, we do not allocate our costs by product candidate or development program, as a significant amount of research and development expenses include compensation costs, materials, supplies, depreciation on and maintenance of research equipment, and the cost of services provided by outside contractors, which are not tracked by product candidate or development program. In particular, with respect to internal costs, several of our departments support multiple product candidate research and development programs, and therefore the costs cannot be allocated to a particular product candidate or development program. Substantially all of our research and development costs are associated with our lead product candidate, PC14586. We initiated a Phase 1/2 clinical trial in October 2020 for our lead product candidate, PC14586. In October 2020, we were granted FDA Fast Track Designation of PC14586 for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation. We dosed our first patient in this clinical trial in the fourth quarter of 2020.

We expect our research and development expenses to increase substantially in absolute dollars in the future as we advance our product candidates into and through clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors including: the safety and efficacy of our product candidates, early clinical data, investment in our clinical program, the ability of any future collaborators to successfully develop our licensed product candidates, competition, manufacturing capability, and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects.

#### ***General and Administrative Expenses***

General and administrative expenses include personnel costs, expenses for outside professional services and other allocated expenses. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation. Outside professional services consist of legal, accounting and audit services and other consulting fees. Allocated

expenses consist of rent expense related to our office and research and development facility. We expect to incur additional expenses as a public company, including expenses related to compliance with the rules and regulations of the SEC, and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services. We expect to increase our headcount significantly to support our operations as a public company. We also expect to increase our general and administrative expenses as we advance our product candidates through preclinical research and development, manufacturing, clinical development and commercialization.

### ***Interest Income, Net***

Interest income, net primarily consists of interest income from our interest-bearing cash, cash equivalents and short-term marketable securities and interest costs related to amortization of premiums and discounts on short-term marketable securities.

## **Results of Operations**

### ***Comparison of the Years Ended December 31, 2020 and 2019***

The following table summarizes our results of operations (in thousands):

<b>Statement of operations data:</b>	<b>Year Ended</b>		<b>Change</b>
	<b>December 31,</b>		
	<b>2020</b>	<b>2019</b>	
Operating expenses:			
Research and development	\$ 23,933	\$ 20,759	\$ 3,174
General and administrative	11,009	5,878	5,131
Total operating expenses	34,942	26,637	8,305
Loss from operations	(34,942)	(26,637)	8,305
Other income (expense):			
Interest income, net	651	1,301	(650)
Other expense	(143)	(8)	(135)
Total other income (expense)	508	1,293	(785)
Loss before provision for income taxes	(34,434)	(25,344)	9,090
Provision for income taxes	6	8	(2)
Net loss	\$ (34,440)	\$ (25,352)	\$ 9,088

### ***Research and Development Expenses***

The following table summarizes our research and development expenses incurred during the periods indicated (in thousands):

<b>Statement of operations data:</b>	<b>Year Ended</b>		<b>Change</b>
	<b>December 31,</b>		
	<b>2020</b>	<b>2019</b>	
Research	\$ 7,999	\$ 9,364	\$ (1,365)
Development	7,706	5,811	1,895
Personnel related	7,392	5,282	2,110
Stock-based compensation	836	302	534
Total	\$ 23,933	\$ 20,759	\$ 3,174

Research and development expenses were \$23.9 million for the year ended December 31, 2020, compared to \$20.8 million for the year ended December 31, 2019. The increase of \$3.2 million was primarily due to the following:

- \$1.4 million decrease in research expenses, driven primarily by a decline in costs from certain of our contract research organizations.
- \$1.9 million increase in development expenses, primarily associated with increased effort advancing our lead compound PC14586 through pre-clinical studies and into a Phase 1/2 clinical trial; and
- \$2.6 million increase in expenses for personnel related costs and stock-based compensation, primarily driven by increased headcount for developing PC14586 and initiation of an investigational new drug, or IND, study for the Y220C mutation.

#### ***General and Administrative Expenses***

General and administrative expenses were \$11.0 million for the year ended December 31, 2020, compared to \$5.9 million for the year ended December 31, 2019. The increase of \$5.1 million was primarily due to the following:

- \$3.0 million increase in expense for employee compensation, driven primarily by increased headcount to build out general and administrative infrastructure for the Company; and
- \$2.1 million increase in expense for insurance and outside services, which is primarily driven by \$1.2 million in regulatory and finance support, \$0.6 million directors and officers insurance, and \$0.3 million associated with legal expenses for patent filings and service contract drafting and review.

#### ***Interest Income, Net***

Interest income, net was \$0.7 million for the year ended December 31, 2020, compared to \$1.3 million for the year ended December 31, 2019. The decrease of \$0.6 million is driven by decreased income from cash investments in marketable securities and U.S treasuries.

### **Liquidity and Capital Resources**

#### ***Sources of Liquidity***

Since our inception, we have not generated any revenue from any product sales or any other sources, and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. As of December 31, 2020, we have cash and cash equivalents of \$361.4 million and an accumulated deficit of \$109.9 million. Prior to our initial public offering, or IPO, we financed our operations primarily through issuances of our convertible preferred stock. In 2019, we sold an aggregate of 5,469,606 shares of our Series C convertible preferred stock to accredited investors, generating gross proceeds of \$61.9 million. In July 2020, we sold an aggregate of 5,321,864 shares of our Series D convertible preferred stock to accredited investors, generating gross proceeds of \$70.0 million.

On September 25, 2020, we completed our IPO pursuant to which we issued and sold 13,529,750 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to 1,764,750 additional shares of common stock, at a public offering price of \$18.00 per share. The gross proceeds from the IPO were approximately \$243.5 million and the net proceeds were approximately \$223.2 million, after deducting underwriting discounts and commissions and other offering expenses.

#### ***Plan of Operation and Future Funding Requirements***

We use our capital resources primarily to fund operating expenses, primarily research and development expenditures. We plan to increase our research and development expenses for the foreseeable future as we continue the preclinical development and move into clinical development of our product candidates. At this time, due to the

inherently unpredictable nature of preclinical and clinical development and given the early stage of our product candidates, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval and commercialize our current product candidates or any future product candidates, if at all. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Due to our significant research and development expenditures, we have generated substantial operating losses in each period since inception. We have incurred an accumulated deficit of \$109.9 million through December 31, 2020. We expect to incur substantial additional losses in the future as we expand our research and development activities. Based on our research and development plans, we expect that our cash balances as of December 31, 2020 will be sufficient to fund our operations at least through 2023. We have based this estimate on assumptions that may prove to be wrong, however, and we could use our capital resources sooner than we expect.

The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the timing and amount of milestone payments we may receive under any future collaboration agreements;
- our ability to maintain future licenses and research and development programs and to establish new collaboration arrangements;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the cost and timing of regulatory approvals; and
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates and satisfy our obligations as a public company.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to fund our operations and capital funding needs through equity and/or debt financing. We may also consider entering into collaboration arrangements or selectively partnering for clinical development and commercialization. The sale of additional equity would result in additional dilution to our stockholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations or our ability to incur additional indebtedness or pay dividends, among other items. If we raise additional funds through governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially and adversely affect our business, financial condition, results of operations and prospects.

## Cash Flows

The following table summarizes our cash flows for the period indicated (in thousands):

	Year Ended		
	December 31,		
	2020	2019	2018
Cash used in operating activities	\$ (32,739)	\$ (22,065)	\$ (15,178)
Cash provided by investing activities	27,911	3,231	21,693
Cash provided by financing activities	292,972	61,805	—
Net increase in cash and cash equivalents	<u>\$ 288,144</u>	<u>\$ 42,971</u>	<u>\$ 6,515</u>

### Operating Activities

Net cash used in operating activities for the year ended December 31, 2020, was \$32.7 million, which consisted primarily of net loss of \$34.4 million increased by non-cash charges of \$2.5 million and decreased by a net change of \$0.9 million in our net operating assets. The non-cash charges primarily consisted of stock-based compensation of \$1.9 million and depreciation of \$0.3 million. The change in our net operating assets and liabilities was primarily due to an increase in current assets, accompanied by a decrease in outstanding payables, and an increase in accrued compensation and accrued liabilities in 2020.

Net cash used in operating activities for the year ended December 31, 2019, was \$22.1 million, which consisted primarily of net loss of \$25.4 million decreased by non-cash charges of \$1.4 million and by a net change of \$1.9 million in our net operating assets. The non-cash charges primarily consisted of stock-based compensation of \$0.9 million and depreciation and amortization expense of \$0.5 million. The change in our net operating assets and liabilities was primarily due to an increase in outstanding payables in 2019.

### Investing Activities

Our investing activities provided \$28.0 million of cash during the year ended December 31, 2020, which consisted primarily of maturities of marketable securities of \$42.6 million, partially offset by purchases of marketable securities of \$14.5 million and purchases of property and equipment of \$0.1 million.

Our investing activities provided \$3.2 million of cash during the year ended December 31, 2019, which consisted primarily of maturities of marketable securities of \$46.8 million, partially offset by purchases of marketable securities of \$43.5 million and purchases of property and equipment of \$0.1 million.

### Financing Activities

Our financing activities provided \$293.0 million of cash during the year ended December 31, 2020, which consisted primarily of gross IPO proceeds of \$243.5 million and Series D Preferred Stock issuance of \$70.0 million, offset by equity issuance costs of \$20.6 million.

Our financing activities provided \$61.8 million of cash during the year ended December 31, 2019, which consisted primarily of proceeds from the issuance of our Series C convertible preferred stock of \$61.9 million, and proceeds from the exercise of stock options of \$0.1 million, partially offset by payments of equity issuance costs of \$0.2 million.

### Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

## Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2020 (in thousands):

	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Operating lease obligations:	\$ 479	\$ 256	\$ —	\$ —	\$ 735
Total:	\$ 479	\$ 256	\$ —	\$ —	\$ 735

We enter into contracts in the normal course of business with CROs and other vendors to assist in the performance of our research and development activities and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments.

In January 2021, we signed a lease for 50,581 square feet of office and laboratory space at One Research Way in Princeton, New Jersey. That lease term extends through 2032, has a five-year extension option, and is intended to replace our two existing facilities. Payments under this lease will total \$19.6 million through May 2032.

## Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and judgments that affect the amounts reported in those financial statements and accompanying notes. Although we believe that the estimates we use are reasonable, due to the inherent uncertainty involved in making those estimates, actual results reported in future periods could differ from those estimates.

We believe that the accounting policies described below involve a high degree of judgment and complexity. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our financial condition and results of our operations.

### *Research and Development Costs, Accrued Research and Development Costs and Related Prepaid Expenses*

Research and development costs are expensed as incurred. Research and development expenses consist principally of personnel costs, including salaries, stock-based compensation and benefits for employees, third-party license fees and other operational costs related to our research and development activities, including allocated facility-related expenses and external costs of outside vendors, and other direct and indirect costs. Non-refundable research and development advance payments are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or services are performed.

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including research laboratories, in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical studies and clinical trials; and

- CMOs in connection with drug substance and drug product formulation of preclinical studies and clinical trial materials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that supply, conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

### ***Stock-Based Compensation***

We measure all stock options and other stock-based awards granted to our employees, directors, consultants and other non-employee service providers based on the fair value on the date of the grant. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is typically the vesting term. Compensation expense related to awards to employees with performance-based vesting conditions is recognized based on grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. Non-employee option awards are measured at the earlier of the commitment date for performance by the counterparty or the date when the performance is complete, and compensation expense is recognized in the same manner as if we had paid cash for goods or services.

We classify stock-based compensation expense in our statement of operations in the same way the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

We use the Black-Scholes option pricing model to estimate the fair value of stock options on the date of grant. Using the Black-Scholes option pricing model requires management to make significant assumptions and judgments. We determined these assumptions for the Black-Scholes option-pricing model as discussed below.

- *Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. As we do not have sufficient historical experience for determining the expected term of the stock option awards granted, we based our expected term for awards issued to employees and non-employees using the simplified method which is presumed to be the midpoint between the vesting date and the end of the contracted term.
- *Contractual Term*—The contractual term represents the nominal period that the stock-based awards are outstanding.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury constant maturity notes with terms approximately equal to the stock-based awards' expected term.
- *Expected Volatility*—Since we do not have a trading history of common stock, the expected volatility was derived from the average historical stock volatilities of the common stock of several public companies within the industry that we consider to be comparable to our business over a period equivalent to the expected term of the stock-based awards.
- *Dividend Rate*—The expected dividend rate is zero as we have not paid and do not anticipate paying any dividends in the foreseeable future.



- *Fair Value of Common Stock*—Prior to our IPO, the fair value of the shares of common stock underlying the stock-based awards was determined by our board of directors with input from management. Because there was no public market for our common stock, our board of directors determined the fair value of our common stock at the time of grant of the stock-based award by considering a number of objective and subjective factors, including having valuations of the common stock performed by a third-party valuation specialist, as further described below.

As of December 31, 2020, the total compensation cost related to nonvested service-based awards not yet recognized is \$4,602. The weighted-average period over which the nonvested awards is expected to be recognized is 2.9 years. The aggregate intrinsic value of options outstanding as of December 31, 2020 was \$238.8 million, of which \$154.1 million related to vested options and \$84.7 million related to unvested options.

### ***Common Stock Valuations***

The fair value of the shares of common stock underlying our stock-based awards prior to our IPO was determined by our board of directors with input from management and contemporaneous third-party valuations. We believe that our board of directors had the relevant experience and expertise to determine the fair value of our common stock prior to our IPO. Given the absence of a public trading market of our common stock, and in accordance with the *American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation*, our board of directors exercised reasonable judgment and considered numerous and subjective factors to determine the best estimate of the fair value of our common stock at each grant date. These factors include:

- contemporaneous valuations of our common stock performed by independent third-party specialists;
- the prices, rights, preferences and privileges of our convertible preferred stock relative to those of our common stock;
- the prices of common or convertible preferred stock sold to third-party investors by us
- lack of marketability of our common stock;
- our actual operating and financial performance;
- current business conditions and projections;
- hiring of key personnel and the experience of our management;
- the history of the company;
- our stage of development;
- likelihood of achieving a liquidity event, such as an initial public offering or a merger or acquisition of our company given prevailing market conditions;
- the market performance of comparable publicly traded companies; and
- the U.S. and global capital market conditions.

In valuing our common stock, our board of directors determined the equity value of our business using the hybrid method with input from management and contemporaneous third-party valuations. The hybrid method is based upon the probability-weighted value across two scenarios, being (i) successfully consummating an initial public offering and (ii) alternative scenarios in which an initial public offering is not consummated. The hybrid method can be a useful alternative to explicitly modeling all probability-weighted expected return scenarios in situations when the company has transparency into one or more near term exits but is unsure about what will occur if current plans do not materialize. In the first scenario, the potential exit date, the probability exit value and the likelihood of interim financings were considered. In the second scenario, which was assigned the residual probability, the potential exit date, the equity volatility, the assumed interest rate, the dividend yield and equity inflection points at which the allocation of proceeds changes were considered. The valuation method considers the total number of shares authorized and outstanding, as well as recent issuances of both preferred and common stock.

Application of these approaches involves the use of estimates, judgment and assumptions that are highly complex and subjective, such as those regarding the time to the liquidation event and volatility. Changes in these estimates and assumptions or the relationships between these assumptions impact our valuations as of each valuation date and may have a material impact on the valuation of common stock.

Following our IPO, the fair value of each share of underlying common stock will be based on the closing price of our common stock as reported by Nasdaq on the date of grant. Future expense amounts for any particular period could be affected by changes in our assumptions or market conditions.

### **Recent Accounting Pronouncements**

For a description of recent accounting pronouncements, see Note 2 of the notes to our audited financial statements for the year ended December 31, 2020 included elsewhere in this Annual Report on Form 10-K for the year ended December 31, 2020.

### **JOBS Act Accounting Election**

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or Jobs Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1 billion in non-convertible debt during the prior three-year period.

Under the Jobs Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use the extended transition period to enable us to comply with new or revised accounting standards and, therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company,” which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rate risks.

We had cash and cash equivalents of \$361.4 million as of December 31, 2020, which consists of interest-bearing U.S. treasury securities and money market funds. Our exposure due to changes in interest rates is not material due to the nature and amount of our money-market funds and short-term marketable securities.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we may contract with foreign vendors that are located outside the United States in the future. This may subject us to fluctuations in foreign currency exchange rates in the future.

**Item 8. Financial Statements and Supplementary Data.**

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**Audited Financial Statements**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of PMV Pharmaceuticals, Inc.

### **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of PMV Pharmaceuticals, Inc. (the Company) as of December 31, 2020 and 2019, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' (deficit) equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

### **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 audit 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/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

Philadelphia, Pennsylvania  
March 3, 2021

**PMV Pharmaceuticals, Inc.**  
**Balance Sheets**

(in thousands, except share and per share amounts)

	December 31, 2020	December 31, 2019
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 361,422	\$ 73,278
Short-term marketable securities	—	28,208
Prepaid expenses and other current assets	3,339	607
Total current assets	364,761	102,093
Property and equipment, net	569	739
Other assets	201	201
Total assets	<u>\$ 365,531</u>	<u>\$ 103,033</u>
<b>Liabilities, Convertible Preferred Stock, and Stockholders' Equity (Deficit)</b>		
Current liabilities		
Accounts payable	\$ 1,607	\$ 2,837
Accrued expenses	4,803	1,686
Total current liabilities	6,410	4,523
Other liabilities	—	51
Total liabilities	6,410	4,574
Commitments and contingencies (see Note 6)	—	—
Convertible preferred stock, accumulated liquidation value of \$0 and \$169,385 at December 31, 2020 and 2019, respectively	—	168,933
Stockholders' equity (deficit):		
Preferred stock, \$0.00001 par value, 5,000,000 and no shares authorized at December 30, 2020 and 2019, respectively, no shares issued or outstanding at December 31, 2020 and 2019, respectively	—	—
Common stock, \$0.00001 par value, 1,000,000,000 and 33,250,829 shares authorized; 44,777,818 and 3,046,200 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	—
Additional paid-in capital	469,001	4,969
Accumulated deficit	(109,880)	(75,440)
Accumulated other comprehensive loss	—	(3)
Total stockholders' equity (deficit)	359,121	(70,474)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	<u>\$ 365,531</u>	<u>\$ 103,033</u>

*The accompanying notes are an integral part of these financial statements.*

**PMV Pharmaceuticals, Inc.**  
**Statements of Operations and Comprehensive Loss**

(in thousands, except share and per share amounts)

	Year Ended		
	December 31, 2020	December 31, 2019	December 31, 2018
<b>Operating Expenses:</b>			
Research and development	\$ 23,933	\$ 20,759	\$ 13,853
General and administrative	11,009	5,878	5,039
Total operating expenses	<u>34,942</u>	<u>26,637</u>	<u>18,892</u>
Loss from operations	(34,942)	(26,637)	(18,892)
Other income:			
Interest income, net	651	1,301	1,341
Other (expense) income	(143)	(8)	16
Total other income	<u>508</u>	<u>1,293</u>	<u>1,357</u>
Loss before provision for income taxes	(34,434)	(25,344)	(17,535)
Provision for income taxes	6	8	3
Net loss	(34,440)	(25,352)	(17,538)
Unrealized gains on marketable securities, net of tax	3	10	52
Comprehensive loss	<u>\$ (34,437)</u>	<u>\$ (25,342)</u>	<u>\$ (17,486)</u>
Net loss per share—basic and diluted	<u>\$ (2.40)</u>	<u>\$ (8.35)</u>	<u>\$ (5.82)</u>
Weighted-average common shares outstanding	14,364,475	3,035,243	3,012,284

*The accompanying notes are an integral part of these financial statements.*

**PMV Pharmaceuticals, Inc.**  
**Statements of Convertible Preferred Stock and Stockholders' (Deficit) Equity**  
(in thousands except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount				
Balances at December 31, 2017	17,396,640	\$ 107,228	3,012,284	\$ —	\$ 2,882	\$ (65)	\$ (32,550)	\$ (29,733)
Stock-based compensation expense	—	—	—	—	1,079	—	—	1,079
Net loss	—	—	—	—	—	—	(17,538)	(17,538)
Unrealized gain on available for sale investments	—	—	—	—	—	52	—	52
Balances at December 31, 2018	17,396,640	107,228	3,012,284	—	3,961	(13)	(50,088)	(46,140)
Issuance of Series C convertible preferred stock, net of issuance costs of \$168	5,469,606	61,705	—	—	—	—	—	—
Exercise of stock options	—	—	33,916	—	100	—	—	100
Stock-based compensation expense	—	—	—	—	908	—	—	908
Net loss	—	—	—	—	—	—	(25,352)	(25,352)
Unrealized gain on available for sale investments	—	—	—	—	—	10	—	10
Balances at December 31, 2019	22,866,246	168,933	3,046,200	—	4,969	(3)	(75,440)	(70,474)
Issuance of Series D convertible preferred stock, net of issuance costs of \$208	5,321,864	69,790	—	—	—	—	—	—
Conversion of convertible preferred stock to common stock	(28,188,110)	(238,723)	28,188,110	—	238,723	—	—	238,723
Exercise of warrants	—	—	9,688	—	194	—	—	194
Issuance of common stock, net of issuance costs of \$20,359	—	—	13,529,750	—	223,176	—	—	223,176
Exercise of stock options	—	—	4,070	—	6	—	—	6
Stock-based compensation expense	—	—	—	—	1,933	—	—	1,933
Net loss	—	—	—	—	—	—	(34,440)	(34,440)
Unrealized gain on available for sale investments	—	—	—	—	—	3	—	3
Balance at December 31, 2020	—	\$ —	44,777,818	\$ —	\$ 469,001	\$ —	\$ (109,880)	\$ 359,121

*The accompanying notes are an integral part of these financial statements.*



**PMV Pharmaceuticals, Inc.**  
**Statements of Cash Flows**

(in thousands)

	Year Ended		
	December 31, 2020	December 31, 2019	December 31, 2018
<b>Cash flows from operating activities:</b>			
Net loss	\$ (34,440)	\$ (25,352)	\$ (17,538)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock based compensation	1,933	908	1,079
Depreciation	318	388	338
Amortization of premiums on marketable securities	152	62	319
Other	143	8	(13)
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(2,732)	(275)	(17)
Accounts payable	(1,230)	1,799	267
Accrued expenses	3,117	397	387
Net cash used in operating activities	<u>(32,739)</u>	<u>(22,065)</u>	<u>(15,178)</u>
<b>Cash flows from investing activities:</b>			
Acquisition of property and equipment	(148)	(109)	(452)
Purchase of marketable securities	(14,512)	(43,452)	(48,678)
Maturities of marketable securities	42,571	46,792	70,823
Net cash provided by investing activities	<u>27,911</u>	<u>3,231</u>	<u>21,693</u>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of convertible preferred stock, net of issuance costs	69,790	61,705	—
Proceeds from issuance of common shares, net of issuance costs	223,176	—	—
Proceeds from exercise of stock options	6	100	—
Net cash provided by financing activities	<u>292,972</u>	<u>61,805</u>	<u>—</u>
Net increase in cash and cash equivalents	288,144	42,971	6,515
<b>Cash and cash equivalents</b>			
Cash and cash equivalents—beginning of period	73,278	30,307	23,792
Cash and cash equivalents—end of period	<u>\$ 361,422</u>	<u>\$ 73,278</u>	<u>\$ 30,307</u>
<b>Supplemental disclosures of noncash financing activities</b>			
Conversion of convertible preferred stock to common stock	\$ 238,723	\$ —	\$ —
Conversion of warrant liability to common stock	\$ 194	\$ —	\$ —
<b>Supplemental disclosures of cash flow information</b>			
Cash paid for income tax	\$ 6	\$ 8	\$ —

*The accompanying notes are an integral part of these financial statements.*

**PMV Pharmaceuticals, Inc.**  
**Notes to Financial Statements**  
**December 31, 2020 and 2019**  
**(in thousands except share and per share amounts)**

**1. Formation and Business of the Company**

**Organization**

PMV Pharmaceuticals, Inc. (the “Company”) was incorporated in the state of Delaware in March 2013. Since inception, the Company has devoted substantially all of its time and efforts to performing research and development activities and raising capital. The Company is a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53 mutations. The Company’s headquarters are located in Cranbury, New Jersey.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, technical risks associated with the successful research, development and manufacturing of product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Current and future programs will require significant research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

On September 25, 2020, the Company completed an initial public offering (the “IPO”) of 13,529,750 shares of common stock, at a public offering price of \$18.00 per share including the exercise in full by the underwriters of their option to purchase up to 1,764,750 additional shares of common stock, for aggregate gross proceeds of \$243,536 and its shares started trading on The Nasdaq Global Select Market under the ticker symbol “PMVP.” The Company received \$223,176 in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by the Company. In connection with the closing of the IPO, all of the Company’s outstanding shares of convertible preferred stock outstanding at the time of the IPO automatically converted into 28,188,110 shares of common stock. On September 18, 2020, the Company amended its certificate of incorporation to effect a 5.2651-for-1 reverse stock split of its issued and outstanding common and convertible preferred stock. The accompanying financial statements and related notes give retroactive effect to the reverse stock split for all periods presented.

The Company has incurred net losses and negative cash flows from operations. During the year ended December 31, 2020, the Company incurred a net loss of \$34,440 and used \$32,739 of cash for operations. At December 31, 2020, the Company had accumulated deficit of \$109,880. Cash and cash equivalents at December 31, 2020 were \$361,422. Management expects to incur substantial additional operating losses for the next several years and may need to obtain additional debt or equity financings in order to complete development of its products, obtain regulatory approvals, launch and commercialize its products and continue research and development programs. The Company believes it has adequate cash and financial resources to operate for at least the next twelve months from the date of issuance of these financial statements.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”). The accompanying financial statements

**PMV Pharmaceuticals, Inc.**  
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have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has limited operating history and its prospects are subject to risks, expenses and uncertainties frequently encountered by companies in the biotechnology industry.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management 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 and reported amounts of revenues and expenses during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the fair values of common stock, convertible preferred stock and stock-based compensation. Actual results could differ materially from those estimates.

***Reverse Stock Split***

In September 2020, the Company's board of directors and stockholders approved an amendment to the Company's amended and restated certificate of incorporation to effect a 5.2651-for-1 reverse stock split of the Company's common stock and convertible preferred stock, which was effected on September 24, 2020. The par value of the common stock and convertible preferred stock were not adjusted as a result of the reverse stock split. Accordingly, all common stock, convertible preferred stock, stock options, and related per share amounts in these financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

***Fair Value of Financial Instruments***

The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

- Level 1 - Inputs that reflect 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 - Inputs other than quoted prices that are observable for the asset or liability either directly or indirectly, including inputs in markets that are not considered to be active.
- Level 3 - Inputs are unobservable in which there is little or no market data available, which require the reporting entity to develop its own assumptions that are unobservable.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

**PMV Pharmaceuticals, Inc.**  
**Notes to Financial Statements**  
**December 31, 2020 and 2019**  
**(in thousands except share and per share amounts)**

***Cash, Cash Equivalents and Marketable Securities***

Management considers all highly liquid investments with original maturities of three months or less to be cash equivalents.

The Company's marketable debt securities have been classified and accounted for as available-for-sale at December 31, 2019. The Company had no marketable debt securities at December 31, 2020. The Company classifies its marketable debt securities as either short-term or long-term based on each instrument's underlying contractual maturity date. Marketable debt securities with maturities of 12 months or less are classified as short-term and marketable debt securities with maturities greater than 12 months are classified as long-term. The Company's marketable debt securities are carried at fair value, with unrealized gains and losses, net of taxes, reported as a component of accumulated other comprehensive loss in stockholders' equity. Premiums and discounts on marketable debt securities are amortized into earnings over the life of the security, which is recorded in Interest income, net. For the years ending December 31, 2020, 2019, and 2018, the Company recorded \$152, \$62, and \$319 of amortization, respectively.

***Property and Equipment***

Property and equipment are recorded at cost net of accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, generally five years, except for leasehold improvements, which are amortized over the remaining term of the lease.

Upon retirement or sale of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations. Repairs and maintenance costs are charged to operations as incurred.

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

Long-lived assets, which are comprised of property and equipment to be held and used are tested for recoverability whenever events or changes in the business environment indicate that the carrying amount of the assets may not be fully recoverable. Factors considered by the Company when deciding when to perform an impairment review include significant underperformance of the business against expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows resulting from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows resulting from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its current fair value. To date, the Company has not recorded any impairment losses on long-lived assets.

***Comprehensive Income/Loss***

The Company recorded \$3, \$10, and \$52 in other comprehensive income related to unrealized gains on marketable securities, net of tax for the years ended December 31, 2020, 2019, and 2018, respectively. The Company presents comprehensive income in a single statement within its financial statements.

**PMV Pharmaceuticals, Inc.**  
**Notes to Financial Statements**  
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**(in thousands except share and per share amounts)**

***Research and Development Expenses***

Research and development expenses include costs directly attributable to the conduct of research and development programs, including compensation costs, which includes allocated stock-based compensation, salary payroll taxes, employee benefits; materials; supplies; depreciation on and maintenance of research equipment; the cost of services provided by outside contractors; and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. Costs for certain research and development activities are recognized based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as a prepaid expenses or as accrued research and development expenses. All costs associated with research and development are expensed as incurred.

***Convertible Preferred Stock***

The Company's convertible preferred stock is classified outside of stockholders' deficit because the shares contain deemed liquidation rights that are a contingent redemption feature not solely within the control of the Company. The Company's policy is not to accrete the carrying value and related issuance costs of the convertible preferred stock to its redemption value until it is probable that the security will become redeemable. The convertible preferred stock converted to common stock in connection with the Company's Initial Public Offering ("IPO") on September 25, 2020.

***Derivative Liabilities***

The Company may issue certain financial instruments with embedded features which may be accounted for as separate derivative assets or liabilities, dependent on their specific contractual terms or other conditions. These derivative assets or liabilities are required to be measured at fair value at issuance and remeasured at the end of each reporting period. To determine the fair value of these instruments the Company uses a discounted cash flow analysis, as these instruments are not quoted on an active market. Increases or decreases in fair value from initial measurement and each reporting period are recorded in the statement of operations and comprehensive loss as change in fair value of derivative liabilities.

***Stock-Based Compensation***

The Company's share-based compensation program allows for grants of stock options and restricted stock awards. Grants are awarded to employees and non-employees, including directors.

The Company accounts for stock-based employee compensation arrangements in accordance with provisions of ASC 718, *Compensation – Stock Compensation* ("ASC 718"). ASC 718 requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. ASC 718 requires companies to estimate the fair value of share-based payment awards on the date of grant using an option pricing or equity valuation model that is applied in a manner consistent with the fair value measurement objectives of ASC 718, is based on established principles of financial theory and reflects all of the substantive terms and conditions of the award. The Company uses the Black-Scholes option-pricing model ("Black-Scholes") to value stock option grants to employees, non-employees and directors. The fair value of the Company's common stock is used to determine the fair value of restricted stock awards and stock options.

The Company's stock-based compensation awards are subject to either service or performance-based vesting conditions. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is typically the vesting term. Compensation expense related to awards to employees with

**PMV Pharmaceuticals, Inc.**  
**Notes to Financial Statements**  
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**(in thousands except share and per share amounts)**

performance-based vesting conditions is recognized based on grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the of performance condition is probable.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of a public market for the Company's common stock and lack of company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with expected term assumption. The Company uses the simplified method to calculate the expected term for options granted to employees whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock. The Company recognizes forfeitures as they occur.

Prior to the Company's IPO, due to the absence of an active market for the Company's common stock, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company considered the estimated fair value of the common stock as of the measurement date. Prior to the Initial Public Offering, the estimated fair value of the common stock was determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including convertible preferred stock), the effect of the rights and preferences of the preferred shareholders, and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition, and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

#### ***Segment Reporting***

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the Company's Chief Operating Decision Maker to make decisions with respect to resource allocation and assessment of performance. To date, the Company has viewed its operations and manages its business as one operating segment.

#### ***Net Loss per Common Share***

Basic net loss per share is computed using the "two-class" method which includes the weighted average number of shares of common stock outstanding during the period and other securities that participate in dividends (a participating security). The Company's convertible preferred stock are participating securities as defined by ASC 260-10, *Earnings per Share*. During the periods where the Company incurs net losses, the Company allocates no loss to participating securities because these securities have no contractual obligation to share in the losses of the Company. Under the two-class method, basic net loss per share applicable to common stockholders is computed by dividing the net loss applicable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed similar to basic net loss per share except that the denominator is increased to include the number of additional shares for the potential dilutive effects of a warrant,

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convertible preferred stock and stock options outstanding during the period calculated in accordance with the treasury stock method, or the two-class method, whichever is more dilutive. The Company allocates net earnings on a *pari passu* (equal) basis to both common and preferred stockholders. Net losses are not allocated to preferred stockholders as they do not have an obligation to share in the Company's net losses. For all periods presented, basic and diluted net loss per share are the same, as any additional share equivalents would be anti-dilutive.

#### ***Income Taxes***

The Company accounts for income taxes in accordance with ASC 740, *Income Taxes* ("ASC 740"), which requires that deferred tax assets and liabilities be recognized using enacted tax rates for the effect of temporary differences between the book and tax bases of recorded assets and liabilities. Under ASC 740, the liability method is used in accounting for income taxes. Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax basis of assets and liabilities and are measured using the enacted tax rates and law that will be in effect when the differences are expected to reverse. ASC 740 also requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some or all of the deferred tax assets will not be realized. The Company evaluates annually the realizability of the deferred tax assets by assessing the valuation allowance and by adjusting the amount of such allowance, if necessary. The factors used to assess the likelihood of realization include forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. In 2020 and 2019, the Company has recorded a full valuation allowance for the deferred tax assets based on the historical loss and the uncertainty regarding the ability to project future taxable income. In future periods if the Company is able to generate income, the Company may reduce or eliminate the valuation allowance.

The Company accounts for uncertain tax positions in accordance with ASC 740. ASC 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax provision that an entity takes or expects to take in a tax return. Additionally, ASC 740 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosures, and transition. Under ASC 740, an entity may only recognize or continue to recognize tax positions that meet a "more likely than not" threshold. In accordance with this accounting policy, the Company recognizes accrued interest and penalties related to unrecognized tax benefits as a component of income tax.

#### ***Recent Accounting Pronouncements***

In February 2016, the FASB issued ASU 2016-02, *Leases* ("ASU 2016-02") requiring lessees to recognize operating and financing lease liabilities on the balance sheet, as well as corresponding right-of-use assets. The new lease standard also makes some changes to lessor accounting and aligns key aspects of the lessor accounting model with the revenue recognition standard. In addition, disclosures will be required to enable users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. In June 2020, the FASB also issued ASU 2020-05, *Revenue from Contracts with Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities*, which requires nonpublic entities to adopt the provisions of ASU 2016-02 for fiscal years beginning after December 15, 2021, and for interim periods within fiscal years beginning after December 15, 2022.

Upon its IPO, the Company qualified as an emerging growth company ("EGC"). Qualifying as an EGC allows the Company to employ extended transition provisions by using nonpublic business entity adoption dates for new or revised accounting standards, so long as the issuer maintains its status as an EGC. The Company expects to adopt this standard for the annual period ending December 31, 2021, with the provisions of the new standard reflected in quarterly periods of that annual period. The Company is currently evaluating the impact of this accounting standard update on its financial statements.

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In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation: Improvements to Nonemployee Share-Based Payment Accounting* (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The ASU supersedes Subtopic 505-50, Equity—Equity-Based Payments to Non-Employees. The pronouncement is effective for the Company in the annual period beginning after December 15, 2019, and early adoption is permitted. The Company adopted this guidance, using the modified retrospective method, on January 1, 2020, and the adoption did not have a material impact on its financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820)*. This standard modifies disclosure requirements related to fair value measurement and is effective for all entities for fiscal years beginning after December 15, 2019. Early adoption is permitted. Implementation on a prospective or retrospective basis varies by specific disclosure requirement. The standard also allows for early adoption of any removed or modified disclosures upon issuance while delaying adoption of the additional disclosures until their effective date. The Company adopted this guidance, using the retrospective method, on January 1, 2020, and the adoption did not have a material impact on its financial statements.

***Concentration of Credit Risk and Other Risks and Uncertainties***

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents and marketable securities. Cash and cash equivalents are held in accounts at two financial institutions. At times, such deposits may be in excess of insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents. The Company's marketable debt securities are carried at fair value with unrealized gains and losses. Any investments with unrealized losses are considered to be temporarily impaired.

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, rapid technological change, uncertainty of market acceptance of the product, competition from substitute products and larger companies, protection of proprietary technology, strategic relationships and dependence on key individuals.

Products developed by the Company require clearances from the U.S. Food and Drug Administration or other international regulatory agencies prior to commercial sales. There can be no assurance the Company's future products will receive the necessary clearances. If the Company was denied clearance, clearance was delayed or it was unable to maintain clearance, it could have a materially adverse impact on the Company.

In January 2020, the World Health Organization declared the outbreak of a novel coronavirus (COVID-19) as a "Public Health Emergency of International Concern," which continues to spread throughout the world and has adversely impacted global commercial activity and contributed to significant declines and volatility in financial markets. The COVID-19 outbreak and government responses are creating disruption in global supply chains and adversely impacting many industries. The outbreak could have a continued material adverse impact on economic and market conditions and trigger a period of global economic slowdown. The Company continues to monitor the impact of the COVID-19 outbreak closely. The extent to which the COVID-19 outbreak will impact its operations or financial results is uncertain.



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**3. Financial Instruments and Fair Value Measurements**

The Company's financial instruments consist of money market funds, U.S. government debt securities and corporate debt securities. The following tables show the Company's cash equivalents and available-for-sale securities' carrying amounts and fair values at December 31, 2020 and 2019:

	As of December 31, 2020				
	Carrying Amount	Fair Value	Quoted priced in active markets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
<b>Assets</b>					
Money market funds	\$ 240,033	\$ 240,033	\$ 240,033	\$ –	\$ –
Corporate securities	120,008	120,008	–	120,008	–
Total assets	<u>\$ 360,041</u>	<u>\$ 360,041</u>	<u>\$ 240,033</u>	<u>\$ 120,008</u>	<u>\$ –</u>
<b>As of December 31, 2019</b>					
	Carrying Amount	Fair Value	Quoted priced in active markets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
<b>Assets</b>					
Money market funds	\$ 1,680	\$ 1,680	\$ 1,680	\$ –	\$ –
Corporate securities	97,819	97,816	–	97,816	–
Total assets	<u>\$ 99,499</u>	<u>\$ 99,496</u>	<u>\$ 1,680</u>	<u>\$ 97,816</u>	<u>\$ –</u>
<b>Liabilities</b>					
Warrant liability	51	51	–	–	51
Total liabilities	<u>\$ 51</u>	<u>\$ 51</u>	<u>\$ –</u>	<u>\$ –</u>	<u>\$ 51</u>

**Cash Equivalents** – Cash equivalents of \$360.0 million as of December 31, 2020 consisted of money market funds of \$240.0 million and corporate debt securities of \$120.0 million. Cash equivalents of \$71.3 million as of December 31, 2019 consisted of money market funds of \$1.7 million and corporate debt securities of \$69.6 million. Money market funds are classified within level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets, whereas corporate securities are classified within level 2 of the fair value hierarchy because they are valued using inputs other than quoted prices that are observable for the asset or liability either directly or indirectly.

**Marketable Securities** – Marketable securities of \$28.2 million as of December 31, 2019 consisted of corporate debt securities classified within level 2 of the fair value hierarchy because they are valued using inputs other than quoted prices that are observable for the asset or liability either directly or indirectly. There were no marketable securities as of December 31, 2020.

**Warrant Liability** – The fair value of the warrants to purchase common stock is based on significant inputs not observable in the market, which represents a level 3 measurement within the fair value hierarchy. The warrants to purchase common stock were exercised on September 24, 2020 and the fair value of the liability was reclassified to additional paid-in capital. Warrant liability consisted of the following:

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		<b>Warrant Liability</b>
Balance at December 31, 2018	\$	43
Changes in fair value		8
Balance at December 31, 2019		51
Changes in fair value		143
Reclassification to additional paid-in capital upon exercise		(194)
Balance at December 31, 2020	\$	<u>–</u>

**4. Property and Equipment, Net**

	<b>December 31,</b>	
	<b>2020</b>	<b>2019</b>
Machinery & equipment	\$ 1,989	\$ 1,898
Computers	8	8
Furniture & fixtures	9	9
Leasehold improvements	73	67
Assets not placed in service	51	–
Total property and equipment	2,130	1,982
Less: Accumulated depreciation	(1,561)	(1,243)
Property and equipment, net	<u>\$ 569</u>	<u>\$ 739</u>

Depreciation expense for the years ended December 31, 2020, 2019, and 2018 was \$318, \$388, and \$338, respectively.

**5. Accrued Expenses**

Accrued expenses consists of the following:

	<b>December 31,</b>	
	<b>2020</b>	<b>2019</b>
Accrued compensation	\$ 3,109	\$ 1,647
Accrued research and development costs	1,595	–
Other accrued liabilities	99	39
Total	<u>\$ 4,803</u>	<u>\$ 1,686</u>

**6. Commitments and Contingencies**

The Company leases office and laboratory space in Cranbury, New Jersey; South Brunswick, New Jersey; and Lexington, Massachusetts. At December 31, 2020, the minimum lease payments under these leases are as follows:

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2021	\$	479
2022		252
2023		4
Thereafter		—
<b>Total future minimum lease payments</b>	<b>\$</b>	<b>735</b>

Rent expense recorded during the years ended December 31, 2020, 2019, and 2018 was \$561, \$580, and \$479, respectively.

In January 2021, we signed a lease for 50,581 square feet of office and laboratory space at One Research Way in Princeton, New Jersey. That lease term extends through 2032, has a five-year extension option, and is intended to replace our two existing facilities. Payments under this lease will total \$19.6 million through May 2032.

At December 31, 2020, there were no purchase commitments with third-party suppliers.

**Contingencies**

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when future expenditures are probable and such expenditures can be reasonably estimated.

**7. Convertible Preferred Stock**

As of December 31, 2019, the Company's Certificate of Incorporation, as amended and restated, authorized the Company to issue up to 22,883,426 shares of convertible preferred stock with a par value of \$0.00001 per share. 1,657,903 shares were designated as Series Seed convertible preferred stock (Series Seed Preferred), 8,076,985 shares were designated as Series A convertible preferred stock (Series A Preferred), 7,672,560 shares were designated as Series B convertible preferred stock (Series B Preferred) and 5,475,978 shares were designated as Series C convertible preferred stock (Series C Preferred). At December 31, 2019, the Company had an aggregate of 22,866,246 shares of Series Seed Preferred, Series A Preferred, Series B Preferred and Series C Preferred (collectively, "Preferred Stock") issued and outstanding. All share amounts presented are reverse-split adjusted.

As of December 31, 2019, the Preferred Stock consisted of the following (in thousands except for share data):

	Preferred stock authorized	Preferred stock issued and outstanding	Carrying value	Liquidation preference	Common stock issuable upon conversion
Series Seed Preferred	1,657,903	1,647,102	\$ 3,008	\$ 3,050	1,647,102
Series A Preferred	8,076,985	8,076,982	30,593	30,734	8,076,982
Series B Preferred	7,672,560	7,672,556	73,627	73,728	7,672,556
Series C Preferred	5,475,978	5,469,606	61,705	61,873	5,469,606
	<b>22,883,426</b>	<b>22,866,246</b>	<b>\$ 168,933</b>	<b>\$ 169,385</b>	<b>22,866,246</b>

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In July 2020, the Company issued 5,321,864 shares of Series D Preferred Stock at a price of \$13.1533 per share, resulting in gross proceeds of \$70,000. In connection with the IPO on September 25, 2020, all of the Company's convertible preferred stock, including Series D Preferred Stock, outstanding at the time of the IPO automatically converted into an aggregate of 28,188,110 shares of common stock.

The holders of Preferred Stock have the rights, preferences, privileges and restrictions as set forth below:

***Dividends:***

The holders of Preferred Stock are entitled to receive non-cumulative dividends prior to and in preference to any declaration of payment of dividends on common stock, when and if declared by the Board of Directors. Any additional dividends will be paid ratably to holders of common and Preferred Stock, with the holders of Preferred Stock participating on an as-if converted basis. No dividends have been declared or paid as of December 31, 2019.

***Voting Rights:***

The holders of each share of Preferred Stock are entitled to voting rights equal to the number of shares of common stock into which the shares could be converted. As long as any shares of Preferred Stock remain outstanding, the holders of Preferred Stock, voting together as a class, shall be entitled to elect four members of the Company's Board of Directors. The holders of common stock, voting together as a single class, shall be entitled to elect two members of the Company's Board of Directors. Remaining members of the Company's Board of Directors will be elected by the holders of a majority of the shares of Preferred Stock and common stock, voting together as a single class.

***Liquidation Rights:***

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of Preferred Stock have liquidation preferences, before any distribution or payment is made to holders of any common stock, in an amount per share equal to the original issue price of \$1.8517 for Series Seed Preferred, \$3.7266 for Series A Preferred, \$9.6093 for Series B Preferred and \$11.3121 for Series C Preferred, as adjusted for stock splits, stock dividends, combinations, recapitalizations and the like, plus any declared but unpaid dividends. If the assets and funds to be distributed among the holders of Preferred Stock are insufficient to permit the payment to such holders, then the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of Preferred Stock in proportion to the preferential amount each such holder is otherwise entitled to receive.

Upon completion of the payment of the full liquidation preference of Preferred Stock, the remaining assets of the Company, if any, shall be distributed with equal priority and ratably to the holders of common stock and Preferred Stock, with the Preferred Stock being treated as if the Preferred Stock had been converted to shares of common stock at the then applicable conversion rate. Notwithstanding the foregoing, the aggregate distributions made with respect to any shares of Preferred Stock may not exceed the greater of (i) an amount equal to two times the original issue price plus any declared but unpaid dividends on such share or (ii) the amount the holder would have received if all shares of the Preferred Stock were deemed to have been converted into common stock as of immediately prior to such liquidation, dissolution or winding up of the Company.

***Conversion:***

Each share of Preferred Stock is convertible into shares of common stock, at the option of the holder, at any time after date of issuance. Each share of Preferred Stock automatically converts to the number of shares of common

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stock determined in accordance with the conversion rate upon the earlier of (i) written consent of two-thirds of the then outstanding shares of Preferred Stock, voting together as a single class, and written consent of the majority of the then outstanding shares of Series C Preferred or (ii) the closing of a public offering, in which the gross cash proceeds are at least \$40,000 and the initial offering price to the public is at least \$11.3121 per share (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations, reorganizations, reclassifications or the like). At December 31, 2019, the conversion price for each share of Series Seed Preferred, Series A Preferred, Series B Preferred and Series C Preferred is \$1.8517, \$3.7266, \$9.6093 and \$11.3121, respectively.

***Redemption:***

The Preferred Stock is not currently redeemable. Upon certain change in control events that are outside of the Company's control, including liquidation, sale or transfer of control of the Company, the Preferred Stock is contingently redeemable.

**8. Common Stock**

The Company is authorized to issue up to 1,000,000,000 shares of common stock with a par value of \$0.00001 per share, and 5,000,000 shares of preferred stock with a par value of \$0.00001 per share. At December 31, 2020 and 2019, there were 44,777,818 and 3,046,200 shares of common stock issued and outstanding, respectively.

As of December 31, 2020, no dividends on common stock had been declared by the Company.

At December 31, 2020 and 2019, the Company had reserved shares of common stock for issuance as follows:

	<b>December 31,</b>	
	<b>2020</b>	<b>2019</b>
Convertible preferred stock outstanding	–	22,866,246
Warrants issued and outstanding	–	10,800
Options issued and outstanding	4,090,970	2,767,868
Shares available for future stock option grants	4,609,725	1,530,523
Shares available for employee stock purchase plan	400,752	–
Total	9,101,447	27,175,437

**9. Stock Plan**

***2020 Equity Incentive Plan***

The 2020 Equity Incentive Plan (the "2020 Plan") was approved by the board of directors on September 24, 2020. The 2020 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company's officers, employees, directors and consultants. The number of shares initially reserved for issuance under the 2020 Plan is 4,406,374, which shall be cumulatively increased on January 1, 2021 and each January 1 thereafter by 5% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31. As of December 31, 2020, there were 4,372,183 shares available for issuance under the Plan.

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**2020 Employee Stock Purchase Plan**

The 2020 Employee Stock Purchase Plan (the “2020 ESPP”) was approved by the board of directors on September 24, 2020. A total of 400,752 shares of common stock were initially reserved for issuance under this plan, which shall be increased on January 1, 2021 to the lesser of (i) 801,504 shares of common stock, (ii) 1% of the outstanding shares of common stock on the last day of the immediately preceding Fiscal Year, or (iii) an amount determined by the Administrator no later than the last day of the immediately preceding Fiscal Year. The 2020 ESPP allows employees to purchase shares of Company common stock at a 15% discount using payroll deductions. Offering periods last six months each, and employees are entitled to purchase shares at the end of the offering period based on the discount as applied to the lower of the price at the beginning of the period or the end of the period. No shares were issued under the 2020 ESPP in 2020.

**2013 Equity Incentive Plan**

In 2014, the Company adopted the 2013 Stock Plan (the “Plan”). On September 24, 2020, this plan was replaced by the 2020 Plan, and future issuances of incentive instruments will be governed by that plan.

	Shares Available for Grant	Number of Options	Options Outstanding		
			Weighted Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in 000s)
<b>Balances, December 31, 2018</b>	697,042	2,685,615	\$ 2.00	7.88	\$ 4,118
Shares reserved for issuance	949,650	-			
Options granted	(249,758)	249,758	\$ 3.53		
Options forfeited / cancelled	133,589	(133,589)	\$ 2.95		
Options exercised	-	(33,916)	\$ 3.00		
<b>Balances, December 31, 2019</b>	1,530,523	2,767,868	\$ 2.05	7.08	\$ 5,048
Shares reserved for issuance	4,406,374	-			
Options granted	(1,375,196)	1,375,196	\$ 5.23		
Options forfeited / cancelled	48,024	(48,024)	\$ 1.89		
Options exercised	-	(4,070)	\$ 1.59		
<b>Balances, December 31, 2020</b>	<u>4,609,725</u>	<u>4,090,970</u>	<u>\$ 3.14</u>	7.13	\$ 238,792
<b>At December 31, 2020</b>					
Vested		<u>2,593,714</u>	\$ 2.11	6.17	\$ 154,075
Exercisable		<u>2,683,468</u>	\$ 2.14	6.20	\$ 159,309

The weighted average grant date fair value of stock options granted during the year ended December 31, 2020 and 2019 was \$3.34 and \$2.30, respectively.

The aggregate intrinsic value of options vested and exercisable as of December 31, 2020 and 2019 is calculated based on the difference between the exercise price and the fair value of our common stock. The intrinsic value of options exercised in 2020 and 2019 was \$245 and \$20, respectively.

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At December 31, 2020, the total compensation cost related to nonvested service-based awards not yet recognized is \$4,602. The weighted-average period over which the nonvested awards is expected to be recognized is 2.9 years.

During the year ended December 31, 2018, the Company granted 119,012 stock options at a grant-date fair value of \$2.58 per share to an executive that begins vesting only upon the attainment of certain liquidity events. With the completion of the IPO on September 25, 2020, the performance condition was satisfied. The compensation cost associated with this award of \$305 will be recognized ratably over the four-year vesting period commencing on September 25, 2020.

During the year ended December 31, 2020, the Company granted 45,332 stock options at a grant-date fair value of \$4.22 per share to a board member that vested upon the attainment of certain liquidity events. With the completion of the IPO on September 25, 2020, the performance condition was satisfied. The compensation cost associated with this award of \$113 was recognized in the year ended December 31, 2020.

The Company estimated the fair value of stock options using the Black-Scholes options valuation model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee stock options was estimated using the following assumptions:

	Year Ended December 31,		
	2020	2019	2018
Risk-free interest rate	0.31% - 1.51%	1.49% - 2.51%	2.68% - 2.83%
Expected life (in years)	4.92 - 6.40	5.27 - 6.37	5.99
Dividend yield	0%	0%	0%
Expected volatility	70.70% - 77.60%	72.07% - 72.69%	63.74% - 81.20%

The weighted average assumptions used to estimate the fair value of stock options granted and stock purchase rights under the ESPP are as follows:

	Year Ended December 31, 2020
Risk-free interest rate	0.11%
Expected life (in years)	0.65
Dividend yield	0%
Expected volatility	76%

***Total Stock-Based Compensation***

Stock-based compensation expense recorded under ASC 718 (and under ASC 718 and ASC 505 in 2019 and 2018, prior to the adoption of ASU 2018-07) related to options granted was allocated to research and development and general and administrative expense as follows:

	For the Years Ended December 31,		
	2020	2019	2018
Research and development	\$ 836	\$ 302	\$ 314
General and administrative	1,097	606	765
Total stock-based compensation	<u>\$ 1,933</u>	<u>\$ 908</u>	<u>\$ 1,079</u>

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**10. Income Taxes**

The provision for income taxes consisted of current state taxes of \$6, \$8, and \$3 for the years ended December 31, 2020, 2019, and 2018, respectively. The effective tax rate for the Company for the years ended December 31, 2020, 2019, and 2018 was zero percent, respectively. A reconciliation of income tax computed at the statutory federal income tax rate to the provision for income taxes included in the accompanying statements of operations for the Company is as follows:

	<b>For the Years Ended</b>		
	<b>December 31, 2020</b>	<b>December 31, 2019</b>	<b>December 31, 2018</b>
Income tax provision at statutory rate	21%	21%	21%
State income taxes, net of federal benefit	8%	7%	8%
Tax credits	2%	1%	1%
Other	(1)%	0%	(1)%
Change in valuation allowance	(30)%	(29)%	(29)%
Effective income tax rate	<u>0%</u>	<u>0%</u>	<u>0%</u>

For the years ended December 31, 2020, 2019, and 2018, the Company's effective tax rate is below the federal statutory income tax rate of 21% primarily due to state income taxes, net of federal benefit and the Company's position to establish a full valuation allowance on its deferred tax assets.

The tax effect of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets and liabilities are presented below:

	<b>As of December 31,</b>	
	<b>2020</b>	<b>2019</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 27,511	\$ 18,707
Stock compensation	748	473
Research and development credits	2,414	1,497
Accruals and reserves	830	490
Total deferred tax assets	31,503	21,167
Valuation allowance	(31,458)	(21,106)
Deferred tax assets recognized	45	61
Deferred tax liabilities:		
Fixed assets and depreciation	(45)	(61)
Total deferred tax liabilities	(45)	(61)
Net deferred tax assets	<u>\$ -</u>	<u>\$ -</u>

The Company has recorded a valuation allowance for its deferred tax assets that it does not believe will be realizable at a more likely than not level based on analysis of all available sources of taxable income.



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At December 31, 2020 and 2019, the Company had net operating loss carryforwards of \$97,665 and \$66,352, respectively. At December 31, 2020, the Company had state net operating loss carryforwards for New Jersey, California and Massachusetts of approximately \$92,805, \$4,912, and \$950 respectively. At December 31, 2019, the Company had state net operating loss carryforwards for New Jersey, California and Massachusetts of approximately \$61,503, \$4,912 and \$901, respectively. The federal and state net operating loss carryforwards expire beginning in the year 2033. The Company also has federal and state research and development credit carryforward of approximately \$3,470 and \$2,169, respectively, at December 31, 2020 and 2019. The federal credits will begin to expire in 2034 if not utilized. The California state credits carryforward indefinitely and the New Jersey state credits expire starting in 2022. The above net operating losses and research and development credits are subject to Sections 382 and 383 of the Internal Revenue Code. In the event of a change in ownership as defined by these code sections, the usage of the net operating losses and research and development credits may be limited.

The Company accrues interest and penalties related to unrecognized tax benefits in the Provision for income taxes line item in the statements of operations and comprehensive loss. As of December 31, 2020 and 2019, the Company had not accrued any interest or penalties related to uncertain tax positions.

If the ending balance of \$877 and \$543 of unrecognized tax benefits as of December 31, 2020 and 2019, respectively, were recognized, none of the recognition would affect the income tax rate. The following table summarized the activity related to the Company's unrecognized tax benefits:

	<b>For the Years Ended</b>	
	<b>December 31, 2020</b>	<b>December 31, 2019</b>
Unrecognized tax benefits, beginning of year	\$ 543	\$ 415
Increases (decreases) related to prior year tax positions	5	(31)
Increases related to current year tax positions	329	159
Unrecognized tax benefits, end of year	<u>\$ 877</u>	<u>\$ 543</u>

The Company does not anticipate any material change in its unrecognized tax benefits over the next twelve months. The unrecognized tax benefits may change during the next year for items that arise in the ordinary course of business.

The Company files U.S. federal and state income tax returns with varying statutes of limitations. The Company's tax years 2013 to 2020 will remain open for examination by the federal and state authorities for three and four years, respectively, from the date of utilization of any net operating loss credits.

**II. Net Loss per Share**

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share for the periods presented due to their antidilutive effect:

	<b>For the Years Ended December 31,</b>		
	<b>2020</b>	<b>2019</b>	<b>2018</b>
Convertible preferred stock (as converted)	–	22,866,246	17,396,640
Warrants to purchase common stock	–	10,800	10,800
Common stock options issued and outstanding	4,090,970	2,767,868	2,685,615
Total	<u>4,090,970</u>	<u>25,644,914</u>	<u>20,093,055</u>

**PMV Pharmaceuticals, Inc.**  
**Notes to Financial Statements**  
**December 31, 2020 and 2019**  
(in thousands except share and per share amounts)

	For the Years Ended December 31,		
	2020	2019	2018
Net loss	\$ (34,440)	\$ (25,352)	\$ (17,538)
Weighted-average number of shares - basic and diluted	14,364,475	3,035,243	3,012,284
Net loss per share - basic and diluted	\$ (2.40)	\$ (8.35)	\$ (5.82)

**12. Related Parties**

The Company has consulting agreements with two members of the Board of Directors. Consulting fees paid in the year ended December 31, 2020, 2019, and 2018 were \$112. There were no amounts owed under the consulting agreement at December 31, 2020 or 2019.

An investor provided financing consulting services to the Company. Fees paid to the investor in the year ended December 31, 2020 were \$65.

**Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.**

None.

**Item 9A. Controls and Procedures.**

**Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures**

Our management maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2020, the Company conducted an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the period covered by this Annual Report on Form 10-K.

**Management's Report on Internal Control Over Financial Reporting**

Our management is also responsible for establishing and maintaining for us adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the *Internal Control—Integrated Framework* (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under this framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2020.

**Changes in Internal Control Over Financial Reporting**

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any changes in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting during the fourth quarter of the year ended December 31, 2020 that has materially affected, or is 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 by this item will be included under the captions “Directors and Corporate Governance,” “Director Compensation” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our definitive proxy statement for the annual meeting of stockholders to be held in June 2021 to be filed with the SEC on or before April 23, 2021, or the Proxy Statement, and is incorporated herein by reference.

### **Item 11. Executive Compensation.**

The information required by this item will be included under the captions “Executive Compensation,” “Director Compensation,” “Equity Compensation Plan Information,” and “Directors and Corporate Governance” in the Proxy Statement and is incorporated herein by reference.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this item will be included under the captions “Beneficial Ownership of Shares of Common Stock” and “Equity Compensation Plan Information” in the Proxy Statement and is incorporated herein by reference.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this item will be included under the captions “Certain Relationships and Related Transactions” and “Directors and Corporate Governance” in the Proxy Statement and is incorporated herein by reference.

### **Item 14. Principal Accounting Fees and Services.**

The information required by this item will be included under the captions “Item 2 – Ratification of Independent Registered Public Accounting Firm” in the Proxy Statement and is incorporated herein by reference.

## PART IV

## Item 15. Exhibits and Financial Statement Schedules.

## EXHIBIT INDEX

Exhibit Number	Description	Form	File No.	Number	Filing Date
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Registrant, as amended, as currently in effect.</a>	8-K	001-39539	3.1	September 29, 2020
3.2	<a href="#">Amended and Restated Bylaws of the Registrant, as currently in effect.</a>	8-K	001-39539	3.2	September 29, 2020
4.1*	<a href="#">Description of Securities of the Registrant</a>				
4.2	<a href="#">Amended and Restated Investors' Rights Agreement, dated July 17, 2020, by and among the Registrant and certain of its stockholders.</a>	S-1	33-248627	4.1	September 4, 2020
4.3	<a href="#">Specimen common stock certificate of the Registrant.</a>	S-1/A	333-248627	4.2	September 21, 2020
10.1+	<a href="#">Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.</a>	S-1	333-248627	10.1	September 4, 2020
10.2+	<a href="#">2013 Equity Incentive Plan, as amended, and forms of agreement thereunder.</a>	S-1/A	333-248627	10.2	September 21, 2020
10.3+	<a href="#">2020 Equity Incentive Plan and forms of agreements thereunder.</a>	S-1/A	333-248627	10.3	September 21, 2020
10.4+	<a href="#">2020 Employee Stock Purchase Plan and forms of agreements thereunder.</a>	S-1/A	333-248627	10.4	September 21, 2020
10.5+	<a href="#">Employment Offer Letter, dated August 17, 2020, by and between the Registrant and David H. Mack, Ph.D.</a>	S-1	333-248627	10.5	September 4, 2020
10.6+	<a href="#">Employment Offer Letter, dated August 17, 2020, by and between the Registrant and Winston Kung.</a>	S-1	333-248627	10.6	September 4, 2020
10.7+	<a href="#">Employment Offer Letter, dated August 18, 2020, by and between the Registrant and Leila Alland, M.D.</a>	S-1	333-248627	10.7	September 4, 2020
10.8+	<a href="#">Employment Offer Letter, dated August 18, 2020, by and between the Registrant and Deepika Jalota, Pharm.D.</a>	S-1	333-248627	10.8	September 4, 2020
10.9+	<a href="#">Employee Incentive Compensation Plan.</a>	S-1	333-248627	10.9	September 4, 2020
10.10+	<a href="#">Change in Control and Severance Policy.</a>	S-1	333-248627	10.10	September 4, 2020
10.11+	<a href="#">Amended and Restated Change in Control and Severance Policy Participation Agreement, dated August 17, 2020, by and between the Registrant and David H. Mack, Ph.D.</a>	S-1	333-248627	10.11	September 4, 2020
10.12+	<a href="#">Amended and Restated Change in Control and Severance Policy Participation Agreement, dated August 17, 2020, by and between the Registrant and Winston Kung.</a>	S-1	333-248627	10.12	September 4, 2020

10.13+	<a href="#">Amended and Restated Change in Control and Severance Policy Participation Agreement, dated August 18, 2020, by and between the Registrant and Leila Alland, M.D.</a>	S-1	333-248627	10.13	September 4, 2020
10.14+	<a href="#">Amended and Restated Change in Control and Severance Policy Participation Agreement, dated August 18, 2020, by and between the Registrant and Deepika Jalota, Pharm.D.</a>	S-1	333-248627	10.14	September 4, 2020
10.15+	<a href="#">Outside Director Compensation Policy.</a>	S-1/A	333-248627	10.15	September 4, 2020
10.16	<a href="#">Consulting Agreement, dated January 1, 2016, by and between the Registrant and Arnold Levine, Ph.D.</a>	S-1	333-248627	10.16	September 4, 2020
10.17	<a href="#">Consulting Agreement, dated July 14, 2017, by and between the Registrant and Richard Heyman, Ph.D.</a>	S-1	333-248627	10.17	September 4, 2020
10.18	<a href="#">Lease Agreement, dated March 3, 2015, by and between the Registrant and Cedar Brook 2005, LP, as amended by the First Amendment to Lease dated April 24, 2017.</a>	S-1	333-248627	10.18	September 4, 2020
10.19*	<a href="#">Lease Agreement, dated January 8, 2021, by and between the Registrant and BMR-ONE RESEARCH WAY LLC.</a>				
23.1*	<a href="#">Consent of Independent Registered Public Accounting Firm.</a>				
24.1*	<a href="#">Power of Attorney (contained in the signature page to this Annual Report on Form 10-K).</a>				
31.1*	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				
31.2*	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				
32.1*#	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				
32.2*#	<a href="#">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.</a>				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

- \* Filed herewith.
- + Indicated management contract or compensatory plan.
- # The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

**Item 16. Form 10-K Summary**

The Company has elected not to include summary information.

## SIGNATURES

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

### PMV PHARMACEUTICALS, INC.

By: /s/ David H. Mack  
David H. Mack, Ph.D.  
*President and Chief Executive Officer*

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David H. Mack, Ph.D. and Winston Kung, jointly and each one of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ David H. Mack</u> David H. Mack, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 3, 2021
<u>/s/ Winston Kung</u> Winston Kung	Chief Operating Officer and Chief Financial Officer (Principal Financial and Accounting Officer)	March 3, 2021
<u>/s/ Richard Heyman</u> Richard Heyman, Ph.D.	Director and Chairman of the Board of Directors	March 3, 2021
<u>/s/ Arnold Levine</u> Arnold Levine, Ph.D.	Director	March 3, 2021
<u>/s/ Thilo Schroeder</u> Thilo Schroeder, Ph.D.	Director	March 3, 2021
<u>/s/ Laurie Stelzer</u> Laurie Stelzer	Director	March 3, 2021
<u>/s/ Peter Thompson</u> Peter Thompson, M.D.	Director	March 3, 2021



**DESCRIPTION OF THE REGISTRANT'S SECURITIES  
REGISTERED PURSUANT TO SECTION 12 OF THE  
SECURITIES EXCHANGE ACT OF 1934**

The following summary describes our common stock and preferred stock, as well as certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, copies of which have been filed as exhibits to this Annual Report on Form 10-K, as well as to the applicable provisions of the Delaware General Corporation Law.

**Authorized Capital Stock**

Our authorized capital stock consists of 1,000,000,000 shares of common stock, par value \$0.00001 per share, and 5,000,000 shares of preferred stock, par value \$0.00001 per share. All of our outstanding shares of common stock are paid and nonassessable.

**Common Stock**

Our common stock is listed on the Nasdaq Global Select Market under the symbol "PMVP." The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15<sup>th</sup> Avenue, Brooklyn, NY 11219, and its telephone number is (800) 937-5449.

***Voting Rights***

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights. Because of this, the holders of a plurality of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. With respect to matters other than the election of directors, at any meeting of the stockholders at which a quorum is present or represented, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at such meeting and entitled to vote on the subject matter shall be the act of the stockholders, except as otherwise required by law. The holders of a majority of the stock issued and outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders.

***Dividends***

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

***Liquidation***

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our

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debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

### ***Rights and Preferences***

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

### **Preferred Stock**

Our amended and restated certificate of incorporation provides that the board of directors is authorized, without further action by the stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock.

The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in our control or other corporate action.

Preferred stock will be fully paid and nonassessable upon issuance.

### **Registration Rights of Certain Stockholders**

Certain of our stockholders have registration rights under our amended and restated investors' rights agreement (the "Investors' Rights Agreement"), between us and such stockholders. These stockholders (and certain of their permitted transferees), may request that we file registration statements under the Securities Act of 1933, as amended, or the Securities Act, and, upon such request and subject to minimum size and other conditions, we will be required to effect any such registration. We are generally obligated to bear the expenses, other than underwriting discounts and sales commissions, of all of these registrations. This summary does not purport to be complete and is qualified in its entirety by the provisions of the Investors' Rights Agreement, a copy of which has been filed as an exhibit to this Annual Report on Form 10-K.

### **Anti-Takeover Effects of Certain Provisions of Delaware Law, Our Amended and Restated Certificate of Incorporation and Our Amended and Restated Bylaws**

Certain provisions of Delaware law and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws summarized below may be deemed to have an anti-takeover effect and may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider to be in its best interests, including attempts that might result in a premium being paid over the market price for the shares held by stockholders.

#### *Classified Board of Directors*

Our board of directors is divided into three classes, designated Class I, Class II and Class III. Each class will be an equal number of directors, as nearly as possible, consisting of one third of the total number of directors

constituting the entire board of directors. At each annual meeting of stockholders, successors to the class of directors whose term expires at that annual meeting will be elected for a three-year term.

#### *Removal of Directors*

Our amended and restated certificate of incorporation provides that stockholders may only remove a director for cause by a vote of at least a majority of the voting power of the issued and outstanding capital stock of the Company entitled to vote.

#### *Director Vacancies*

Only our board of directors may fill vacant directorships.

#### *No Cumulative Voting*

Our amended and restated certificate of incorporation provides that Stockholders do not have the right to cumulate votes in the election of directors.

#### *Special Meetings of Stockholders*

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, except as otherwise required by law or subject to the terms of any series of Preferred Stock, special meetings of the stockholders may be called only by the chairperson of our board of directors, our Chief Executive Officer, our President or our board of directors acting pursuant to a resolution adopted by a majority of our board of directors.

#### *Advance Notice Procedures for Director Nominations*

Our amended and restated bylaws provide that stockholders seeking to nominate candidates for election as directors at an annual or special meeting of stockholders or seeking to propose matters that can be acted upon by stockholders at annual stockholder meetings must provide timely notice thereof in writing. To be timely, a stockholder's notice generally will have to be delivered to and received at our principal executive offices before notice of the meeting is issued by the secretary of the company, with such notice being served not less than 90 nor more than 120 days before the meeting. Although our amended and restated bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates to be elected at an annual meeting, our amended and restated bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

#### *Action by Written Consent*

Our amended and restated certificate of incorporation and amended and restated bylaws provide that any action to be taken by the stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by written consent.

#### *Amending our Certificate of Incorporation and Bylaws*

Our amended and restated certificate of incorporation may be amended or altered in any manner provided by the General Corporation Law of the State of Delaware, or DGCL, except that amendment of certain

provisions would require the approval of two-thirds of our then outstanding voting securities. Our amended and restated bylaws may be adopted, amended, altered or repealed by stockholders only upon approval of at least majority of the voting power of all the then outstanding shares of the common stock, except for any amendment of certain provisions, which would require the approval of a two-thirds majority of our then outstanding voting securities. Additionally, our amended and restated certificate of incorporation provides that our bylaws may be amended, altered or repealed by the board of directors.

#### *Authorized but Unissued Shares*

Our authorized but unissued shares of common stock and preferred stock will be available for future issuances without stockholder approval, except as required by the listing standards of the Nasdaq Stock Market LLC, and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of the company by means of a proxy contest, tender offer, merger or otherwise.

#### *Delaware Anti-takeover Statute*

We are governed by Section 203 of the DGCL, which, subject to certain exceptions, prohibits a public Delaware corporation from engaging in a business combination (as defined in such section) with an “interested stockholder” (defined generally as any person who beneficially owns 15% or more of the outstanding voting stock of such corporation or any person affiliated with such person) for a period of three years following the time that such stockholder became an interested stockholder, unless (i) prior to such time the board of directors of such corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (ii) upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of such corporation at the time the transaction commenced (excluding for purposes of determining the voting stock of such corporation outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (A) by persons who are directors and also officers of such corporation and (B) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer); or (iii) at or subsequent to such time the business combination is approved by the board of directors of such corporation and authorized at a meeting of stockholders (and not by written consent) by the affirmative vote of at least 66 2/3% of the outstanding voting stock of such corporation not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation’s outstanding voting stock.

LEASE

by and between

BMR-ONE RESEARCH WAY LLC,  
a Delaware limited liability company

and

PMV PHARMACEUTICALS, INC.,  
a Delaware corporation

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## LEASE

THIS LEASE (this "Lease") is entered into as of this 8th day of January, 2021 (the "Execution Date"), by and between BMR-ONE RESEARCH WAY LLC, a Delaware limited liability company ("Landlord"), and PMV PHARMACEUTICALS, INC., a Delaware corporation ("Tenant").

## RECITALS

A. WHEREAS, Landlord owns certain real property (the "Property") and the improvements on the Property located at One Research Way, Princeton, New Jersey, in the office and warehouse complex known as Forrestal Center (the "Project"), including the building located thereon (the "Building"); and

B. WHEREAS, Landlord wishes to lease to Tenant, and Tenant desires to lease from Landlord, the Premises (as defined below), pursuant to the terms and conditions of this Lease, as detailed below.

## AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

1. Lease of Premises. Effective on the Term Commencement Date (as defined below), Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord, the premises shown on Exhibit A attached hereto, including shafts, cable runs, mechanical spaces, rooftop areas, landscaping, parking facilities, private drives and other improvements and appurtenances related thereto (including the Building), together with the benefit of the rights and easements appurtenant to the Property as part of the Project, for the use by Tenant in accordance with the Permitted Use (as defined below) and no other uses (collectively, the "Premises").

2. Basic Lease Provisions. For convenience of the parties, certain basic provisions of this Lease are set forth herein. The provisions set forth herein are subject to the remaining terms and conditions of this Lease and are to be interpreted in light of such remaining terms and conditions.

2.1. This Lease shall take effect upon the Execution Date and, except as specifically otherwise provided within this Lease, each of the provisions hereof shall be binding upon and inure to the benefit of Landlord and Tenant from the date of execution and delivery hereof by all parties hereto.

2.2. "Rentable Area" of the Premises: The Parties stipulate and agree that the Rentable Area of the Premises is 50,581 square feet. In no event shall the Rentable Area of the Premises be deemed to have increased unless due to a change in the outer dimensions of the exterior walls of the Premises.

2.3. Monthly and annual installments of Base Rent for the Premises ("Base Rent") as of the Rent Commencement Date (as defined below), subject to adjustment under this Lease, will

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be as described in the Base Rent table in this Section 2.3. For the avoidance of doubt, the following Base Rent table assumes the Term Commencement Date occurs on the Estimated Term Commencement Date (as such terms are defined below). If the Term Commencement Date occurs on a date other than the Estimated Term Commencement Date, then, pursuant to Section 7.1, annual increases to Base Rent shall occur on the anniversary of the actual Term Commencement Date established pursuant to Section 4.1:

<b><u>Dates</u></b>	<b><u>Square Feet of Rentable Area</u></b>	<b><u>Base Rent per Square Foot of Rentable Area**</u></b>	<b><u>Monthly Base Rent**</u></b>	<b><u>Annual Base Rent**</u></b>
January 1, 2022 – February 28, 2022	30,000*	\$32.50 annually	\$81,250.00	\$975,000.00
March 1, 2022 – December 31, 2022	30,000*	\$33.48 annually	\$83,700.00	\$1,004,400.00
January 1, 2023 – February 28, 2023	50,581	\$33.48 annually	\$141,120.00	\$1,693,451.88
March 1, 2023 – February 29, 2024	50,581	\$34.48 annually	\$145,336.07	\$1,744,032.88
March 1, 2024 – February 28, 2025	50,581	\$35.51 annually	\$149,677.61	\$1,796,131.31
March 1, 2025 – February 28, 2026	50,581	\$36.58 annually	\$154,187.75	\$1,850,252.98
March 1, 2026 – February 28, 2027	50,581	\$37.68 annually	\$158,824.34	\$1,905,892.08
March 1, 2027 – February 29, 2028	50,581	\$38.81 annually	\$163,587.38	\$1,963,048.67
March 1, 2028 – February 28, 2029	50,581	\$39.97 annually	\$168,476.88	\$2,021,722.57
March 1, 2029 – February 28, 2030	50,581	\$41.17 annually	\$173,534.98	\$2,082,419.77
March 1, 2030 – February 28, 2031	50,581	\$42.41 annually	\$178,761.68	\$2,145,140.21
March 1, 2031 – February 29, 2032	50,581	\$43.68 annually	\$184,114.84	\$2,209,378.08
March 1, 2032 – May 31, 2032	50,581	\$44.99 annually	\$189,636.60	\$2,275,639.19

\* Note: *The square feet of Rentable Area for the Premises is 50,581 Square Feet; however, for the first twelve (12) months of the Term following the Rent*



*Commencement Date it is agreed that the square feet used to calculate Base Rent shall be 30,000 Square Feet*

**\*\* Note:** *Rent table reflects annual adjustments described in Section 7.1, and is subject to Section 7.2*

2.4. Estimated Term Commencement Date: April 15, 2021

2.5. Term Expiration Date: May 31, 2032

2.6. Security Deposit: Eight Hundred and Twenty One Thousand Nine Hundred Forty One and 25/100 Dollars (\$821,941.25), subject to adjustment in accordance with the terms hereof.

2.7. Permitted Use: Office and laboratory use in conformity with all federal, state, municipal and local laws, codes, ordinances, rules and regulations of Governmental Authorities (as defined below), committees, associations, or other regulatory committees, agencies or governing bodies having jurisdiction over the Premises or any portion thereof, Landlord or Tenant, including both statutory and common law and hazardous waste rules and regulations (“Applicable Laws”)

2.8. Address for Rent Payment:

BMR-One Research Way LLC  
Attention Entity 540  
P.O. Box 511415  
Los Angeles, California 90051-7970

2.9. Address for Notices to Landlord:

BMR-One Research Way LLC  
4570 Executive Drive, Suite 400  
San Diego, California 92121  
Attn: Legal Department  
Email: legalreview@biomedrealty.com

2.10. Address for Notices to Tenant:

*Prior to Term Commencement Date:*

PMV Pharmaceuticals, Inc.  
8 Clarke Drive, Unit 3  
Cranbury, NJ 08512  
Attn: Rob Ticktin  
Email: rticktin@pmvpharma.com

*From and after Term Commencement Date:*

PMV Pharmaceuticals, Inc.  
One Research Way  
Princeton, New Jersey 08540  
Attn: Rob Ticktin  
Email: rticktin@pmvpharma.com

2.11. Address for Invoices to Tenant:

*Prior to Term Commencement Date:*

PMV Pharmaceuticals, Inc.  
8 Clarke Drive, Unit 3  
Cranbury, NJ 08512  
Attn: JD Kern  
Email: invoices@pmvpharma.com

*From and after Term Commencement Date:*

PMV Pharmaceuticals, Inc.  
One Research Way  
Princeton, New Jersey 08540  
Attn: JD Kern  
Email: invoices@pmvpharma.com

2.12. The following Exhibits are attached hereto and incorporated herein by reference:

Exhibit A	Premises
Exhibit B	Work Letter
Exhibit B-1	Tenant Work Insurance Schedule
Exhibit B-2	Building Standards
Exhibit C	Acknowledgement of Term Commencement Date and Term Expiration Date
Exhibit D	[Intentionally Omitted]
Exhibit E	Form of Letter of Credit
Exhibit F	Rules and Regulations

Exhibit G	[Intentionally Omitted]
Exhibit H	Tenant's Personal Property
Exhibit I	Form of Estoppel Certificate
Exhibit J	Forrestal Center Signage Criteria

3. Term. The term of the leasehold granted by this Lease (as the same may be extended pursuant to Article 41 hereof, and as the same may be earlier terminated in accordance with this Lease, the "Term") shall commence on the actual Term Commencement Date (as defined in Article 4) and end on May 31, 2032 (the "Term Expiration Date").

4. Possession and Commencement Date.

4.1. The "Term Commencement Date" shall be the date Landlord tenders possession of the Premises to Tenant. Tenant shall execute and deliver to Landlord written acknowledgment of the actual Term Commencement Date within ten (10) days after Tenant takes occupancy of the Premises, in the form attached as Exhibit C hereto. Failure to execute and deliver such acknowledgment, however, shall not affect the Term Commencement Date or Landlord's or Tenant's liability hereunder. Failure by Tenant to obtain any governmental licensing or similar governmental approval of the Premises required for the Permitted Use by Tenant shall not serve to extend the Term Commencement Date. Tenant agrees that in the event Landlord does not tender possession of the Premises to Tenant on or before the Estimated Term Commencement Date for any reason, then (a) this Lease shall not be void or voidable and (b) Landlord shall not be liable to Tenant for any loss or damage resulting therefrom. Notwithstanding the foregoing, but subject to any Force Majeure (as hereinafter defined) or any action or omission of Tenant that delays the delivery of the Premises to Tenant, if Landlord has not tendered possession of the Premises to Tenant by the day that is sixty (60) days after the Estimated Term Commencement Date, the per diem Base Rent shall abate by one (1) day for each day after such 60<sup>th</sup> day that Landlord has not delivered the Premises to Tenant. If possession of Landlord's delivery of the Premises to Tenant is delayed by any action or omission of Tenant, then the Term Commencement Date shall be the date that the Term Commencement Date would have occurred but for such delay.

4.2. Following the Term Commencement Date, Tenant shall cause the Tenant Improvements to be constructed in the Premises pursuant to the Work Letter attached hereto as Exhibit B (the "Work Letter") at a cost to Landlord not to exceed Four Million Forty-Six Thousand Four Hundred Eighty Dollars (\$4,046,480.00) (based upon Eighty Dollars (\$80.00) per square foot of Rentable Area (as defined below)) (the "TI Allowance"). The TI Allowance may be applied to the costs of (m) construction, (n) project review by Landlord (which fee shall equal three percent (3%) of the cost of the TI Allowance), (o) commissioning of mechanical, electrical and plumbing systems by a licensed, qualified commissioning agent hired by Tenant, and review of such party's commissioning report by a licensed, qualified commissioning agent hired by Landlord, (p) space planning, architect, engineering and other related services performed by third parties unaffiliated with Tenant, (q) building permits and other taxes, fees, charges and levies by Governmental Authorities (as defined below) for permits or for inspections of the Tenant Improvements, and (r) costs and expenses for labor, material, equipment and fixtures. Additionally, up to Two Hundred Fifty-Two Thousand Nine Hundred Five Dollars (\$252,905.00) of the TI Allowance may be applied to the costs of telecommunications and data

cabling or other infrastructure, information technology (IT) infrastructure, and Tenant's furniture, fixtures and equipment. In no event shall the TI Allowance be used for (v) the cost of work that is not authorized by the Approved Plans (as defined in the Work Letter and as the same may be modified by Change Requests (as defined in and in accordance with the Work Letter) or otherwise approved in writing by Landlord, (w) payments to Tenant or any affiliates of Tenant, (x) the purchase of any furniture, personal property or other non-building system equipment, except and to the extent expressly provided in the immediately foregoing sentence, (y) costs arising from any default by Tenant of its obligations under this Lease or (z) costs that are recoverable by Tenant from a third party (e.g., insurers, warrantors, or tortfeasors).

4.3. Tenant shall have until eighteen (18) months after the Term Commencement Date (the "TI Deadline"), to submit Fund Requests (as defined in the Work Letter) to Landlord for disbursement of the unused portion of the TI Allowance, after which date Landlord's obligation to fund any such costs for which Tenant has not submitted a Fund Request to Landlord shall expire.

4.4. In no event shall any unused TI Allowance entitle Tenant to a credit against Rent payable under this Lease. Tenant shall deliver to Landlord (a) a certificate of occupancy (or its substantial equivalent) for the Premises suitable for the Permitted Use and (b) a Certificate of Substantial Completion in the form of the American Institute of Architects document G704, executed by the project architect and the general contractor.

4.5. Prior to entering upon the Premises, Tenant shall furnish to Landlord evidence satisfactory to Landlord that insurance coverages required of Tenant under the provisions of Article 22 are in effect, and such entry shall be subject to all the terms and conditions of this Lease other than the payment of Base Rent.

4.6. Landlord and Tenant shall mutually agree upon the selection of the architect, engineer, general contractor and major subcontractors, and Landlord and Tenant shall each participate in the review of the competitive bid process. Landlord may refuse to approve any architects, consultants, contractors, subcontractors or material suppliers that Landlord reasonably believes could cause labor disharmony or may not have sufficient experience, in Landlord's reasonable opinion, to perform work in an occupied Class "A" laboratory research building and in lab areas.

5. Condition of Premises. Tenant acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of the Premises or with respect to the suitability of the Premises for the conduct of Tenant's business. Tenant acknowledges that (a) it is fully familiar with the condition of the Premises and agrees to take the same in its condition "as is" as of the Term Commencement Date and (b) Landlord shall have no obligation to alter, repair or otherwise prepare the Premises for Tenant's occupancy or to pay for or construct any improvements to the Premises, except with respect to payment of the TI Allowance, and except that the Premises shall be delivered to Tenant in broom clean condition; provided, that the Premises may contain personal property, trade fixtures, furniture and equipment to the extent that Tenant has purchased same by bill of sale from the previous tenant of the Premises. Tenant's taking of possession of the Premises shall, except as otherwise agreed

to in writing by Landlord and Tenant, conclusively establish that the Premises were at such time in good, sanitary and satisfactory condition and repair.

6. Rent.

6.1. Tenant shall pay to Landlord as Base Rent for the Premises, commencing on January 1, 2022 (the "Rent Commencement Date"), the sums set forth in Section 2.3, subject to the rental adjustments provided in Article 7 hereof. Base Rent shall be paid in equal monthly installments as set forth in Section 2.3, subject to the rental adjustments provided in Article 7 hereof, each in advance on the first day of each and every calendar month during the Term.

6.2. In addition to Base Rent, Tenant shall pay to Landlord as additional rent ("Additional Rent") at times hereinafter specified in this Lease (a) amounts related to Insurance Costs and Taxes (each as defined below), (b) the Property Management Fee (as defined below) and (c) any other amounts that Tenant assumes or agrees to pay under the provisions of this Lease that are owed to Landlord, including any and all other sums that may become due by reason of any default of Tenant or failure on Tenant's part to comply with the agreements, terms, covenants and conditions of this Lease to be performed by Tenant, after notice and the lapse of any applicable cure periods.

6.3. Base Rent and Additional Rent shall together be denominated "Rent." Rent shall be paid to Landlord, without abatement, deduction or offset, in lawful money of the United States of America to the address set forth in Section 2.8 or to such other person or at such other place as Landlord may from time designate in writing. In the event the Term commences or ends on a day other than the first day of a calendar month, then the Rent for such fraction of a month shall be prorated for such period on the basis of the number of days in the month and shall be paid at the then-current rate for such fractional month.

6.4. Tenant's obligation to pay Rent shall not be discharged or otherwise affected by (a) any Applicable Laws now or hereafter applicable to the Premises, (b) any other restriction on Tenant's use, (c) except as expressly provided herein, any casualty or taking or (d) any other occurrence; and Tenant waives all rights now or hereafter existing to terminate or cancel this Lease or quit or surrender the Premises or any part thereof, or to assert any defense in the nature of constructive eviction to any action seeking to recover rent. Tenant's obligation to pay Rent with respect to any period or obligations arising, existing or pertaining to the period prior to the date of the expiration or earlier termination of the Term or this Lease shall survive any such expiration or earlier termination; provided, however, that nothing in this sentence shall in any way affect Tenant's obligations with respect to any other period.

7. Rent Adjustments.

7.1. Base Rent shall be subject to an annual upward adjustment of three percent (3%) of the then-current Base Rent. The first such adjustment shall become effective commencing on the first (1st) annual anniversary of the Term Commencement Date, and subsequent adjustments shall become effective on every successive annual anniversary for so long as this Lease continues in effect.

7.2. Notwithstanding anything to the contrary contained in this Lease, and so long as no Default (as defined below) by Tenant has occurred, Tenant shall not be required to pay Base Rent for the period prior to the Rent Commencement Date (such period, the “Free Rent Period”). During the Free Rent Period, Tenant shall continue to be responsible for the payment of all of Tenant’s other Rent obligations under this Lease, including all Additional Rent such as (a) amounts related to Insurance Costs and Taxes (each as defined below), (b) the Property Management Fee (as defined below) and (c) any other amounts that Tenant assumes or agrees to pay under the provisions of this Lease that are owed to Landlord. Upon the occurrence of any Default, the Free Rent Period shall immediately expire, and Tenant shall no longer be entitled to any further abatement of Base Rent pursuant to this Section. In the event of any Default that results in termination of this Lease, then, as part of the recovery to which Landlord is entitled pursuant to this Lease, and in addition to any other rights or remedies to which Landlord may be entitled pursuant to this Lease (including Article 31), at law or in equity, Landlord shall be entitled to the immediate recovery, as of the day immediately prior to such termination of the Lease, of the unamortized amount of Base Rent that Tenant would have paid had the Free Rent Period not been in effect.

8. Taxes.

8.1. Commencing on the Term Commencement Date and continuing for each calendar year or, at Landlord’s option, tax year (each such “tax year” being a period of twelve (12) consecutive calendar months for which the applicable taxing authority levies or assesses Taxes), for the balance of the Term Tenant shall pay to Landlord the amount of all Taxes levied and assessed for any such year upon the Premises. “Taxes” means all government impositions, including property tax costs consisting of real and personal property taxes (including amounts due under any improvement bond upon the Premises or any portion thereof) or assessments in lieu thereof imposed by any federal, state, regional, local or municipal governmental authority, agency or subdivision (each, a “Governmental Authority”); taxes on or measured by gross rentals received from the rental of space at the Premises; taxes based on the square footage of the Premises or any portion thereof, as well as any parking charges, utilities surcharges or any other costs levied, assessed or imposed by, or at the direction of, or arising from Applicable Laws or interpretations thereof, promulgated by any Governmental Authority in connection with the use or occupancy of the Premises or the parking facilities serving the Premises; taxes on this transaction or any document to which Tenant is a party creating or transferring an interest in the Premises; any fee for a business license to operate an office building; and any expenses, including the reasonable cost of attorneys or experts, reasonably incurred by Landlord in seeking reduction by the taxing authority of the applicable taxes, less tax refunds obtained as a result of an application for review thereof. Taxes shall not include any net income, franchise, capital stock, estate or inheritance taxes, or taxes that are the personal obligation of Tenant.

8.2. Tenant shall be solely responsible for the payment of any and all taxes levied upon (a) personal property and trade fixtures located at the Premises and (b) any gross or net receipts of or sales by Tenant, and shall pay the same at least twenty (20) days prior to delinquency.

8.3. To the extent Landlord is required by a lender, Tenant shall timely pay all tax and insurance impound payments due on the Premises.

8.4. Tenant shall not be responsible for Taxes attributable to the time period prior to the Term Commencement Date; provided, however, that if Landlord shall permit Tenant possession of the Premises prior to the Term Commencement Date, Tenant shall be responsible for Taxes from such earlier date of possession. Tenant's responsibility for Taxes shall continue to the latest of (a) the date of termination of the Lease, (b) the date Tenant has fully vacated the Premises and (c) if termination of the Lease is due to a default by Tenant, the date of rental commencement of a replacement tenant.

8.5. Taxes for the calendar year in which Tenant's obligation to share therein commences and for the calendar year in which such obligation ceases shall be prorated on a basis reasonably determined by Landlord. Taxes that are incurred for an extended time period shall be prorated based upon the time periods to which they apply so that the amounts attributed to the Premises relate in a reasonable manner to the time period wherein Tenant has an obligation to share in Taxes.

8.6. Within thirty (30) days after the end of each calendar month, Tenant shall submit to Landlord an invoice, or, in the event an invoice is not available, an itemized list, of all costs and expenses that (a) Tenant has incurred (either internally or by employing third parties) during the prior month and (b) for which Tenant reasonably believes it is entitled to reimbursements from Landlord pursuant to the terms of this Lease or that Tenant reasonably believes is the responsibility of Landlord pursuant to this Lease or the Work Letter.

9. Property Management Fee. Tenant shall pay to Landlord on the first day of each calendar month of the Term, as Additional Rent, the Property Management Fee (as defined below). Commencing on the Term Commencement Date, the "Property Management Fee" shall be Two Thousand and Fifty-Four and 00/100 Dollars (\$2,054.85) per month, and shall be subject to an annual upward adjustment of three percent (3%) of the then-current Property Management Fee, effective on every annual anniversary of the Term Commencement Date for so long as this Lease continues in effect. Tenant shall pay the Property Management Fee with respect to the entire Term, including any extensions thereof or any holdover periods, regardless of whether Tenant is obligated to pay Base Rent or any other Rent with respect to any such period or portion thereof.

10. Security Deposit.

10.1. Tenant shall deposit with Landlord on or before the Execution Date the sum set forth in Section 2.6 (the "Security Deposit"), which sum shall be held by Landlord as security for the faithful performance by Tenant of all of the terms, covenants and conditions of this Lease to be kept and performed by Tenant. If Tenant Defaults (as defined below) with respect to any provision of this Lease, including any provision relating to the payment of Rent, then Landlord may (but shall not be required to) use, apply or retain all or any part of the Security Deposit for the payment of any Rent or any other sum in default, or to compensate Landlord for any other loss or damage that Landlord may suffer by reason of Tenant's default. If any portion of the Security Deposit is so used or applied, then Tenant shall, within ten (10) days following demand therefor, deposit cash with Landlord in an amount sufficient to restore the Security Deposit to its original amount, and Tenant's failure to do so shall be a material breach of this Lease. The provisions of this Article shall survive the expiration or earlier termination of this Lease.

10.2. In the event of bankruptcy or other debtor-creditor proceedings against Tenant, the Security Deposit shall be deemed to be applied first to the payment of Rent and other charges due Landlord for all periods prior to the filing of such proceedings.

10.3. Landlord may deliver to any purchaser of Landlord's interest in the Premises the funds deposited hereunder by Tenant, and thereupon Landlord shall be discharged from any further liability with respect to such deposit. This provision shall also apply to any subsequent transfers.

10.4. If Tenant shall fully and faithfully perform every provision of this Lease to be performed by it, then the Security Deposit, or any balance thereof, shall be returned to Tenant (or, at Landlord's option, to the last assignee of Tenant's interest hereunder) within sixty (60) days after the expiration or earlier termination of this Lease.

10.5. If the Security Deposit shall be in cash, Landlord shall hold the Security Deposit in an account at a banking organization selected by Landlord; provided, however, that Landlord shall not be required to maintain a separate account for the Security Deposit, but may intermingle it with other funds of Landlord. Landlord shall be entitled to all interest and/or dividends, if any, accruing on the Security Deposit. Landlord shall not be required to credit Tenant with any interest for any period during which Landlord does not receive interest on the Security Deposit.

10.6. The Security Deposit may be in the form of cash, a letter of credit or any other security instrument acceptable to Landlord in its sole discretion. Tenant may at any time, except when Tenant is in Default (as defined below), deliver a letter of credit (the "L/C Security") as the entire Security Deposit, as follows:

(a) If Tenant elects to deliver L/C Security, then Tenant shall provide Landlord, and maintain in full force and effect throughout the Term and until the date that is ninety (90) days after the then-current Term Expiration Date, a letter of credit in the form of Exhibit E issued by an issuer reasonably satisfactory to Landlord, in the amount of the Security Deposit, with an initial term of at least one year. Landlord may require the L/C Security to be re-issued by a different issuer at any time during the Term if Landlord reasonably believes that the issuing bank of the L/C Security is or may soon become insolvent; provided, however, Landlord shall return the existing L/C Security to the existing issuer immediately upon receipt of the substitute L/C Security. If any issuer of the L/C Security shall become insolvent or placed into FDIC receivership, then Tenant shall immediately deliver to Landlord (without the requirement of notice from Landlord) substitute L/C Security issued by an issuer reasonably satisfactory to Landlord, and otherwise conforming to the requirements set forth in this Article. As used herein with respect to the issuer of the L/C Security, "insolvent" means the determination of insolvency as made by such issuer's primary bank regulator (*i.e.*, the state bank supervisor for state chartered banks; the OCC or OTS, respectively, for federally chartered banks or thrifts; or the Federal Reserve for its member banks). If, at the Term Expiration Date, any Rent remains uncalculated or unpaid, then (i) Landlord shall with reasonable diligence complete any necessary calculations, (ii) Tenant shall extend the expiry date of such L/C Security from time to time as Landlord reasonably requires and (iii) in such extended period, Landlord shall not unreasonably refuse to consent to an appropriate reduction of the L/C Security. Tenant shall reimburse



Landlord's legal costs (as estimated by Landlord's counsel) in handling Landlord's acceptance of L/C Security or its replacement or extension.

(b) If Tenant delivers to Landlord satisfactory L/C Security in place of the entire Security Deposit, Landlord shall remit to Tenant any cash Security Deposit Landlord previously held.

(c) Landlord may draw upon the L/C Security, and hold and apply the proceeds in the same manner and for the same purposes as the Security Deposit, if (i) an uncured Default (as defined below) exists, (ii) as of the date that is forty-five (45) days before any L/C Security expires (even if such scheduled expiry date is after the Term Expiration Date) Tenant has not delivered to Landlord an amendment or replacement for such L/C Security, reasonably satisfactory to Landlord, extending the expiry date to the earlier of (1) six (6) months after the then-current Term Expiration Date or (2) the date that is one year after the then-current expiry date of the L/C Security, (iii) the L/C Security provides for automatic renewals, Landlord asks the issuer to confirm the current L/C Security expiry date, and the issuer fails to do so within ten (10) business days, (iv) Tenant fails to pay (when and as Landlord reasonably requires) any bank charges for Landlord's transfer of the L/C Security or (v) the issuer of the L/C Security ceases, or announces that it will cease, to maintain an office in the city where Landlord may present drafts under the L/C Security (and fails to permit drawing upon the L/C Security by overnight courier or facsimile). This Section does not limit any other provisions of this Lease allowing Landlord to draw the L/C Security under specified circumstances.

(d) Tenant shall not seek to enjoin, prevent, or otherwise interfere with Landlord's draw under L/C Security, even if it violates this Lease. Tenant acknowledges that the only effect of a wrongful draw would be to substitute a cash Security Deposit for L/C Security, causing Tenant no legally recognizable damage. Landlord shall hold the proceeds of any draw in the same manner and for the same purposes as a cash Security Deposit. In the event of a wrongful draw, the parties shall cooperate to allow Tenant to post replacement L/C Security simultaneously with the return to Tenant of the wrongfully drawn sums, and Landlord shall upon request confirm in writing to the issuer of the L/C Security that Landlord's draw was erroneous.

(e) If Landlord transfers its interest in the Premises, then Tenant shall at Tenant's expense, within five (5) business days after receiving a request from Landlord, deliver (and, if the issuer requires, Landlord shall consent to) an amendment to the L/C Security naming Landlord's grantee as substitute beneficiary. If the required Security Deposit changes while L/C Security is in force, then Tenant shall deliver (and, if the issuer requires, Landlord shall consent to) a corresponding amendment to the L/C Security.

10.7 If, as of the fourth (4<sup>th</sup>) anniversary of the Rent Commencement Date, Tenant has not been in Default under this Lease prior to such date (the "SD Reduction Obligation"), then Tenant, within ninety (90) days after the fourth (4<sup>th</sup>) anniversary of the Rent Commencement Date so long as no Default is then existing, may notify Landlord in writing that it wishes to decrease the Security Deposit to Four Hundred and Ten Thousand Nine Hundred Seventy and 63/100 Dollars (\$410,970.63) (the "Reduced Security Deposit"). Within ten (10) Business Days following Landlord's receipt of such notice, Landlord shall (x) confirm in writing that the SD Reduction Obligation has been satisfied and that the Security Deposit shall be deemed to equal

the Reduced Security Deposit, or (y) provide Tenant with satisfactory written evidence that such SD Reduction Obligation has not been satisfied. Upon Landlord's confirmation that the SD Reduction Obligation has been satisfied, (i) if the Security Deposit is in the form of cash, Landlord shall return to Tenant the excess amount within ten (10) Business Days following Landlord's correspondence in the immediately preceding sentence, or (ii) if the Security Deposit is in the form of the L/C Security, the Tenant may provide to Landlord, and Landlord shall accept, a replacement L/C Security in the amount of the Reduced Security Deposit.

11. Use.

11.1. Tenant shall use the Premises for the Permitted Use, and shall not use the Premises, or permit or suffer the Premises to be used, for any other purpose without Landlord's prior written consent, which consent Landlord may withhold in its sole and absolute discretion.

11.2. Tenant shall not use or occupy the Premises in violation of Applicable Laws; zoning ordinances; or the certificate of occupancy (or its substantial equivalent) issued for the Premises or any portion thereof, and shall, upon five (5) days' written notice from Landlord, discontinue any use of the Premises that is declared or claimed by any Governmental Authority having jurisdiction to be a violation of any of the above, or that in Landlord's reasonable opinion violates any of the above. Tenant shall take such further actions and execute such further documents in connection with this Lease as are necessary to comply with Applicable Laws relating to privacy, personal information and data security. Tenant acknowledges that Landlord may collect certain personal information (e.g., names, email addresses and contact information) of Tenant's and its affiliates' employees (and, if applicable, subcontractors and consultants), and use such information in connection with performing Landlord's duties and obligations, and exercising its rights under this Lease. Tenant shall not retain, use or disclose any personal information received from Landlord pursuant to this Lease for any purpose other than to perform its duties and obligations, and exercise its rights under this Lease or as required by Applicable Law. In the event of a conflict between this Section and Article 37, this Section shall govern. Tenant shall comply with any direction of any Governmental Authority having jurisdiction that shall, by reason of the nature of Tenant's use or occupancy of the Premises, impose any duty upon Tenant or Landlord with respect to the Premises or with respect to the use or occupation thereof, and shall indemnify, defend (at the option of and with counsel reasonably acceptable to the indemnified party(ies)), save, reimburse and hold harmless (collectively, "Indemnify," "Indemnity" or "Indemnification," as the case may require) Landlord and its affiliates, employees, agents and contractors; and any lender, mortgagee, ground lessor or beneficiary (each, a "Lender" and, collectively with Landlord and its affiliates, employees, agents and contractors, the "Landlord Indemnitees") harmless from and against any and all demands, claims, liabilities, losses, costs, expenses, actions, causes of action, damages, suits or judgments, and all reasonable expenses (including reasonable attorneys' fees, charges and disbursements, regardless of whether the applicable demand, claim, action, cause of action or suit is voluntarily withdrawn or dismissed) incurred in investigating or resisting the same (collectively, "Claims") of any kind or nature that arise before, during or after the Term as a result of Tenant's breach of this Section.

11.3. Tenant shall not do or permit to be done anything that will invalidate or increase the cost of any fire, environmental, extended coverage or any other insurance policy covering the

Premises or any portion thereof, and shall comply with all rules, orders, regulations and requirements of the insurers of the Premises or any portion thereof, and Tenant shall promptly, upon demand, reimburse Landlord for any additional premium charged for such policy by reason of Tenant's failure to comply with the provisions of this Article.

11.4. Tenant shall keep all doors opening onto public corridors closed, except when in use for ingress and egress.

11.5. No additional locks or bolts of any kind shall be placed upon any of the doors or windows by Tenant, nor shall any changes be made to existing locks or the mechanisms thereof without Landlord's prior written consent. Tenant shall, upon termination of this Lease, return to Landlord all keys to offices and restrooms either furnished to or otherwise procured by Tenant. In the event any key so furnished to Tenant is lost, Tenant shall pay to Landlord the cost of replacing the same or of changing the lock or locks opened by such lost key if Landlord shall deem it necessary to make such change.

11.6. No awnings or other projections shall be attached to any outside wall of the Building. No curtains, blinds, shades or screens shall be attached to or hung in, or used in connection with, any window or door of the Premises other than Landlord's standard window coverings. Neither the interior nor exterior of any windows shall be coated or otherwise sunscreened without Landlord's prior written consent, nor shall any bottles, parcels or other articles be placed on the windowsills or items attached to windows that are visible from outside the Premises. No equipment, furniture or other items of personal property shall be placed on any exterior balcony without Landlord's prior written consent.

11.7. No sign, advertisement or notice ("Signage") shall be exhibited, painted or affixed by Tenant on any exterior part of the Premises without Landlord's prior written consent. Signage shall conform to the criteria and design for the Project set forth in Exhibit J attached hereto. For any Signage, Tenant shall, at Tenant's own cost and expense, (a) acquire all permits for such Signage in compliance with Applicable Laws and (b) design, fabricate, install and maintain such Signage in a first-class condition. Tenant shall be responsible for reimbursing Landlord for costs incurred by Landlord in removing any of Tenant's Signage upon the expiration or earlier termination of the Lease. At Landlord's option, Landlord may install any such Signage, and Tenant shall pay all costs associated with such installation within thirty (30) days after demand therefor. Notwithstanding the immediately foregoing sentence, Landlord shall provide exterior wayfinding Signage for Tenant at Landlord's sole cost and expense, which shall be of a size, color and type and be located in a place acceptable to Landlord. Tenant shall have the right to install two (2) signs on the facade of the Building and branding at the main entrance of the Building identifying Tenant, subject to all Applicable Laws and Landlord's prior written approval with regards to installation, size, design, location and other reasonable criteria, which approval shall not be unreasonably withheld, conditioned or delayed; provided, however, that Tenant shall be responsible for removing such Signage upon the expiration or earlier termination of this Lease at its sole cost and expense.

11.8. Tenant may only place equipment within the Premises with floor loading consistent with the Building's structural design unless Tenant obtains Landlord's prior written

approval. Tenant may place such equipment only in a location designed to carry the weight of such equipment.

11.9. Tenant shall not (a) use or allow the Premises to be used for immoral, unlawful or objectionable purposes or (b) cause, maintain or permit any nuisance or waste in, on or about the Premises.

11.10. Notwithstanding any other provision herein to the contrary, Tenant shall be responsible for all liabilities, costs and expenses arising from or in connection with the compliance of the Premises with the Americans with Disabilities Act, 42 U.S.C. § 12101, et seq., and any state and local accessibility laws, codes, ordinances and rules (collectively, and together with regulations promulgated pursuant thereto, the “ADA”), and Tenant shall Indemnify the Landlord Indemnitees from and against any Claims arising from any such failure of the Premises to comply with the ADA. For the avoidance of doubt, “Lenders” shall also include historic tax credit investors and new market tax credit investors. The provisions of this Section shall survive the expiration or earlier termination of this Lease.

11.11 Tenant shall establish and maintain a chemical safety program administered by a licensed, qualified individual in accordance with the requirements of the New Jersey Water Supply Authority (“NJWSA”) and any other applicable Governmental Authority. Tenant shall be solely responsible for all costs incurred in connection with such chemical safety program, and Tenant shall provide Landlord with such documentation as Landlord may reasonably require evidencing Tenant’s compliance with the requirements of (a) the NJWSA and any other applicable Governmental Authority with respect to such chemical safety program and (b) this Section, including without limitation a list of all chemicals used, handled or stored by the Tenant at the Premises. Notwithstanding the foregoing, Landlord shall obtain and maintain during the Term (m) any permit required by the NJWSA (“NJWSA Permit”) and (n) to the extent Tenant installs an acid neutralization tank system (the “Acid Neutralization Tank”) in accordance with Article 16, a wastewater treatment operator license from the State of New Jersey with respect to Tenant’s use of the Acid Neutralization Tank in the Building. Tenant shall not introduce anything into the Acid Neutralization Tank (x) in violation of the terms of the NJWSA Permit, (y) in violation of Applicable Laws or (z) that would interfere with the proper functioning of the Acid Neutralization Tank. Tenant agrees to reasonably cooperate with Landlord in order to obtain the NJWSA Permit and the wastewater treatment operator license. Tenant shall reimburse Landlord within ten (10) business days after demand for any costs incurred by Landlord pursuant to this Section.

12. Rules and Regulations, CC&Rs and Parking Facilities.

12.1. Tenant shall and shall ensure that its contractors, subcontractors, employees, subtenants and invitees faithfully observe and comply with the rules and regulations adopted by Landlord and attached hereto as Exhibit F, together with such other reasonable and nondiscriminatory rules and regulations as are hereafter promulgated by Landlord in its sole and absolute discretion (the “Rules and Regulations”).

12.2. This Lease is subject to any recorded covenants, conditions or restrictions on the Property or Premises, as the same may be amended, amended and restated, supplemented or

otherwise modified from time to time (the “CC&Rs”). Tenant shall, at its sole cost and expense, comply with the CC&Rs.

12.3. Notwithstanding anything in this Lease to the contrary, Tenant may not install any security systems (including cameras) outside the Premises or that record sounds or images outside the Premises without Landlord’s prior written consent, which Landlord may withhold in its sole and absolute discretion.

12.4. Tenant shall have a non-exclusive, irrevocable license to use all available parking spaces in the parking facilities serving the Premises, which, to Landlord’s knowledge and without having undertaken any independent or internal investigation or due diligence, is approximately 211 parking spaces, during the Term at no additional cost. Landlord makes no representations or warranties to Tenant with respect to the number of parking spaces in such parking facilities, and Landlord shall have no liability to Tenant if the number of parking spaces in such parking facilities is more or less than 211 parking spaces.

13. Control by Landlord.

13.1. Landlord reserves full control over the Premises to the extent not inconsistent with Tenant’s enjoyment of the same as provided by this Lease. This reservation includes Landlord’s right to subdivide the Premises; convert the Premises to condominium units; change the size of the Premises by selling all or a portion of the Premises or adding real property and any improvements thereon to the Premises; grant easements and licenses to third parties; and maintain or establish ownership of the Premises separate from fee title to the Property; provided, however, that such rights shall be exercised in a way that does not materially adversely affect Tenant’s beneficial use and occupancy of the Premises, including the Permitted Use and Tenant’s access to the Premises.

13.2. Tenant shall, at Landlord’s request, promptly execute such further documents as may be reasonably appropriate to assist Landlord in the performance of its obligations hereunder; provided that Tenant need not execute any document that creates additional liability for Tenant or that deprives Tenant of the quiet enjoyment and use of the Premises as provided for in this Lease.

13.3. Landlord may, at any and all reasonable times during business hours (or during non-business hours, if (a) with respect to Subsections 13.3(v) through 13.3(y), Tenant so requests, and (b) with respect to Subsection 13.3(z), if Landlord so requests), and upon twenty-four (24) hours’ prior notice (which may be oral or by email to the office manager or other Tenant-designated individual at the Premises; but provided that no time restrictions shall apply or advance notice be required if an emergency necessitates immediate entry), enter the Premises to (v) inspect the same and to determine whether Tenant is in compliance with its obligations hereunder, (w) supply any service Landlord is required to provide hereunder, (x) post notices of nonresponsibility, (y) access the telephone equipment, electrical substation and fire risers and (z) show the Premises to prospective tenants during the final year of the Term and current and prospective purchasers and lenders at any time or permit a future tenant of the Premises to inspect and measure the Premises in anticipation of such tenant’s future occupancy of the Premises. In no event shall Tenant’s Rent abate as a result of Landlord’s activities pursuant to

this Section; provided, however, that all such activities shall be conducted in such a manner so as to cause as little interference to Tenant as is reasonably possible. Landlord shall at all times retain a key with which to unlock all of the doors in the Premises. If an emergency necessitates immediate access to the Premises, Landlord may use whatever force is necessary to enter the Premises, and any such entry to the Premises shall not constitute a forcible or unlawful entry to the Premises, a detainer of the Premises, or an eviction of Tenant from the Premises or any portion thereof.

14. Quiet Enjoyment. Landlord covenants that Tenant, upon paying the Rent and performing its obligations contained in this Lease, may peacefully and quietly have, hold and enjoy the Premises, free from any claim by Landlord or persons claiming under Landlord, but subject to all of the terms and provisions hereof, provisions of Applicable Laws and rights of record to which this Lease is or may become subordinate. This covenant is in lieu of any other quiet enjoyment covenant, either express or implied.

15. Utilities and Services.

15.1 Tenant shall, at its sole cost and expense, promptly and properly observe and comply with (including in the making by Tenant of any Alterations to the Premises) all present and Applicable Laws.

15.2 Tenant shall, at Tenant's sole cost and expense, procure and maintain contracts, with copies of the same and of any related records furnished promptly to Landlord after execution thereof, in customary form and substance for, and with contractors specializing and experienced in, the maintenance of the following equipment and improvements, if any, if and when installed on the Premises: (a) heating, ventilating and air conditioning ("HVAC") equipment, (b) boilers and pressure vessels, (c) fire extinguishing systems, including fire alarm and smoke detection devices, (d) landscaping and irrigation systems, (e) roof coverings and drains, (f) clarifiers, (g) basic utility feeds to the perimeter of the Building and (h) any other equipment reasonably required by Landlord. Notwithstanding the foregoing, Landlord reserves the right, upon notice to Tenant, to procure and maintain any or all of such service contracts, and if Landlord so elects, Tenant shall reimburse Landlord, upon demand, for the costs thereof. Tenant shall maintain temperature and humidity in the Premises in accordance with ASHRAE standards at all times.

15.3 Within sixty (60) days after the Term Commencement Date, and within sixty (60) days after the beginning of each calendar year during the Term, Landlord shall give Tenant a written estimate for such calendar year of Taxes and the cost of insurance provided by Landlord ("Insurance Costs"). Tenant shall pay such estimated amounts to Landlord in advance in equal monthly installments. Within ninety (90) days after the end of each calendar year, Landlord shall furnish to Tenant a statement showing in reasonable detail the costs incurred by Landlord for Taxes and Insurance Costs related to the Premises during such year (the "Annual Statement"), and Tenant shall pay to Landlord the costs incurred in excess of the payments previously made by Tenant within ten (10) days of receipt of the Annual Statement. In the event that the payments previously made by Tenant for the Taxes and Insurance Costs exceed Tenant's obligation, such excess amount shall be credited by Landlord to the Rent or other charges next

due and owing, provided that, if the Term has expired, Landlord shall remit such excess amount to Tenant.

15.4 All utilities currently serving the Premises are separately metered. Tenant shall make all arrangements for and pay directly for all water, electricity, air, sewer, refuse, gas, heat, light, power, telephone service and any other service or utility Tenant requires at the Premises. Landlord shall reasonably cooperate with Tenant in transferring the billing for water service to the Premises from Landlord to Tenant.

15.5 Landlord shall not be liable for, nor shall any eviction of Tenant result from, the failure to furnish any utility or service, whether or not such failure is caused by Force Majeure (as defined below) or, to the extent permitted by Applicable Laws, Landlord's negligence. In the event of such failure, Tenant shall not be entitled to termination of this Lease or any abatement or reduction of Rent, nor shall Tenant be relieved from the operation of any covenant or agreement of this Lease.

15.6 Tenant shall pay for, prior to delinquency of payment therefor, any utilities and services that may be furnished to the Premises during or, if Tenant occupies the Premises after the expiration or earlier termination of the Term, after the Term.

15.7 Tenant shall not, without Landlord's prior written consent, use any device in the Premises (including data processing machines) that will in any way increase the amount of ventilation, air exchange, gas, steam, electricity or water beyond the existing capacity of the Premises usually furnished or supplied for the Permitted Use.

15.8 A back-up generator is currently connected to the Premises' emergency electrical panel (the "Generator"). Tenant shall maintain, repair and (if necessary) replace the Generator at its sole cost and expense. Landlord expressly disclaims any warranties with regard to the Generator or the installation thereof, including any warranty of merchantability or fitness for a particular purpose. The provisions of Section 15.5 of this Lease shall apply to the Generator.

15.9 For any utilities serving the Premises for which Tenant is billed directly by such utility provider, Tenant agrees to furnish to Landlord (a) any invoices or statements for such utilities within thirty (30) days after Tenant's receipt thereof, (b) within thirty (30) days after Landlord's request, any other utility usage information reasonably requested by Landlord, and (c) within thirty (30) days after each calendar year during the Term, authorization to allow Landlord to access Tenant's usage information necessary for Landlord to complete an ENERGY STAR® Statement of Performance (or similar comprehensive utility usage report (e.g., related to Labs 21), if requested by Landlord) and any other information reasonably requested by Landlord for the immediately preceding year; and Tenant shall comply with any other energy usage or consumption requirements required by Applicable Laws. Tenant shall retain records of utility usage at the Premises, including invoices and statements from the utility provider, for at least sixty (60) months, or such other period of time as may be requested by Landlord. Tenant acknowledges that any utility information for the Premises may be shared with third parties, including Landlord's consultants and Governmental Authorities. In the event that Tenant fails to comply with this Section, Tenant hereby authorizes Landlord to collect utility usage information directly from the applicable utility providers, and Tenant shall pay Landlord a fee of One

Thousand Dollars (\$1,000) per month to collect such utility usage information. In addition to the foregoing, Tenant shall comply with all Applicable Laws related to the disclosure and tracking of energy consumption at the Premises. The provisions of this Section shall survive the expiration or earlier termination of this Lease.

16. Alterations.

16.1. Tenant shall make no alterations, additions or improvements other than the Tenant Improvements in or to the Premises or engage in any construction, demolition, reconstruction, renovation or other work (whether major or minor) of any kind in, at or serving the Premises ("Alterations") without Landlord's prior written approval, which approval may be subject to the consent of one or more Lenders, if required under any applicable Loan Document, but which approval Landlord shall not otherwise unreasonably withhold; provided, however, that, in the event any proposed Alteration affects (a) any structural portions of the Building, including exterior walls, the roof, the foundation or slab, foundation or slab systems (including barriers and subslab systems) or the core of the Building, (b) the exterior of the Building or (c) any Building systems, including elevator, plumbing, HVAC, electrical, security, life safety and power, then Landlord may withhold its approval in its sole and absolute discretion. Tenant shall, in making any Alterations, use only those architects, contractors, suppliers and mechanics of which Landlord has given prior written approval, which approval shall be in Landlord's sole and absolute discretion. In seeking Landlord's approval, Tenant shall provide Landlord, at least sixty (60) days in advance of the desired commencement date of any proposed construction, with plans, specifications, bid proposals, certified stamped engineering drawings and calculations by Tenant's engineer of record or architect of record (including connections to the Building's structural system, modifications to the Building's envelope, non-structural penetrations in slabs or walls, and modifications or tie-ins to life safety systems), work contracts, requests for laydown areas and such other information concerning the nature and cost of the Alterations as Landlord may reasonably request, provided that Tenant shall not commence any such Alterations that require Landlord's consent unless and until Tenant has received the written approval of Landlord and any and all Lenders whose consent is required under any applicable Loan Document. In no event shall Tenant use or Landlord be required to approve any architects, consultants, contractors, subcontractors or material suppliers that Landlord reasonably believes could cause labor disharmony or may not have sufficient experience, in Landlord's reasonable opinion, to perform work in an occupied Class "A" laboratory research building and in lab areas. Notwithstanding the foregoing, Landlord shall not unreasonably withhold, condition, or delay its approval of strictly cosmetic changes to the Premises that do not require any permits or more than three (3) total contractors and subcontractors ("Cosmetic Alterations"); provided that (y) the cost of any Cosmetic Alterations does not exceed Fifty Thousand Dollars (\$50,000) in any one instance or One Hundred Thousand Dollars (\$100,000) annually, (z) such Cosmetic Alterations are not reasonably expected to have any material adverse effect on the Project and do not (i) require any structural or other substantial modifications to the Premises, (ii) require any changes to or adversely affect the Building systems, (iii) affect any portion of the Building or Project that is exterior to the Premises or (iv) trigger any requirement under Applicable Laws that would require Landlord to make any alteration or improvement to the Premises, the Building or the Project.



16.2. Tenant shall not construct or permit to be constructed partitions or other obstructions that might interfere with free access to mechanical installation or service facilities of the Building, or interfere with the moving of Landlord's equipment to or from the enclosures containing such installations or facilities.

16.3. Tenant shall accomplish any work performed on the Premises in such a manner as to permit any life safety systems to remain fully operable at all times.

16.4. Any work performed on the Premises by Tenant or Tenant's contractors shall be done at such times and in such manner as Landlord may from time to time designate. Tenant covenants and agrees that all work done by Tenant or Tenant's contractors shall be performed in full compliance with Applicable Laws. Within thirty (30) days after completion of any Alterations, Tenant shall provide Landlord with complete "as built" drawing print sets and electronic CADD files on disc (or files in such other current format in common use as Landlord reasonably approves or requires) showing any changes in the Premises, as well as a commissioning report prepared by a licensed, qualified commissioning agent hired by Tenant and approved by Landlord for all new or affected mechanical, electrical and plumbing systems. Any such "as built" plans shall show the applicable Alterations as an overlay on the Building as-built plans; provided that Landlord provides the Building "as built" plans to Tenant.

16.5. Before commencing any Alterations or Tenant Improvements, Tenant shall (a) give Landlord at least sixty (60) days' prior written notice of the proposed commencement of such work and the names and addresses of the persons supply labor or materials therefor so that Landlord may enter the Premises to post and keep posted thereon and therein notices or to take any further action that Landlord may reasonably deem proper for the protection of Landlord's interest in the Premises and (b) shall, if required by Landlord, secure, at Tenant's own cost and expense, a completion and lien indemnity bond satisfactory to Landlord for any such work exceeding \$300,000 in the aggregate.

16.6. Tenant shall repair any damage to the Premises arising from Tenant's removal of any property from the Premises. During any such restoration period, Tenant shall pay Rent to Landlord as provided herein as if such space were otherwise occupied by Tenant. The provisions of this Section shall survive the expiration or earlier termination of this Lease.

16.7. The Premises plus any Alterations; Signage; Tenant Improvements; attached equipment, decorations, fixtures and trade fixtures; movable laboratory casework and related appliances; and other additions and improvements attached to or built into the Premises made by either of the parties (including all floor and wall coverings; paneling; sinks and related plumbing fixtures; laboratory benches; exterior venting fume hoods; walk-in freezers and refrigerators and attached machinery and equipment existing in the Premises as of the Execution Date or which are paid for, in whole or in part, with the TI Allowance; ductwork; conduits; electrical panels and circuits; and built-in furniture and cabinets, in each case, together with all additions and accessories thereto), shall (unless, prior to such construction or installation, Landlord elects otherwise in writing) at all times remain the property of Landlord, shall remain in the Premises and shall (unless, prior to construction or installation thereof, Landlord elects otherwise in writing) be surrendered to Landlord upon the expiration or earlier termination of this Lease. For the avoidance of doubt, the items listed on Exhibit H attached hereto (which Exhibit H may be

updated by Tenant from and after the Term Commencement Date, subject to Landlord's written consent) constitute Tenant's property and shall be removed by Tenant upon the expiration or earlier termination of the Lease.

16.8. Notwithstanding any other provision of this Article to the contrary, in no event shall Tenant remove any improvement from the Premises in which any Lender has a security interest or as to which Landlord contributed payment, including the Tenant Improvements, without Landlord's prior written consent, which consent Landlord may withhold in its sole and absolute discretion.

16.9. If Tenant shall fail to remove any of its property from the Premises prior to the expiration or earlier termination of this Lease, then Landlord may, at its option, remove the same in any manner that Landlord shall choose and store such effects without liability to Tenant for loss thereof or damage thereto, and Tenant shall pay Landlord, upon demand, any costs and expenses incurred due to such removal and storage or Landlord may, at its sole option and without notice to Tenant, sell such property or any portion thereof at private sale and without legal process for such price as Landlord may obtain and apply the proceeds of such sale against any (a) amounts due by Tenant to Landlord under this Lease and (b) any expenses incident to the removal, storage and sale of such personal property.

16.10. Tenant shall pay to Landlord an amount equal to three percent (3%) of the cost to Tenant of all Alterations to cover Landlord's overhead and expenses for plan review, engineering review, coordination, scheduling and supervision thereof or obtaining any required Lender consent. For purposes of payment of such sum, Tenant shall submit to Landlord copies of all bills, invoices and statements covering the costs of such charges, accompanied by payment to Landlord of the fee set forth in this Section. Tenant shall reimburse Landlord for any extra expenses incurred by Landlord by reason of faulty work done by Tenant or its contractors, or by reason of delays arising from such faulty work, or by reason of inadequate clean-up.

16.11. Within sixty (60) days after final completion of the Tenant Improvements or any Alterations performed by Tenant with respect to the Premises, Tenant shall submit to Landlord documentation showing the amounts expended by Tenant with respect to such Tenant Improvements and Alterations, together with supporting documentation reasonably acceptable to Landlord.

16.12. Tenant shall take, and shall cause its contractors to take, commercially reasonable steps to protect the Premises during the performance of any Alterations or Tenant Improvements, including covering or temporarily removing any window coverings so as to guard against dust, debris or damage.

16.13. Tenant shall require its contractors and subcontractors performing work on the Premises to name Landlord and BioMed Realty, L.P. and their respective officers, employees, directors, representatives, agents, general partners, members, subsidiaries, affiliates and Lenders (collectively with Landlord, the "Landlord Parties") as additional insureds on their respective insurance policies.

17. Repairs and Maintenance.

17.1 Tenant, at its sole cost and expense, shall maintain and keep the Premises, all improvements thereon, and all appurtenances thereto, including sidewalks, parking areas, curbs, roads, driveways, lighting standards, landscaping, sewers, water, gas and electrical distribution systems and facilities, drainage facilities, and all signs, both illuminated and non-illuminated that are now or hereafter on the Premises, in good condition and in a manner consistent with the Permitted Use. Tenant shall make all repairs, replacements and improvements, including all structural, roof, HVAC, plumbing and electrical repairs, replacements and improvements required, and shall keep the same free and clear from all rubbish, debris, insects, rodents and other vermin and pests. Tenant shall, no later than January 31<sup>st</sup> of each calendar year during the Term, provide to Landlord a copy of the budget for maintenance, repairs and replacements at the Premises for the preceding calendar year, as well as a detailed summary of the amounts actually expended by Tenant during such period for maintenance, repairs and replacements at the Premises. During the Term of this Lease, and in addition to the maintenance contracts required by Section 15.2 of the Lease, Tenant, at its sole cost and expense, shall hire a reputable property and building manager with experience in managing first class office and laboratory properties, which shall be subject to Landlord's prior written consent, not to be unreasonably withheld, conditioned or delayed, to manage the Building and the Project in accordance with the terms of this Lease, including this Article 17. In addition, Tenant shall, within ten (10) days after receipt of written notice from Landlord, provide to Landlord any maintenance records that Landlord reasonably requests. All repairs made by Tenant shall be at least equal in quality to the original work, and shall be made only by a licensed, bonded contractor approved in advance by Landlord; provided, however, that such contractor need not be bonded or approved by Landlord if the non-structural alterations, repairs, additions or improvements to be performed do not exceed Twenty-Five Thousand Dollars (\$25,000) in value. Landlord may impose reasonable restrictions and requirements with respect to such repairs. Tenant shall not take or omit to take any action, the taking or omission of which shall cause waste, damage or injury to the Premises. Tenant shall Indemnify Landlord from and against any and all Claims (as defined below) arising from the failure of Tenant or Tenant's Agents to perform the covenants contained in this paragraph. "Tenant's Agents" shall be defined to include Tenant's officers, employees, agents, contractors, invitees, customers and subcontractors.

17.2 Tenant shall maintain the lines designating the parking spaces in good condition and paint the same as often as may be necessary, so that they are easily discernable at all times; resurface the parking areas as necessary to maintain them in good condition; paint any exterior portions of the Building as necessary to maintain them in good condition; maintain the roof and landscaping in good condition; maintain sightly screens, barricades or enclosures around any waste or storage areas; and take all reasonable precautions to insure that the drainage facilities of the roof are not clogged and are in good and operable condition at all times.

17.3 There shall be no abatement of Rent and no liability of Landlord by reason of any injury to or interference with Tenant's business arising from the making of any repairs, alterations or improvements in or to any portion of the Premises, or in or to improvements, fixtures, equipment and personal property therein.

17.4 During the Term, Landlord shall not be required to maintain or make any repairs or replacements of any nature or description whatsoever to the Premises. Tenant hereby expressly waives the right to make repairs at the expense of Landlord as provided for in any Applicable Laws in effect at the time of execution of this Lease, or in any other Applicable Laws that may hereafter be enacted, and waives its rights under Applicable Laws relating to a landlord's duty to maintain its premises in a tenable condition. Notwithstanding the foregoing, if Tenant shall fail, after reasonable notice, to maintain or to commence and thereafter to proceed with diligence to make any repair required of it pursuant to the terms of this Lease, Landlord, without being under any obligation to do so and without thereby waiving such default by Tenant, may so maintain or make such repair and may charge Tenant for the costs thereof. Any expense reasonably incurred by Landlord in connection with the making of such repairs may be billed by Landlord to Tenant monthly or, at Landlord's option, immediately, and shall be due and payable within ten (10) days after such billing or, at Landlord's option, may be deducted from the Security Deposit.

17.5 Landlord and Landlord's agents shall have the right to enter upon the Premises or any portion thereof for the purposes of performing any repairs or maintenance Landlord is permitted to make pursuant to this Lease, and of ascertaining the condition of the Premises or whether Tenant is observing and performing Tenant's obligations hereunder, all without unreasonable interference from Tenant or Tenant's Agents. Except for emergency maintenance or repairs, the right of entry contained in this paragraph shall be exercisable at reasonable times, at reasonable hours and on reasonable notice.

17.6 [Intentionally omitted.]

17.7 Tenant shall, upon the expiration or sooner termination of the Term, surrender the Premises to Landlord in as good a condition as when received, ordinary wear and tear excepted and with the Tenant Improvements in substantially the same condition as existed upon Substantial Completion of the Tenant Improvements; and shall, at Landlord's request and Tenant's sole cost and expense, remove all telephone and data systems, wiring and equipment from the Premises, and repair any damage to the Premises caused thereby. Landlord shall have no obligation to alter, remodel, improve, repair, decorate or paint the Premises or any part thereof.

17.8 If any excavation shall be made upon land adjacent to or under the Building, or shall be authorized to be made, Tenant shall afford to the person causing or authorized to cause such excavation, license to enter the Premises for the purpose of performing such work as such person shall deem necessary or desirable to preserve and protect the Building from injury or damage and to support the same by proper foundations, without any claim for damages or liability against Landlord and without reducing or otherwise affecting Tenant's obligations under this Lease.

17.9 This Article relates to repairs and maintenance arising in the ordinary course of operation of the Premises. In the event of a casualty described in Article 23, Article 23 shall apply in lieu of this Article. In the event of eminent domain, Article 24 shall apply in lieu of this Article.

18. Liens.

18.1. Subject to the immediately succeeding sentence, Tenant shall keep the Premises free from any liens arising from work or services performed, materials furnished to or obligations incurred by Tenant. Tenant further covenants and agrees that any mechanic's or materialman's lien filed against the Premises for work or services claimed to have been done for, or materials claimed to have been furnished to, or obligations incurred by Tenant shall be discharged or bonded by Tenant within ten (10) days after the filing thereof, at Tenant's sole cost and expense.

18.2. Should Tenant fail to discharge or bond against any lien of the nature described in Section 18.1, Landlord may, at Landlord's election, pay such claim or post a statutory lien bond or otherwise provide security to eliminate the lien as a claim against title, and Tenant shall immediately reimburse Landlord for the costs thereof as Additional Rent. Tenant shall Indemnify the Landlord Indemnitees from and against any Claims arising from any such liens, including any administrative, court or other legal proceedings related to such liens.

18.3. In the event that Tenant leases or finances the acquisition of office equipment, furnishings or other personal property of a removable nature utilized by Tenant in the operation of Tenant's business, Tenant warrants that any Uniform Commercial Code financing statement shall, upon its face or by exhibit thereto, indicate that such financing statement is applicable only to removable personal property of Tenant located within the Premises. In no event shall the address of the Premises be furnished on a financing statement without qualifying language as to applicability of the lien only to removable personal property located in an identified suite leased by Tenant. Should any holder of a financing statement record or place of record a financing statement that appears to constitute a lien against any interest of Landlord or against equipment that may be located other than within an identified suite leased by Tenant, Tenant shall, within ten (10) days after filing such financing statement, cause (a) a copy of the lender security agreement or other documents to which the financing statement pertains to be furnished to Landlord to facilitate Landlord's ability to demonstrate that the lien of such financing statement is not applicable to Landlord's interest and (b) Tenant's lender to amend such financing statement and any other documents of record to clarify that any liens imposed thereby are not applicable to any interest of Landlord in the Premises.

19. Estoppel Certificate. Tenant shall, within ten (10) days after receipt of written notice from Landlord, execute, acknowledge and deliver a statement in writing substantially in the form attached to this Lease as Exhibit I, or on any other form reasonably requested by a current or proposed Lender or encumbrancer or proposed purchaser, (a) certifying that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of such modification and certifying that this Lease as so modified is in full force and effect) and the dates to which rental and other charges are paid in advance, if any, (b) acknowledging that there are not, to Tenant's knowledge, any uncured defaults on the part of Landlord hereunder, or specifying such defaults if any are claimed, and (c) setting forth such further information with respect to this Lease or the Premises as may be requested thereon. Any such statements may be relied upon by any prospective purchaser or encumbrancer of all or any portion of the Property. Tenant's failure to deliver any such statement within such the prescribed time shall, at Landlord's option, constitute a Default (as defined below) under this Lease, and, in any event, shall be binding upon

Tenant that the Lease is in full force and effect and without modification except as may be represented by Landlord in any certificate prepared by Landlord and delivered to Tenant for execution.

20. Hazardous Materials.

20.1. Tenant shall not cause or permit any Hazardous Materials (as defined below) to be brought upon, kept or used in or about the Premises in violation of Applicable Laws by Tenant or any of its employees, agents, contractors or invitees (collectively with Tenant, each a "Tenant Party"). If (a) Tenant breaches such obligation, (b) the presence of Hazardous Materials as a result of such a breach results in contamination of the Premises, any portion thereof, or any adjacent property, (c) contamination of the Premises otherwise occurs during the Term or any extension or renewal hereof or holding over hereunder or (d) contamination of the Premises occurs as a result of Hazardous Materials that are placed on or under or are released into the Premises by a Tenant Party, then Tenant shall Indemnify the Landlord Indemnitees from and against any and all Claims of any kind or nature, including (w) diminution in value of the Premises or any portion thereof, (x) damages for the loss or restriction on use of rentable or usable space or of any amenity of the Premises, (y) damages arising from any adverse impact on marketing of space in the Premises or any portion thereof and (z) sums paid in settlement of Claims that arise before, during or after the Term as a result of such breach or contamination. This Indemnification by Tenant includes costs incurred in connection with any investigation of site conditions or any clean-up, remedial, removal or restoration work required by any Governmental Authority because of Hazardous Materials present in the air, soil or groundwater above, on, under or about the Premises. Without limiting the foregoing, if the presence of any Hazardous Materials in, on, under or about the Premises, any portion thereof or any adjacent property caused or permitted by any Tenant Party results in any contamination of the Premises, any portion thereof or any adjacent property, then Tenant shall promptly take all actions at its sole cost and expense as are necessary to return the Premises, any portion thereof or any adjacent property to its respective condition existing prior to the time of such contamination; provided that Landlord's written approval of such action shall first be obtained, which approval Landlord shall not unreasonably withhold; and provided, further, that it shall be reasonable for Landlord to withhold its consent if such actions could have a material adverse long-term or short-term effect on the Premises, any portion thereof or any adjacent property. Tenant's obligations under this Section shall not be affected, reduced or limited by any limitation on the amount or type of damages, compensation or benefits payable by or for Tenant under workers' compensation acts, disability benefit acts, employee benefit acts or similar legislation.

20.2. Landlord acknowledges that it is not the intent of this Article to prohibit Tenant from operating its business for the Permitted Use. Tenant may operate its business according to the custom of Tenant's industry so long as the use or presence of Hazardous Materials is strictly and properly monitored in accordance with Applicable Laws. As a material inducement to Landlord to allow Tenant to use Hazardous Materials in connection with its business, Tenant agrees to deliver to Landlord (a) a list identifying each type of Hazardous Material to be present at the Premises that is subject to regulation under any environmental Applicable Laws in the form of a Tier II form pursuant to Section 312 of the Emergency Planning and Community Right-to-Know Act of 1986 (or any successor statute) or any other form reasonably requested by Landlord, (b) a list of any and all approvals or permits from Governmental Authorities required

in connection with the presence of such Hazardous Material at the Premises and (c) correct and complete copies of (i) notices of violations of Applicable Laws related to Hazardous Materials and (ii) plans relating to the installation of any storage tanks to be installed in, on, under or about the Premises (provided that installation of storage tanks shall only be permitted after Landlord has given Tenant its written consent to do so, which consent Landlord may withhold in its sole and absolute discretion) and closure plans or any other documents required by any and all Governmental Authorities for any storage tanks installed in, on, under or about the Premises for the closure of any such storage tanks (collectively, "Hazardous Materials Documents"). Tenant shall deliver to Landlord updated Hazardous Materials Documents, within fourteen (14) days after receipt of a written request therefor from Landlord, not more often than once per year, unless (m) there are any changes to the Hazardous Materials Documents or (n) Tenant initiates any Alterations or changes its business, in either case in a way that involves any material increase in the types or amounts of Hazardous Materials, in which case Tenant shall deliver updated Hazardous Materials documents (without Landlord having to request them) before or, if not practicable to do so before, as soon as reasonably practicable after the occurrence of the events in Subsection 20.2(m) or (n). For each type of Hazardous Material listed, the Hazardous Materials Documents shall include (t) the chemical name, (u) the material state (e.g., solid, liquid, gas or cryogen), (v) the concentration, (w) the storage amount and storage condition (e.g., in cabinets or not in cabinets), (x) the use amount and use condition (e.g., open use or closed use), (y) the location (e.g., room number or other identification) and (z) if known, the chemical abstract service number. Notwithstanding anything in this Section to the contrary, Tenant shall not be required to provide Landlord with any documents containing information of a proprietary nature, unless such documents contain a reference to Hazardous Materials or activities related to Hazardous Materials. Landlord may, at Landlord's expense, cause the Hazardous Materials Documents to be reviewed by a person or firm qualified to analyze Hazardous Materials to confirm compliance with the provisions of this Lease and with Applicable Laws. In the event that a review of the Hazardous Materials Documents indicates non-compliance with this Lease or Applicable Laws, Tenant shall, at its expense, diligently take steps to bring its storage and use of Hazardous Materials into compliance. Notwithstanding anything in this Lease to the contrary or Landlord's review into Tenant's Hazardous Materials Documents or use or disposal of hazardous materials, however, Landlord shall not have and expressly disclaims any liability related to Tenant's or other tenants' use or disposal of Hazardous Materials, it being acknowledged by Tenant that Tenant is best suited to evaluate the safety and efficacy of its Hazardous Materials usage and procedures.

20.3. Tenant represents and warrants to Landlord that it is not nor has it been, in connection with the use, disposal or storage of Hazardous Materials, (a) subject to a material enforcement order issued by any Governmental Authority or (b) required to take any remedial action.

20.4. At any time, and from time to time, prior to the expiration of the Term, Landlord shall have the right to conduct appropriate tests of the Premises or any portion thereof to demonstrate that Hazardous Materials are present or that contamination has occurred due to the acts or omissions of a Tenant Party. Tenant shall pay all reasonable costs of such tests if such tests reveal that Hazardous Materials exist at the Premises in violation of this Lease.

20.5. If underground or other storage tanks storing Hazardous Materials installed or utilized by Tenant are located on the Premises, or are hereafter placed on the Premises by Tenant (or by any other party, if such storage tanks are utilized by Tenant), then Tenant shall monitor the storage tanks, maintain appropriate records, implement reporting procedures, properly close any underground storage tanks, and take or cause to be taken all other steps necessary or required under the Applicable Laws. Tenant shall have no responsibility or liability for underground or other storage tanks installed by anyone other than Tenant unless Tenant utilizes such tanks, in which case Tenant's responsibility for such tanks shall be as set forth in this Section.

20.6. Tenant shall promptly report to Landlord any actual or suspected presence of mold or water intrusion at the Premises.

20.7. Tenant's obligations under this Article shall survive the expiration or earlier termination of the Lease. During any period of time needed by Tenant or Landlord after the termination of this Lease to complete the removal from the Premises of any such Hazardous Materials, Tenant shall be deemed a holdover tenant and subject to the provisions of Article 26.

20.8. As used herein, the term "Hazardous Material" means any toxic, explosive, corrosive, flammable, infectious, radioactive, carcinogenic, mutagenic or otherwise hazardous substance, material or waste that is or becomes regulated by Applicable Laws or any Governmental Authority.

21. Odors and Exhaust. Tenant acknowledges that Landlord would not enter into this Lease with Tenant unless Tenant assured Landlord that under no circumstances will the Premises be damaged by any exhaust from Tenant's operations, including Tenant's vivarium. Landlord and Tenant therefore agree as follows:

21.1. Tenant shall not cause or permit (or conduct any activities that would cause) any release of any odors or fumes of any kind from the Premises.

21.2. If the Building has a ventilation system that, in Landlord's judgment, is adequate, suitable, and appropriate to vent the Premises in a manner that does not release odors affecting any indoor or outdoor part of the Premises, Tenant shall vent the Premises through such system. If Landlord at any time determines that any existing ventilation system is inadequate, or if no ventilation system exists, Tenant shall in compliance with Applicable Laws vent all fumes and odors from the Premises (and remove odors from Tenant's exhaust stream) as Landlord requires. The placement and configuration of all ventilation exhaust pipes, louvers and other equipment shall be subject to Landlord's approval. Tenant acknowledges Landlord's legitimate desire to maintain the Premises (indoor and outdoor areas) in an odor-free manner, and Landlord may require Tenant to abate and remove all odors in a manner that goes beyond the requirements of Applicable Laws.

21.3. Tenant shall, at Tenant's sole cost and expense, provide odor eliminators and other devices (such as filters, air cleaners, scrubbers and whatever other equipment may in Landlord's judgment be necessary or appropriate from time to time) to completely remove, eliminate and abate any odors, fumes or other substances in Tenant's exhaust stream that, in



Landlord's judgment, emanate from Tenant's Premises. Any work Tenant performs under this Section shall constitute Alterations.

21.4. Tenant's responsibility to remove, eliminate and abate odors, fumes and exhaust shall continue throughout the Term. Landlord's approval of the Tenant Improvements shall not preclude Landlord from requiring additional measures to eliminate odors, fumes and other adverse impacts of Tenant's exhaust stream (as Landlord may designate in Landlord's discretion). Tenant shall install additional equipment as Landlord requires from time to time under the preceding sentence. Such installations shall constitute Alterations.

21.5. If Tenant fails to install satisfactory odor control equipment within ten (10) business days after Landlord's demand made at any time, then Landlord may, without limiting Landlord's other rights and remedies, require Tenant to cease and suspend any operations in the Premises that, in Landlord's determination, cause odors, fumes or exhaust. For example, if Landlord determines that Tenant's production of a certain type of product causes odors, fumes or exhaust, and Tenant does not install satisfactory odor control equipment within ten (10) business days after Landlord's request, then Landlord may require Tenant to stop producing such type of product in the Premises unless and until Tenant has installed odor control equipment satisfactory to Landlord.

## 22. Insurance.

22.1. Landlord shall maintain insurance for the Premises in amounts equal to full replacement cost (exclusive of the costs of excavation, foundations and footings, engineering costs or such other costs to the extent the same are not incurred in the event of a rebuild and without reference to depreciation taken by Landlord upon its books or tax returns) or such lesser coverage as Landlord may elect, provided that such coverage shall not be less than the amount of such insurance Landlord's Lender, if any, requires Landlord to maintain, providing protection against any peril generally included within the classification "Fire and Extended Coverage," together with insurance against sprinkler damage (if applicable), vandalism and malicious mischief. Landlord, subject to availability thereof, shall further insure, if Landlord deems it appropriate, coverage against flood, environmental hazard, earthquake, loss or failure of building equipment, rental loss during the period of repairs or rebuilding, Workers' Compensation insurance and fidelity bonds for employees employed to perform services. Notwithstanding the foregoing, Landlord may, but shall not be deemed required to, provide insurance for any improvements installed by Tenant or that are in addition to the standard improvements customarily furnished by Landlord, without regard to whether or not such are made a part of or are affixed to the Building.

22.2. In addition, Landlord shall carry Commercial General Liability insurance with limits of not less than One Million Dollars (\$1,000,000) per occurrence/general aggregate for bodily injury (including death), or property damage with respect to the Premises.

22.3. Tenant shall, at its own cost and expense, procure and maintain during the Term the following insurance for the benefit of Tenant and Landlord (as their interests may appear) with insurers financially acceptable and lawfully authorized to do business in the state where the Premises are located:

(a) Commercial General Liability insurance on a broad-based occurrence coverage form, with coverages including but not limited to bodily injury (including death), property damage (including loss of use resulting therefrom), premises/operations, personal & advertising injury, and contractual liability with limits of liability of not less than \$5,000,000 for bodily injury and property damage per occurrence, \$10,000,000 general aggregate, which limits may be met by use of excess and/or umbrella liability insurance; provided that such coverage is at least as broad as the primary coverages required herein.

(b) Commercial Automobile Liability insurance covering liability arising from the use or operation of any auto on behalf of Tenant or invited by Tenant (including those owned, hired, rented, leased, borrowed, scheduled or non-owned). Coverage shall be on a broad-based occurrence form in an amount not less than \$2,000,000 combined single limit per accident for bodily injury and property damage. Such coverage shall apply to all vehicles and persons, whether accessing the property with active or passive consent.

(c) Commercial Property insurance covering property damage to the full replacement cost value and business interruption. Covered property shall include all tenant improvements in the Premises (to the extent not insured by Landlord pursuant to Section 22.1) and Tenant's Property including personal property, furniture, fixtures, machinery, equipment, stock, inventory and improvements and betterments, which may be owned by Tenant or Landlord and required to be insured hereunder, or which may be leased, rented, borrowed or in the care custody or control of Tenant, or Tenant's agents, employees or subcontractors. Such insurance, with respect only to all Tenant Improvements, Alterations or other work performed on the Premises by Tenant (collectively, "Tenant Work"), shall name Landlord and Landlord's current and future mortgagees as loss payees as their interests may appear. Such insurance shall be written on an "all risk" of physical loss or damage basis including the perils of fire, extended coverage, electrical injury, mechanical breakdown, windstorm, vandalism, malicious mischief, sprinkler leakage, back-up of sewers or drains, flood, earthquake, terrorism and such other risks Landlord may from time to time designate, for the full replacement cost value of the covered items with an agreed amount endorsement with no co-insurance. Business interruption coverage shall have limits sufficient to cover Tenant's lost profits and necessary continuing expenses, including rents due Landlord under the Lease. The minimum period of indemnity for business interruption coverage shall be twenty-four (24) months.

(d) Workers' Compensation in compliance with all Applicable Laws or as may be available on a voluntary basis. Employer's Liability must be at least in the amount of \$1,000,000 for bodily injury by accident for each employee, \$1,000,000 for bodily injury by disease for each employee, and \$1,000,000 bodily injury by disease for policy limit.

(e) Medical malpractice insurance at limits of not less than \$1,000,000 each claim during such periods, if any, that Tenant engages in the practice of medicine or clinical trials involving human beings at the Premises.

(f) During all construction by Tenant at the Premises, with respect to tenant improvements being constructed (including the Tenant Improvements and any Alterations, insurance required in Exhibit B-1 must be in place.

22.4. The insurance required of Tenant by this Article shall be with companies at all times having a current rating of not less than A- and financial category rating of at least Class VII in "A.M. Best's Insurance Guide" current edition. Tenant shall obtain for Landlord from the insurance companies/broker or cause the insurance companies/broker to furnish certificates of insurance evidencing all coverages required herein to Landlord. Landlord reserves the right to require complete, certified copies of all required insurance policies including any endorsements. No such policy shall be cancelable or subject to reduction of coverage or other modification or cancellation except after thirty (30) days' prior written notice to Landlord from Tenant or its insurers (except in the event of non-payment of premium, in which case ten (10) days' written notice shall be given). All such policies shall be written as primary policies, not contributing with and not in excess of the coverage that Landlord may carry. Tenant's required policies shall contain severability of interests clauses stating that, except with respect to limits of insurance, coverage shall apply separately to each insured or additional insured. Tenant shall, on the date of expiration of such policies, furnish Landlord with renewal certificates of insurance or binders. Tenant agrees that if Tenant does not take out and maintain such insurance, Landlord may (but shall not be required to) procure such insurance on Tenant's behalf and at its cost to be paid by Tenant as Additional Rent. Commercial General Liability, Commercial Automobile Liability, Umbrella Liability and Pollution Legal Liability insurance as required above shall name the Landlord Parties as additional insureds as respects liability arising from work or operations performed by or on behalf of Tenant, Tenant's use or occupancy of Premises, and ownership, maintenance or use of vehicles by or on behalf of Tenant. Tenant must disclose any self-insurance, including self-insurance retentions, to Landlord in writing in advance, which shall be subject to Landlord's prior written approval in its sole discretion. If Tenant self-insures with Landlord's prior written approval, Tenant is itself acting as though it were providing the insurance required under the provisions of this Lease, and Tenant shall pay those amounts due in lieu of insurance proceeds that would have been covered and payable if the insurance policies had been carried for such self-insured coverages, which amounts shall be treated as insurance proceeds for all purposes under this Lease.

22.5. In each instance where insurance is to name the Landlord Parties as additional insureds, Tenant shall, upon Landlord's written request, also designate and furnish certificates evidencing the Landlord Parties as additional insureds to (a) any Lender of Landlord holding a security interest in the Premises, (b) the landlord under any lease whereunder Landlord is a tenant of the real property upon which the Premises is located if the interest of Landlord is or shall become that of a tenant under a ground lease rather than that of a fee owner and (c) any management company retained by Landlord to manage the Premises.

22.6. Tenant assumes the risk of damage to any fixtures, goods, inventory, merchandise, equipment and leasehold improvements, and Landlord shall not be liable for injury to Tenant's business or any loss of income therefrom, relative to such damage, all as more particularly set forth within this Lease. Tenant shall, at Tenant's sole cost and expense, carry such insurance as Tenant desires for Tenant's protection with respect to personal property of Tenant or business interruption.

22.7. Tenant, on behalf of itself and its insurers, hereby waives any and all rights of recovery against the Landlord Parties with respect to any loss, damage, claims, suits or demands, howsoever caused, that are covered, or should have been covered, by valid and collectible

workers' compensation, employer's liability insurance and other liability insurance required to be obtained and carried by Tenant pursuant to this Article, including any deductibles or self-insurance maintained thereunder. Tenant agrees to endorse the required workers' compensation, employer's liability and other liability insurance policies to permit waivers of subrogation as required hereunder and hold harmless and indemnify the Landlord Parties for any loss or expense incurred as a result of a failure to obtain such waivers of subrogation from insurers. Such waivers shall continue so long as Tenant's insurers so permit. Any termination of such a waiver shall be by written notice to Landlord, containing a description of the circumstances hereinafter set forth in this Section. Tenant, upon obtaining the policies of workers' compensation, employer's liability and other liability insurance required or permitted under this Lease, shall give notice to its insurance carriers that the foregoing waiver of subrogation is contained in this Lease. If such policies shall not be obtainable with such waiver or shall be so obtainable only at a premium over that chargeable without such waiver, then Tenant shall notify Landlord of such conditions.

22.8. Landlord may require insurance policy limits required under this Lease to be raised to conform with requirements of Landlord's Lender.

22.9. In addition to other insurance required by this Lease to be carried by Tenant, if Tenant sells, merchandises, transfers, gives away or exchanges alcoholic beverages in, upon or from any part of the Premises, then Tenant shall, at Tenant's sole cost and expense, purchase and maintain in full force and effect during the Term dram shop insurance in form and substance satisfactory to Landlord, with total limits of liability for bodily injury, loss of means of support and property damage for each occurrence in an amount and with a carrier reasonably acceptable to Landlord, and otherwise in compliance with the general provisions of this Article governing the provision of insurance by Tenant. Such policy shall name the Landlord Parties as additional insureds against any liability by virtue of Applicable Laws concerning the use, sale or giving away of alcoholic beverages. If at any time such insurance is for any reason not in force, then during all and any such times no selling, merchandising, transferring, giving away or exchanging of alcoholic beverages shall be conducted by Tenant in, upon or from any part of the Premises.

22.10. Any costs incurred by Landlord pursuant to this Article shall be included as Insurance Costs payable by Tenant pursuant to this Lease

22.11. The provisions of this Article shall survive the expiration or earlier termination of this Lease.

23. Damage or Destruction.

23.1. In the event of a partial destruction of the Premises by fire or other perils covered by extended coverage insurance not exceeding twenty-five percent (25%) of the full insurable value thereof, and provided that (a) the damage thereto is such that the Premises may be repaired, reconstructed or restored within a period of twelve (12) months from the date of the happening of such casualty, (b) Landlord shall receive insurance proceeds from its insurer or Lender sufficient to cover the cost of such repairs, reconstruction and restoration (except for any deductible amount provided by Landlord's policy, which deductible amount, if paid by Landlord, shall constitute an Insurance Cost, (c) the repair, reconstruction or restoration of the damage or

destruction is permitted by all applicable Loan Documents or otherwise consented to by any and all Lenders whose consent is required thereunder and (d) such casualty was not intentionally caused by a Tenant Party, then Landlord shall commence and proceed diligently with the work of repair, reconstruction and restoration of the Premises, and this Lease shall continue in full force and effect.

In the event of any damage or destruction (regardless of whether such damage is governed by Section 23.1 or this Article 23), if (a) the damage and destruction occurs within the last twenty-four (24) months of the then-current Term, and in Landlord's determination as set forth in the Damage Repair Estimate (as defined below), the Affected Areas cannot be repaired, reconstructed or restored within twelve (12) months after the date of such casualty, or (b) the damage and destruction occurs within the last twelve (12) months of the then-current Term, then Tenant shall have the right to terminate this Lease, effective as of the date of such damage or destruction, by delivering to Landlord its written notice of termination (a "Termination Notice") no later than fifteen (15) days after Landlord delivers to Tenant Landlord's Damage Repair Estimate.

23.2. In the event of any damage to or destruction of the Premises other than as described in Section 23.1, Landlord may elect to repair, reconstruct and restore the Premises, in which case this Lease shall continue in full force and effect. If Landlord elects not to repair, reconstruct and restore the Premises, then this Lease shall terminate as of the date of such damage or destruction. As soon as reasonably practicable, but in any event within sixty (60) days following the date of damage or destruction, Landlord shall notify Tenant of Landlord's good faith estimate of the period of time in which the repairs, reconstruction and restoration will be completed (the "Damage Repair Estimate"), which estimate shall be based upon the opinion of a contractor reasonably selected by Landlord and experienced in comparable repair, reconstruction and restoration of similar buildings. Additionally, Landlord shall give written notice to Tenant within sixty (60) days following the date of damage or destruction of its election not to repair, reconstruct or restore the Building or the Project, as applicable.

23.3. Landlord shall give written notice to Tenant within sixty (60) days following the date of damage or destruction of its election not to repair, reconstruct or restore the Premises.

23.4. Upon any termination of this Lease under any of the provisions of this Article, the parties shall be released thereby without further obligation to the other from the date possession of the Premises is surrendered to Landlord, except with regard to (a) items occurring prior to the damage or destruction and (b) provisions of this Lease that, by their express terms, survive the expiration or earlier termination hereof.

23.5. In the event of repair, reconstruction and restoration as provided in this Article, all Rent to be paid by Tenant under this Lease shall be abated proportionately based on the extent to which Tenant's use of the Premises is impaired during the period of such repair, reconstruction or restoration, unless Landlord provides Tenant with other space during the period of repair, reconstruction and restoration that, in Tenant's reasonable opinion, is suitable for the temporary conduct of Tenant's business; provided, however, that the amount of such abatement shall be reduced by the amount of Rent that is received by Tenant as part of the business interruption or

loss of rental income with respect to the Premises from the proceeds of business interruption or loss of rental income insurance.

23.6. Notwithstanding anything to the contrary contained in this Article, (a) Landlord shall not be required to repair, reconstruct or restore any damage or destruction to the extent that Landlord is prohibited from doing so by any applicable Loan Document or any Lender whose consent is required thereunder withholds its consent, and (b) should Landlord be delayed or prevented from completing the repair, reconstruction or restoration of the damage or destruction to the Premises after the occurrence of such damage or destruction by Force Majeure (as defined below) or delays caused by a Lender or Tenant Party, then the time for Landlord to commence or complete repairs, reconstruction and restoration shall be extended on a day-for-day basis; provided, however, that, at Landlord's election, Landlord shall be relieved of its obligation to make such repairs, reconstruction and restoration.

23.7. If Landlord is obligated to or elects to repair, reconstruct or restore as herein provided, then Landlord shall be obligated to make such repairs, reconstruction or restoration only with regard to those portions of the Premises that were originally provided at Landlord's expense. The repairs, reconstruction or restoration of improvements not originally provided by Landlord or at Landlord's expense shall be the obligation of Tenant. In the event Tenant has elected to upgrade certain improvements from Landlord's building standards (the "Building Standard"), Landlord shall, upon the need for replacement due to an insured loss, provide only the Building Standard, unless Tenant again elects to upgrade such improvements and pay any incremental costs related thereto, except to the extent that excess insurance proceeds, if received, are adequate to provide such upgrades, in addition to providing for basic repairs, reconstruction and restoration of the Premises.

23.8. Notwithstanding anything to the contrary contained in this Article, Landlord shall not have any obligation whatsoever to repair, reconstruct or restore the Premises if the damage resulting from any casualty covered under this Article occurs during the last twenty-four (24) months of the Term or any extension thereof, or to the extent that insurance proceeds are not available therefor.

23.9. Landlord's obligation, should it elect or be obligated to repair, reconstruct or restore, shall be limited to the Premises, and shall be conditioned upon Landlord receiving any permits or authorizations required by Applicable Laws. Tenant shall, at its expense, replace or fully repair all of Tenant's personal property and any Alterations installed by Tenant existing at the time of such damage or destruction. If the Premises are to be repaired, reconstructed or restored in accordance with the foregoing, Landlord shall make available to Tenant any portion of insurance proceeds it receives that are allocable to the Alterations constructed by Tenant pursuant to this Lease; provided Tenant is not then in default under this Lease, and subject to the requirements of any Lender of Landlord.

23.10. This Article sets forth the terms and conditions upon which this Lease may terminate in the event of any damage or destruction. Accordingly, the parties hereby waive the provisions of any Applicable Laws (and any successor statutes) permitting the parties to terminate this Lease as a result of any damage or destruction. Tenant waives the benefit of New Jersey Revised Statutes, Title 46, Chapter 8, Sections 6 and 7, and agrees that Tenant will not be

relieved of its obligation to pay Rent in case of any damage or destruction described in this Article, except as may be expressly provided in this Article.

24. Eminent Domain.

24.1. In the event (a) the whole of the Premises or (b) such part thereof as shall substantially interfere with Tenant's use and occupancy of the Premises for the Permitted Use shall be taken for any public or quasi-public purpose by any lawful power or authority by exercise of the right of appropriation, condemnation or eminent domain, or sold to prevent such taking, Tenant or Landlord may terminate this Lease effective as of the date possession is required to be surrendered to such authority, except with regard to (y) items occurring prior to the taking and (z) provisions of this Lease that, by their express terms, survive the expiration or earlier termination hereof.

24.2. In the event of a partial taking of the Premises for any public or quasi-public purpose by any lawful power or authority by exercise of right of appropriation, condemnation, or eminent domain, or sold to prevent such taking, then, without regard to whether any portion of the Premises occupied by Tenant was so taken, Landlord may elect to terminate this Lease (except with regard to (a) items occurring prior to the taking and (b) provisions of this Lease that, by their express terms, survive the expiration or earlier termination hereof) as of such taking if such taking is, in Landlord's sole opinion, of a material nature such as to make it uneconomical to continue use of the unappropriated portion for purposes of renting office or laboratory space.

24.3. To the extent permitted under all applicable Loan Documents or otherwise consented to by any and all Lenders whose consent is required thereunder, Tenant shall be entitled to any award that is specifically awarded as compensation for (a) the taking of Tenant's personal property that was installed at Tenant's expense and (b) the costs of Tenant moving to a new location. Except as set forth in the previous sentence, any award for such taking shall be the property of Landlord.

24.4. If, upon any taking of the nature described in this Article, this Lease continues in effect, then Landlord shall promptly proceed to restore the Premises to substantially their same condition prior to such partial taking. To the extent such restoration is infeasible, as determined by Landlord in its sole and absolute discretion, the Rent shall be decreased proportionately to reflect the loss of any portion of the Premises no longer available to Tenant. Notwithstanding anything to the contrary contained in this Article, Landlord shall not be required to restore the Premises affected by a taking to the extent that Landlord is prohibited from doing so by any applicable Loan Document or any Lender whose consent is required thereunder withholds its consent.

24.5. This Article sets forth the terms and conditions upon which this Lease may terminate in the event of any damage or destruction. Accordingly, the parties hereby waive the provisions of any Applicable Laws (and any successor statutes) permitting the parties to terminate this Lease as a result of any taking.

25. Surrender.

25.1. At least thirty (30) days prior to Tenant's surrender of possession of any part of the Premises, Tenant shall provide Landlord with a facility decommissioning and Hazardous Materials closure plan for the Premises ("Exit Survey") prepared by an independent third party state-certified professional with appropriate expertise, which Exit Survey must be reasonably acceptable to Landlord. The Exit Survey shall comply with the American National Standards Institute's Laboratory Decommissioning guidelines (ANSI/AIHA Z9.11-2008) or any successor standards published by ANSI or any successor organization (or, if ANSI and its successors no longer exist, a similar entity publishing similar standards). In addition, at least ten (10) days prior to Tenant's surrender of possession of any part of the Premises, Tenant shall (a) provide Landlord with written evidence of all appropriate governmental releases obtained by Tenant in accordance with Applicable Laws, including laws pertaining to the surrender of the Premises, (b) place Laboratory Equipment Decontamination Forms on all decommissioned equipment to assure safe occupancy by future users and (c) conduct a site inspection with Landlord. In addition, Tenant agrees to remain responsible after the surrender of the Premises for the remediation of any recognized environmental conditions set forth in the Exit Survey and comply with any recommendations set forth in the Exit Survey. Tenant's obligations under this Section shall survive the expiration or earlier termination of the Lease.

25.2. No surrender of possession of any part of the Premises shall release Tenant from any of its obligations hereunder, unless such surrender is accepted in writing by Landlord.

25.3. The voluntary or other surrender of this Lease by Tenant shall not effect a merger with Landlord's fee title or leasehold interest in the Premises or any portion thereof, unless Landlord consents in writing, and shall, at Landlord's option, operate as an assignment to Landlord of any or all subleases.

25.4. The voluntary or other surrender of any ground or other underlying lease that now exists or may hereafter be executed affecting the Premises or any portion thereof, or a mutual cancellation thereof or of Landlord's interest therein by Landlord and its lessor shall not effect a merger with Landlord's fee title or leasehold interest in the Premises and shall, at the option of the successor to Landlord's interest in the Premises or any portion thereof operate as an assignment of this Lease.

25.5. Tenant shall, at Tenant's sole cost, comply with the requirements of the New Jersey Industrial Site Recovery Act (as amended, and together with any successor statutes and regulations, "ISRA") in connection with any expiration or earlier termination of this Lease, including (a) filing any required notices with the New Jersey Department of Environmental Protection or (b) causing any (i) assessments, reports or work plans to be prepared, (ii) necessary site investigations or remedial investigations to be conducted and (iii) necessary remediation work to be performed. If required pursuant to ISRA, at least thirty (30) days prior to Tenant's surrender to Landlord of possession of any part of the Premises, Tenant shall provide Landlord with a preliminary assessment prepared in accordance with the Technical Requirements for Site Remediation (N.J.A.C. 7:26E) by a New Jersey Licensed Site Remediation Professional ("LSRP") and, if no areas of concern are identified in the preliminary assessment, a response action outcome issued by the LSRP. If areas of concern are identified in the preliminary



assessment, then Tenant shall cause any necessary site investigations and/or remedial investigations to be performed, and, if required by ISRA, shall cause a remedial action work plan to be prepared. Tenant agrees to remain responsible after the surrender of the Premises to Landlord for the remediation of any recognized environmental conditions identified in the preliminary assessment, any site investigations or remedial investigations, or any remedial action work plan, and shall perform any remediation to the remediation standards required by Applicable Laws. Tenant's obligations under this Section shall survive the expiration or earlier termination of this Lease.

26. Holding Over.

26.1. If, with Landlord's prior written consent, Tenant holds possession of all or any part of the Premises after the Term, Tenant shall become a tenant from month to month after the expiration or earlier termination of the Term, and in such case Tenant shall continue to pay (a) Base Rent in accordance with Article 6, as adjusted in accordance with Article 7, and (b) any amounts for which Tenant would otherwise be liable under this Lease if the Lease were still in effect, including payments for Taxes, Insurance Costs, Tenant's electricity and other utility costs, and all other Additional Rent. Any such month-to-month tenancy shall be subject to every other term, covenant and agreement contained herein.

26.2. Notwithstanding the foregoing, if Tenant remains in possession of the Premises after the expiration or earlier termination of the Term without Landlord's prior written consent, (a) Tenant shall become a tenant at sufferance subject to the terms and conditions of this Lease, except that the monthly rent shall be equal to one hundred fifty percent (150%) of the Rent in effect during the last thirty (30) days of the Term, and (b) if such holdover continues for more than thirty (30) days after the earlier of (i) the expiration or earlier termination of the Term and (ii) the date Landlord notifies Tenant that Landlord has procured a tenant that is ready, willing, and able to sign a lease for the Premises (or portion thereof), Tenant shall be liable to Landlord for any and all damages suffered by Landlord as a result of such holdover, including any lost rent or consequential, special and indirect damages (in each case, regardless of whether such damages are foreseeable). Acceptance by Landlord of Rent after the expiration or earlier termination of the Term shall not result in an extension, renewal or reinstatement of this Lease.

26.3. The foregoing provisions of this Article are in addition to and do not affect Landlord's right of reentry or any other rights of Landlord hereunder or as otherwise provided by Applicable Laws.

26.4. The provisions of this Article shall survive the expiration or earlier termination of this Lease.

27. Indemnification and Exculpation.

27.1. Tenant agrees to Indemnify the Landlord Indemnitees from and against any and all Claims of any kind or nature, real or alleged, arising from (a) injury to or death of any person or damage to any property occurring within or about the Premises arising directly or indirectly out of (i) the presence at or use or occupancy of the Premises by a Tenant Party or (ii) an act or omission on the part of any Tenant Party, (b) a breach or default by Tenant in the performance of

any of its obligations hereunder (including any Claim asserted by a Lender against any Landlord Indemnitees under any Loan Document as a direct result of such breach or default by Tenant) or (c) injury to or death of persons or damage to or loss of any property, real or alleged, arising from the serving of alcoholic beverages at the Premises, including liability under any dram shop law, host liquor law or similar Applicable Law, except to the extent arising directly from Landlord's negligence or willful misconduct. Tenant's obligations under this Section shall not be affected, reduced or limited by any limitation on the amount or type of damages, compensation or benefits payable by or for Tenant under workers' compensation acts, disability benefit acts, employee benefit acts or similar legislation. Tenant's obligations under this Section shall survive the expiration or earlier termination of this Lease.

27.2. Notwithstanding anything in this Lease to the contrary, Landlord shall not be liable to Tenant for and Tenant assumes all risk of (a) damage or losses arising from fire, electrical malfunction, gas explosion or water damage of any type (including broken water lines, malfunctioning fire sprinkler systems, roof leaks or stoppages of lines), unless any such loss is due to Landlord's willful disregard of written notice by Tenant of need for a repair that Landlord is responsible to make for an unreasonable period of time, and (b) damage to personal property or scientific research, including loss of records kept by Tenant within the Premises (in each case, regardless of whether such damages are foreseeable). Tenant further waives any claim for injury to Tenant's business or loss of income relating to any such damage or destruction of personal property as described in this Section. Notwithstanding anything in the foregoing or this Lease to the contrary, except (x) as otherwise provided herein (including Section 26.2), (y) as may be provided by Applicable Laws or (z) in the event of Tenant's breach of Article 20 or Section 25.1, in no event shall Landlord or Tenant be liable to the other for any consequential, special or indirect damages arising from this Lease, including lost profits (provided that this Subsection 27.2(z) shall not limit Tenant's liability for Base Rent or Additional Rent pursuant to this Lease).

27.3. Landlord shall not be liable for any damages arising from any act, omission or neglect of any third party.

27.4. Tenant acknowledges that security devices and services, if any, while intended to deter crime, may not in given instances prevent theft or other criminal acts. Landlord shall not be liable for injuries or losses arising from criminal acts of third parties, and Tenant assumes the risk that any security device or service may malfunction or otherwise be circumvented by a criminal, or that Landlord may decide (in its sole and absolute discretion) not to monitor any installed security devices. If Tenant desires protection against such criminal acts, then Tenant shall, at Tenant's sole cost and expense, obtain appropriate insurance coverage. Tenant's security programs and equipment for the Premises shall be coordinated with Landlord and subject to Landlord's reasonable approval.

27.5. The provisions of this Article shall survive the expiration or earlier termination of this Lease.

28. Assignment or Subletting.

28.1. Except as hereinafter expressly permitted, none of the following (each, a "Transfer"), either voluntarily or by operation of Applicable Laws, shall be directly or indirectly

performed without Landlord's prior written consent, not to be unreasonably withheld, conditioned, or delayed: (a) Tenant selling, hypothecating, assigning, pledging, encumbering or otherwise transferring its interest in this Lease or subletting all or a portion of the Premises, (b) a controlling interest in Tenant being sold, assigned or otherwise transferred (other than as a result of shares in Tenant being sold on a public stock exchange) or (c) the sale of all or substantially of Tenant's assets. For purposes of the preceding sentence, "control" means (f) owning (directly or indirectly) more than fifty percent (50%) of the stock or other equity interests of another person or (g) possessing, directly or indirectly, the power to direct or cause the direction of the management and policies of such person. Notwithstanding the foregoing, Tenant shall have the right to Transfer, without Landlord's prior written consent, Tenant's interest in this Lease or the Premises or any part thereof to (i) any person that as of the date of determination and at all times thereafter directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with Tenant, or (ii) any successor resulting from an acquisition, merger, spin-off or consolidation ("Tenant's Affiliate"); provided that Tenant shall notify Landlord in writing at least thirty (30) days prior to the effectiveness of such Transfer to Tenant's Affiliate (an "Exempt Transfer") and otherwise comply with the requirements of this Lease regarding such Transfer; and provided, further, that the person that will be the tenant under this Lease after the Exempt Transfer of the type set forth in subsection (ii) above has a net worth (as of both the day immediately prior to and the day immediately after the Exempt Transfer) that is equal to or greater than the net worth (as of both the Execution Date and the date of the Exempt Transfer) of the transferring Tenant. For purposes of the immediately preceding sentence, "control" requires both (m) owning (directly or indirectly) more than fifty percent (50%) of the stock or other equity interests of another person and (n) possessing, directly or indirectly, the power to direct or cause the direction of the management and policies of such person. In no event shall Tenant perform a Transfer to or with an entity that is a tenant at the Project or that is in discussions or negotiations with Landlord or an affiliate of Landlord to lease premises at a property owned by Landlord or an affiliate of Landlord.

28.2. In the event Tenant desires to effect a Transfer, then, at least thirty (30) but not more than ninety (90) days prior to the date when Tenant desires the Transfer to be effective (the "Transfer Date"), Tenant shall provide written notice to Landlord (the "Transfer Notice") containing information (including references) concerning the character of the proposed transferee, assignee or sublessee; the Transfer Date; the most recent unconsolidated financial statements of Tenant and of the proposed transferee, assignee or sublessee satisfying the requirements of Section 39.2 ("Required Financials"); any ownership or commercial relationship between Tenant and the proposed transferee, assignee or sublessee; copies of Hazardous Materials Documents for the proposed transferee, assignee or sublessee; and the consideration and all other material terms and conditions of the proposed Transfer, all in such detail as Landlord shall reasonably require.

28.3. Landlord, in determining whether consent should be given to a proposed Transfer, may give consideration to such factors as Landlord reasonably deems material, including (a) the financial strength of Tenant and of such transferee, assignee or sublessee (notwithstanding Tenant remaining liable for Tenant's performance), (b) any change in use that such transferee, assignee or sublessee proposes to make in the use of the Premises and (c) Landlord's desire to exercise its rights under Section 28.7 to recapture the Premises. In no event shall Landlord be deemed to be unreasonable for declining to consent to a Transfer if any applicable Loan

Document prohibits such assignment or any Lender whose consent is required thereunder withholds its consent, or if the Transfer is to a transferee, assignee or sublessee of poor reputation, lacking financial qualifications or seeking a change in the Permitted Use, or jeopardizing directly or indirectly the status of Landlord or any of Landlord's affiliates as a Real Estate Investment Trust under the Internal Revenue Code of 1986 (as the same may be amended from time to time, the "Revenue Code"). Notwithstanding anything contained in this Lease to the contrary, (w) no Transfer shall be consummated on any basis such that the rental or other amounts to be paid by the occupant, assignee, manager or other transferee thereunder would be based, in whole or in part, on the income or profits derived by the business activities of such occupant, assignee, manager or other transferee; (x) Tenant shall not furnish or render any services to an occupant, assignee, manager or other transferee with respect to whom transfer consideration is required to be paid, or manage or operate the Premises or any capital additions so transferred, with respect to which transfer consideration is being paid; (y) Tenant shall not consummate a Transfer with any person in which Landlord owns an interest, directly or indirectly (by applying constructive ownership rules set forth in Section 856(d)(5) of the Revenue Code); and (z) Tenant shall not consummate a Transfer with any person or in any manner that could cause any portion of the amounts received by Landlord pursuant to this Lease or any sublease, license or other arrangement for the right to use, occupy or possess any portion of the Premises to fail to qualify as "rents from real property" within the meaning of Section 856(d) of the Revenue Code, or any similar or successor provision thereto or which could cause any other income of Landlord to fail to qualify as income described in Section 856(c)(2) of the Revenue Code. Notwithstanding anything in this Lease to the contrary, if (a) Tenant or any proposed transferee, assignee or sublessee of Tenant has been required by any prior landlord, Lender or Governmental Authority to take material remedial action in connection with Hazardous Materials contaminating a property if the contamination resulted from such party's action or omission or use of the property in question or (b) Tenant or any proposed transferee, assignee or sublessee is subject to a material enforcement order issued by any Governmental Authority in connection with the use, disposal or storage of Hazardous Materials, then Landlord shall have the right to terminate this Lease in Landlord's sole and absolute discretion (with respect to any such matter involving Tenant), and it shall not be unreasonable for Landlord to withhold its consent to any proposed transfer, assignment or subletting (with respect to any such matter involving a proposed transferee, assignee or sublessee).

28.4. The following are conditions precedent to a Transfer or to Landlord considering a request by Tenant to a Transfer:

(a) Tenant shall remain fully liable under this Lease. Tenant agrees that it shall not be (and shall not be deemed to be) a guarantor or surety of this Lease, however, and waives its right to claim that it is a guarantor or surety or to raise in any legal proceeding any guarantor or surety defenses permitted by this Lease or by Applicable Laws;

(b) If Tenant or the proposed transferee, assignee or sublessee does not or cannot deliver the Required Financials, then Landlord may elect to have either Tenant's ultimate parent company or the proposed transferee's, assignee's or sublessee's ultimate parent company provide a guaranty of the applicable entity's obligations under this Lease, in a form acceptable to Landlord, which guaranty shall be executed and delivered to Landlord by the applicable guarantor prior to the Transfer Date;

(c) In the case of an Exempt Transfer, Tenant shall provide Landlord with evidence reasonably satisfactory to Landlord that the Transfer qualifies as an Exempt Transfer;

(d) Tenant shall provide Landlord with evidence reasonably satisfactory to Landlord that the value of Landlord's interest under this Lease shall not be diminished or reduced by the proposed Transfer. Such evidence shall include evidence respecting the relevant business experience and financial responsibility and status of the proposed transferee, assignee or sublessee;

(e) Tenant shall reimburse Landlord for Landlord's actual costs and expenses, including reasonable attorneys' fees, charges and disbursements incurred in connection with the review, processing and documentation of such request;

(f) If Tenant's transfer of rights or sharing of the Premises provides for the receipt by, on behalf of or on account of Tenant of any consideration of any kind whatsoever (including a premium rental for a sublease or lump sum payment for an assignment, but excluding Tenant's reasonable costs in marketing and subleasing the Premises) in excess of the rental and other charges due to Landlord under this Lease, Tenant shall (unless Landlord directs in writing otherwise) pay fifty percent (50%) of all of such excess to Landlord, after making deductions for any reasonable marketing expenses, tenant improvement funds expended by Tenant, alterations, cash concessions, brokerage commissions, attorneys' fees and free rent actually paid by Tenant. If such consideration consists of cash paid to Tenant, payment to Landlord shall be made upon receipt by Tenant of such cash payment;

(g) The proposed transferee, assignee or sublessee shall agree that, in the event Landlord gives such proposed transferee, assignee or sublessee notice that Tenant is in default under this Lease, such proposed transferee, assignee or sublessee shall thereafter make all payments otherwise due Tenant directly to Landlord, which payments shall be received by Landlord without any liability being incurred by Landlord, except to credit such payment against those due by Tenant under this Lease, and any such proposed transferee, assignee or sublessee shall agree to attorn to Landlord or its successors and assigns should this Lease be terminated for any reason; provided, however, that in no event shall Landlord or its Lenders, successors or assigns be obligated to accept such attornment;

(h) Landlord's consent to any such Transfer shall be effected on Landlord's forms;

(i) Tenant shall not then be in default hereunder in any respect;

(j) Such proposed transferee, assignee or sublessee's use of the Premises shall be the same as the Permitted Use;

(k) Landlord shall not be bound by any provision of any agreement pertaining to the Transfer, except for Landlord's written consent to the same;

(l) Tenant shall pay all transfer and other taxes (including interest and penalties) assessed or payable for any Transfer;

(m) Landlord's consent (or waiver of its rights) for any Transfer shall not waive Landlord's right to consent or refuse consent to any later Transfer;

(n) Tenant shall deliver to Landlord one executed copy of any and all written instruments evidencing or relating to the Transfer; and

(o) Tenant shall deliver to Landlord a list of Hazardous Materials (as defined below), certified by the proposed transferee, assignee or sublessee to be true and correct, that the proposed transferee, assignee or sublessee intends to use or store in the Premises. Additionally, Tenant shall deliver to Landlord, on or before the date any proposed transferee, assignee or sublessee takes occupancy of the Premises, all of the items relating to Hazardous Materials of such proposed transferee, assignee or sublessee as described in Section 20.2.

28.5. Any Transfer that is not in compliance with the provisions of this Article or with respect to which Tenant does not fulfill its obligations pursuant to this Article shall (a) constitute a Default, (b) be voidable by Landlord and (c), at Landlord's option, terminate this Lease, except for those provisions that, by their express terms, survive the expiration or earlier termination hereof.

28.6. Notwithstanding any Transfer, Tenant shall remain fully and primarily liable for the payment of all Rent and other sums due or to become due hereunder, and for the full performance of all other terms, conditions and covenants to be kept and performed by Tenant. The acceptance of Rent or any other sum due hereunder, or the acceptance of performance of any other term, covenant or condition thereof, from any person or entity other than Tenant shall not be deemed a waiver of any of the provisions of this Lease or a consent to any Transfer.

28.7. If Tenant delivers to Landlord a Transfer Notice indicating a desire to transfer this Lease to a proposed transferee or assignee, or a desire to sublease in one or a series of transactions fifty percent (50%) or more of the Rentable Area of the Premises for any term, other than pursuant to an Exempt Transfer, then Landlord shall have the option, exercisable by giving notice to Tenant at any time within thirty (30) days after Landlord's receipt of such Transfer Notice, to terminate this Lease as of the date specified in the Transfer Notice as the Transfer Date, except for those provisions that, by their express terms, survive the expiration or earlier termination hereof. If Landlord exercises such option, then Tenant shall have the right to withdraw such Transfer Notice by delivering to Landlord written notice of such election within five (5) days after Landlord's delivery of notice electing to exercise Landlord's option to terminate this Lease. In the event Tenant withdraws the Transfer Notice as provided in this Section, this Lease shall continue in full force and effect. No failure of Landlord to exercise its option to terminate this Lease shall be deemed to be Landlord's consent to a proposed Transfer.

28.8. If Tenant sublets the Premises or any portion thereof, Tenant hereby immediately and irrevocably assigns to Landlord, as security for Tenant's obligations under this Lease, all rent from any such subletting, and appoints Landlord as assignee and attorney-in-fact for Tenant, and Landlord (or a receiver for Tenant appointed on Landlord's application) may collect such rent and apply it toward Tenant's obligations under this Lease; provided that, until the occurrence of a Default (as defined below) by Tenant, Tenant shall have the right to collect such rent.

28.9. In the event that Tenant enters into a sublease for the entire Premises in accordance with this Article that expires within two (2) days of the Term Expiration Date, the term expiration date of such sublease shall, notwithstanding anything in this Lease, the sublease or any consent to the sublease to the contrary, be deemed to be the date that is two (2) days prior to the Term Expiration Date.

29. Subordination and Attornment.

29.1. This Lease shall be subject and subordinate to the lien of any mortgage, deed of trust, or lease in which Landlord is tenant now or hereafter in force against the Premises or any portion thereof and to all advances made or hereafter to be made upon the security thereof without the necessity of the execution and delivery of any further instruments on the part of Tenant to effectuate such subordination. Landlord shall use commercially reasonable efforts to obtain a commercially reasonable subordination, non-disturbance and attornment agreement on Tenant's behalf from any Lenders existing on the date hereof, and any future Lenders.

29.2. Notwithstanding the foregoing, Tenant shall execute and deliver upon demand such further instrument or instruments evidencing such subordination of this Lease to the lien of any such mortgage or mortgages or deeds of trust or lease in which Landlord is tenant as may be required by Landlord. c. If Tenant fails to execute any document required from Tenant under this Section within ten (10) days after written request therefor, Tenant hereby constitutes and appoints Landlord or its special attorney-in-fact to execute and deliver any such document or documents in the name of Tenant. Such power is coupled with an interest and is irrevocable. For the avoidance of doubt, "Lenders" shall also include historic tax credit investors and new market tax credit investors.

29.3. Upon written request of Landlord and opportunity for Tenant to review, Tenant agrees to execute any Lease amendments not materially altering the terms of this Lease, if required by a Lender incident to the financing of the real property of which the Premises constitute a part.

29.4. In the event any proceedings are brought for foreclosure, or in the event of the exercise of the power of sale under any mortgage or deed of trust made by Landlord covering the Premises, Tenant shall at the election of the purchaser at such foreclosure or sale attorn to the purchaser upon any such foreclosure or sale and recognize such purchaser as Landlord under this Lease.

30. Defaults and Remedies.

30.1. Late payment by Tenant to Landlord of Rent and other sums due shall cause Landlord to incur costs not contemplated by this Lease, the exact amount of which shall be extremely difficult and impracticable to ascertain. Such costs include processing and accounting charges and late charges that may be imposed on Landlord by the terms of any mortgage or trust deed covering the Premises. Therefore, if any installment of Rent due from Tenant is not received by Landlord within three (3) days after the date such payment is due, Tenant shall pay to Landlord (a) an additional sum of six percent (6%) of the overdue Rent as a late charge plus (b) interest at an annual rate (the "Default Rate") equal to the lesser of (a) twelve percent (12%)

and (b) the highest rate permitted by Applicable Laws. The parties agree that this late charge represents a fair and reasonable estimate of the costs that Landlord shall incur by reason of late payment by Tenant and shall be payable as Additional Rent to Landlord due with the next installment of Rent or within five (5) business days after Landlord's demand, whichever is earlier. Landlord's acceptance of any Additional Rent (including a late charge or any other amount hereunder) shall not be deemed an extension of the date that Rent is due or prevent Landlord from pursuing any other rights or remedies under this Lease, at law or in equity.

30.2. No payment by Tenant or receipt by Landlord of a lesser amount than the Rent payment herein stipulated shall be deemed to be other than on account of the Rent, nor shall any endorsement or statement on any check or any letter accompanying any check or payment as Rent be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such Rent or pursue any other remedy provided in this Lease or in equity or at law.

30.3. If Tenant fails to pay any sum of money required to be paid by it hereunder or perform any other act on its part to be performed hereunder, in each case within the applicable cure period (if any) described in Section 30.4, then Landlord may (but shall not be obligated to), without waiving or releasing Tenant from any obligations of Tenant, make such payment or perform such act; provided that such failure by Tenant unreasonably interfered with the efficient operation of the Premises, or resulted or could have resulted in a violation of Applicable Laws or the cancellation of an insurance policy maintained by Landlord. Notwithstanding the foregoing, in the event of an emergency, Landlord shall have the right to enter the Premises and act in accordance with its rights as provided elsewhere in this Lease. In addition to the late charge described in Section 30.1, Tenant shall pay to Landlord as Additional Rent all sums so paid or incurred by Landlord, together with interest at the Default Rate, computed from the date such sums were paid or incurred.

30.4. The occurrence of any one or more of the following events shall constitute a "Default" hereunder by Tenant:

(a) Tenant abandons or vacates the Premises for a period of thirty (30) consecutive days or longer;

(b) Tenant fails to make any payment of Rent, as and when due, or to satisfy its obligations under Article 18, where such failure shall continue for a period of three (3) days after written notice thereof from Landlord to Tenant;

(c) Tenant fails to observe or perform any obligation or covenant contained herein (other than described in Sections 30.4(a) and 30.4(b)) to be performed by Tenant, where such failure continues for a period of ten (10) days after written notice thereof from Landlord to Tenant; provided that, if the nature of Tenant's default is such that it reasonably requires more than ten (10) days to cure, Tenant shall not be deemed to be in Default if Tenant commences such cure within such ten (10) day period and thereafter diligently prosecutes the same to completion; and provided, further, that such cure is completed no later than thirty (30) days after Tenant's receipt of written notice from Landlord;



- (d) Tenant makes an assignment for the benefit of creditors;
- (e) A receiver, trustee or custodian is appointed to or does take title, possession or control of all or substantially all of Tenant's assets;
- (f) Tenant files a voluntary petition under the United States Bankruptcy Code or any successor statute (as the same may be amended from time to time, the "Bankruptcy Code") or an order for relief is entered against Tenant pursuant to a voluntary or involuntary proceeding commenced under any chapter of the Bankruptcy Code;
- (g) Any involuntary petition is filed against Tenant under any chapter of the Bankruptcy Code and is not dismissed within one hundred twenty (120) days;
- (h) Tenant fails to deliver an estoppel certificate in accordance with Article 19; or
- (i) Tenant's interest in this Lease is attached, executed upon or otherwise judicially seized and such action is not released within one hundred twenty (120) days of the action.

Notices given under this Section shall specify the alleged default and shall demand that Tenant perform the provisions of this Lease or pay the Rent that is in arrears, as the case may be, within the applicable period of time, or quit the Premises. No such notice shall be deemed a forfeiture or a termination of this Lease unless Landlord elects otherwise in such notice.

30.5. In the event of a Chronic Delinquency (as defined below), Landlord may, in addition to all other remedies under this Lease, at law or in equity, require that Tenant thereafter pay Rent quarterly in advance. This provision shall not limit in any way nor be construed as a waiver of Landlord's rights and remedies contained in this Lease, at law or in equity in the event of a default. "Chronic Delinquency" means that Tenant commits a Default pursuant to Section 31.4(b) three (3) times in any twelve (12) month period.

30.6. In the event of a Default by Tenant, and at any time thereafter, with or without notice or demand and without limiting Landlord in the exercise of any right or remedy that Landlord may have, Landlord has the right to do any or all of the following:

- (a) Halt any Tenant Improvements and Alterations and order Tenant's contractors, subcontractors, consultants, designers and material suppliers to stop work;
- (b) Terminate Tenant's right to possession of the Premises by written notice to Tenant or by any lawful means, in which case Tenant shall immediately surrender possession of the Premises to Landlord. In such event, Landlord shall have the immediate right to re-enter and remove all persons and property, and such property may be removed and stored in a public warehouse or elsewhere at the cost and for the account of Tenant, all without service of notice or resort to legal process and without being deemed guilty of trespass or becoming liable for any loss or damage that may be occasioned thereby; and

(c) Terminate this Lease, in which event Tenant shall immediately surrender possession of the Premises to Landlord. In such event, Landlord shall have the immediate right to re-enter and remove all persons and property, and such property may be removed and stored in a public warehouse or elsewhere at the cost and for the account of Tenant, all without service of notice or resort to legal process and without being deemed guilty of trespass or becoming liable for any loss or damage that may be occasioned thereby. In the event that Landlord shall elect to so terminate this Lease, then Landlord shall be entitled to recover from Tenant all damages incurred by Landlord by reason of Tenant's default, including:

(i) The sum of:

A. The worth at the time of award of any unpaid Rent that had accrued at the time of such termination; plus

B. The worth at the time of award of the amount by which the unpaid Rent that would have accrued during the period commencing with termination of the Lease and ending at the time of award exceeds that portion of the loss of Landlord's rental income from the Premises that Tenant proves to Landlord's reasonable satisfaction could have been reasonably avoided; plus

C. The worth at the time of award of the amount by which the unpaid Rent for the balance of the Term after the time of award exceeds that portion of the loss of Landlord's rental income from the Premises that Tenant proves to Landlord's reasonable satisfaction could have been reasonably avoided; plus

D. Any other amount necessary to compensate Landlord for all the detriment arising from Tenant's failure to perform its obligations under this Lease or that in the ordinary course of things would be likely to result therefrom, including the cost of restoring the Premises to the condition required under the terms of this Lease, including any rent payments not otherwise chargeable to Tenant (e.g., during any "free" rent period or rent holiday); plus

E. At Landlord's election, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by Applicable Laws; or

(ii) At Landlord's election, as minimum liquidated damages in addition to any (A) amounts paid or payable to Landlord pursuant to Section 30.5(c)(i)(A), prior to such election and (B) costs of restoring the Premises to the condition required under the terms of this Lease, an amount (the "Election Amount") equal to either (Y) the positive difference (if any, and measured at the time of such termination) between (1) the then-present value of the total Rent and other benefits that would have accrued to Landlord under this Lease for the remainder of the Term if Tenant had fully complied with the Lease minus (2) the then-present cash rental value of the Premises as determined by Landlord for what would be the then-unexpired Term if the Lease remained in effect, computed using the discount rate of the Federal Reserve Bank of San Francisco at the time of the award plus one (1) percentage point (the "Discount Rate") or (Z) twelve (12) months (or such lesser number of months as may then be remaining in the Term) of Base Rent and Additional Rent at the rate last payable by Tenant pursuant to this Lease, in either case as Landlord specifies in such election. Landlord and Tenant agree that the Election Amount

represents a reasonable forecast of the minimum damages expected to occur in the event of a breach, taking into account the uncertainty, time and cost of determining elements relevant to actual damages, such as fair market rent, time and costs that may be required to re-lease the Premises, and other factors; and that the Election Amount is not a penalty.

As used in Sections 30.5(c)(i)(A) and (B), “worth at the time of award” shall be computed by allowing interest at the Default Rate. As used in Section 30.5(c)(i)(C), the “worth at the time of the award” shall be computed by taking the present value of such amount, using the Discount Rate.

30.7. In addition to any other remedies available to Landlord at law or in equity and under this Lease, Landlord may continue this Lease in effect after Tenant’s Default or abandonment and recover Rent as it becomes due. In addition, Landlord shall not be liable in any way whatsoever for its failure or refusal to relet the Premises. For purposes of this Section, the following acts by Landlord will not constitute the termination of Tenant’s right to possession of the Premises:

(a) Acts of maintenance or preservation or efforts to relet the Premises, including alterations, remodeling, redecorating, repairs, replacements or painting as Landlord shall consider advisable for the purpose of reletting the Premises or any part thereof; or

(b) The appointment of a receiver upon the initiative of Landlord to protect Landlord’s interest under this Lease or in the Premises.

Notwithstanding the foregoing, in the event of a Default by Tenant, Landlord may elect at any time to terminate this Lease and to recover damages to which Landlord is entitled.

30.8. If Landlord does not elect to terminate this Lease as provided in Section 30.5, then Landlord may, from time to time, recover all Rent as it becomes due under this Lease. At any time thereafter, Landlord may elect to terminate this Lease and to recover damages to which Landlord is entitled.

30.9. In the event Landlord elects to terminate this Lease and relet the Premises, Landlord may execute any new lease in its own name. Tenant shall have no right or authority whatsoever to collect any Rent from such tenant. The proceeds of any such reletting shall be applied as follows:

(a) First, to the payment of any indebtedness other than Rent due hereunder from Tenant to Landlord, including storage charges or brokerage commissions owing from Tenant to Landlord as the result of such reletting;

(b) Second, to the payment of the costs and expenses of reletting the Premises, including (i) alterations and repairs that Landlord deems reasonably necessary and advisable and (ii) reasonable attorneys’ fees, charges and disbursements incurred by Landlord in connection with the retaking of the Premises and such reletting;

(c) Third, to the payment of Rent and other charges due and unpaid hereunder; and

(d) Fourth, to the payment of future Rent and other damages payable by Tenant under this Lease.

30.10. All of Landlord's rights, options and remedies hereunder shall be construed and held to be nonexclusive and cumulative. Landlord shall have the right to pursue any one or all of such remedies, or any other remedy or relief that may be provided by Applicable Laws, whether or not stated in this Lease. No waiver of any default of Tenant hereunder shall be implied from any acceptance by Landlord of any Rent or other payments due hereunder or any omission by Landlord to take any action on account of such default if such default persists or is repeated, and no express waiver shall affect defaults other than as specified in such waiver. Notwithstanding any provision of this Lease to the contrary, in no event shall Landlord be required to mitigate its damages with respect to any default by Tenant, except as required by Applicable Laws. Any such obligation imposed by Applicable Laws upon Landlord to relet the Premises after any termination of this Lease shall be subject to the reasonable requirements of Landlord to (a) lease to high quality tenants on such terms as Landlord may from time to time deem appropriate in its discretion and (b) develop the Premises in a harmonious manner with a mix of uses, tenants, floor areas, terms of tenancies, etc., as determined by Landlord. Landlord shall not be obligated to relet the Premises to (y) any Tenant's Affiliate or (z) any party (i) unacceptable to a Lender, (ii) that requires Landlord to make improvements to or re-demise the Premises, (iii) that desires to change the Permitted Use, (iv) that desires to lease the Premises for more or less than the remaining Term or (v) to whom Landlord or an affiliate of Landlord may desire to lease other available space at another property owned by Landlord or an affiliate of Landlord.

30.11. Landlord's termination of (a) this Lease or (b) Tenant's right to possession of the Premises shall not relieve Tenant of any liability to Landlord that has previously accrued or that shall arise based upon events that occurred prior to the later to occur of (y) the date of Lease termination and (z) the date Tenant surrenders possession of the Premises.

30.12. To the extent permitted by Applicable Laws, Tenant waives any and all rights of redemption granted by or under any present or future Applicable Laws if Tenant is evicted or dispossessed for any cause, or if Landlord obtains possession of the Premises due to Tenant's default hereunder or otherwise.

30.13. Landlord shall not be in default or liable for damages under this Lease unless Landlord fails to perform obligations required of Landlord within a reasonable time, but in no event shall such failure continue for more than thirty (30) days after written notice from Tenant specifying the nature of Landlord's failure; provided, however, that if the nature of Landlord's obligation is such that more than thirty (30) days are required for its performance, then Landlord shall not be in default if Landlord commences performance within such thirty (30) day period and thereafter diligently prosecutes the same to completion. In no event shall Tenant have the right to terminate or cancel this Lease or to withhold or abate rent or to set off any Claims against Rent as a result of any default or breach by Landlord of any of its covenants, obligations, representations, warranties or promises hereunder, except as may otherwise be expressly set forth in this Lease.

30.14. In the event of any default by Landlord, Tenant shall give notice by registered or certified mail to any (a) beneficiary of a deed of trust or (b) mortgagee under a mortgage

covering the Premises or any portion thereof and to any landlord of any lease of land upon or within which the Premises are located, and shall offer such beneficiary, mortgagee or landlord a reasonable opportunity to cure the default, including time to obtain possession of the Premises by power of sale or a judicial action if such should prove necessary to effect a cure; provided that Landlord shall furnish to Tenant in writing, upon written request by Tenant, the names and addresses of all such persons who are to receive such notices.

31. Bankruptcy. In the event a debtor, trustee or debtor in possession under the Bankruptcy Code, or another person with similar rights, duties and powers under any other Applicable Laws, proposes to cure any default under this Lease or to assume or assign this Lease and is obliged to provide adequate assurance to Landlord that (a) a default shall be cured, (b) Landlord shall be compensated for its damages arising from any breach of this Lease and (c) future performance of Tenant's obligations under this Lease shall occur, then such adequate assurances shall include any or all of the following, as designated by Landlord in its sole and absolute discretion:

31.1. Those acts specified in the Bankruptcy Code or other Applicable Laws as included within the meaning of "adequate assurance," even if this Lease does not concern a shopping center or other facility described in such Applicable Laws;

31.2. A prompt cash payment to compensate Landlord for any monetary defaults or actual damages arising directly from a breach of this Lease;

31.3. A cash deposit in an amount at least equal to the then-current amount of the Security Deposit; or

31.4. The assumption or assignment of all of Tenant's interest and obligations under this Lease.

32. Brokers.

32.1 Tenant represents and warrants that it has had no dealings with any real estate broker or agent in connection with the negotiation of this Lease other than CBRE, T3 Advisors, and Jones Lang LaSalle Brokerage, Inc. (collectively, the "Broker"), and that it knows of no other real estate broker or agent that is or might be entitled to a commission in connection with this Lease. Landlord shall compensate Broker in relation to this Lease pursuant to a separate agreement between Landlord and Broker.

32.2 Tenant represents and warrants that no broker or agent has made any representation or warranty relied upon by Tenant in Tenant's decision to enter into this Lease, other than as contained in this Lease.

32.3 Tenant acknowledges and agrees that the employment of brokers by Landlord is for the purpose of solicitation of offers of leases from prospective tenants and that no authority is granted to any broker to furnish any representation (written or oral) or warranty from Landlord unless expressly contained within this Lease. Landlord is executing this Lease in reliance upon Tenant's representations, warranties and agreements contained within Sections 32.1 and 32.2.

32.4 Tenant agrees to Indemnify the Landlord Indemnitees from any and all cost or liability for compensation claimed by any broker or agent, other than Broker, employed or engaged by Tenant or claiming to have been employed or engaged by Tenant.

33. Definition of Landlord. With regard to obligations imposed upon Landlord pursuant to this Lease, the term "Landlord," as used in this Lease, shall refer only to Landlord or Landlord's then-current successor-in-interest. In the event of any transfer, assignment or conveyance of Landlord's interest in this Lease or in Landlord's fee title to or leasehold interest in the Property, as applicable, Landlord herein named (and in case of any subsequent transfers or conveyances, the subsequent Landlord) shall be automatically freed and relieved, from and after the date of such transfer, assignment or conveyance, from all liability for the performance of any covenants or obligations contained in this Lease thereafter to be performed by Landlord and, without further agreement, the transferee, assignee or conveyee of Landlord's in this Lease or in Landlord's fee title to or leasehold interest in the Property, as applicable, shall be deemed to have assumed and agreed to observe and perform any and all covenants and obligations of Landlord hereunder during the tenure of its interest in the Lease or the Property. Landlord or any subsequent Landlord may transfer its interest in the Premises or this Lease without Tenant's consent.

34. Limitation of Landlord's Liability.

34.1 If Landlord is in default under this Lease and, as a consequence, Tenant recovers a monetary judgment against Landlord, the judgment shall be satisfied only out of (a) the proceeds of sale received on execution of the judgment and levy against the right, title and interest of Landlord in the Premises, (b) rent or other income from such real property receivable by Landlord or (c) the consideration received by Landlord from the sale, financing, refinancing or other disposition of all or any part of Landlord's right, title or interest in the Premises.

34.2 Neither Landlord nor any of its affiliates, nor any of their respective partners, shareholders, directors, officers, employees, members or agents shall be personally liable for Landlord's obligations or any deficiency under this Lease, and service of process shall not be made against any shareholder, director, officer, employee or agent of Landlord or any of Landlord's affiliates. No partner, shareholder, director, officer, employee, member or agent of Landlord or any of its affiliates shall be sued or named as a party in any suit or action, and service of process shall not be made against any partner or member of Landlord except as may be necessary to secure jurisdiction of the partnership, joint venture or limited liability company, as applicable. No partner, shareholder, director, officer, employee, member or agent of Landlord or any of its affiliates shall be required to answer or otherwise plead to any service of process, and no judgment shall be taken or writ of execution levied against any partner, shareholder, director, officer, employee, member or agent of Landlord or any of its affiliates.

34.3 Each of the covenants and agreements of this Article shall be applicable to any covenant or agreement either expressly contained in this Lease or imposed by Applicable Laws and shall survive the expiration or earlier termination of this Lease.

35. Joint and Several Obligations. If more than one person or entity executes this Lease as Tenant, then:

35.1. Each of them is jointly and severally liable for the keeping, observing and performing of all of the terms, covenants, conditions, provisions and agreements of this Lease to be kept, observed or performed by Tenant, and such terms, covenants, conditions, provisions and agreements shall be binding with the same force and effect upon each and all of the persons executing this Agreement as Tenant; and

35.2. The term “Tenant,” as used in this Lease, means and includes each of them, jointly and severally. The act of, notice from, notice to, refund to, or signature of any one or more of them with respect to the tenancy under this Lease, including any renewal, extension, expiration, termination or modification of this Lease, shall be binding upon each and all of the persons executing this Lease as Tenant with the same force and effect as if each and all of them had so acted, so given or received such notice or refund, or so signed.

36. Representations. Tenant guarantees, warrants and represents that (a) Tenant is duly incorporated or otherwise established or formed and validly existing under the laws of its state of incorporation, establishment or formation, (b) Tenant has and is duly qualified to do business in the state in which the Property is located, (c) Tenant has full corporate, partnership, trust, association or other appropriate power and authority to enter into this Lease and to perform all Tenant’s obligations hereunder, (d) each person (and all of the persons if more than one signs) signing this Lease on behalf of Tenant is duly and validly authorized to do so and (e) neither (i) the execution, delivery or performance of this Lease nor (ii) the consummation of the transactions contemplated hereby will violate or conflict with any provision of documents or instruments under which Tenant is constituted or to which Tenant is a party. In addition, Tenant guarantees, warrants and represents that none of (x) it, (y) its affiliates or partners nor (z) to the best of its knowledge, its members, shareholders or other equity owners or any of their respective employees, officers, directors, representatives or agents is a person or entity with whom U.S. persons or entities are restricted from doing business under regulations of the Office of Foreign Asset Control (“OFAC”) of the Department of the Treasury (including those named on OFAC’s Specially Designated and Blocked Persons List) or under any statute, executive order (including the September 24, 2001, Executive Order Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism) or other similar governmental action. Landlord represents that, to its current, actual knowledge (without duty of inquiry), it is not an entity with whom U.S. persons or entities are restricted from doing business under regulations of OFAC of the Department of the Treasury (including those named on OFAC’s Specially Designated and Blocked Persons List) or under any statute, executive order (including the September 24, 2001, Executive Order Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism) or other similar governmental action.

37. Confidentiality. Tenant shall keep the terms and conditions of this Lease confidential and shall not (a) disclose to any third party any terms or conditions of this Lease or any other Lease-related document (including subleases, assignments, work letters, construction contracts, letters of credit, subordination agreements, non-disturbance agreements, brokerage agreements or stoppels) or the contents of any documents, reports, surveys or evaluations related to the

Premises or any portion thereof or (b) provide to any third party an original or copy of this Lease (or any Lease-related document or other document referenced in Subsection 37(a)). Landlord shall not release to any third party any non-public financial information or non-public information about Tenant's ownership structure that Tenant gives Landlord. Notwithstanding the foregoing, confidential information under this Section may be released by Landlord or Tenant under the following circumstances: (x) if required by Applicable Laws or in any judicial proceeding; provided that the releasing party has given the other party reasonable notice of such requirement, if feasible, (y) to a party's attorneys, accountants, brokers, lenders, potential lenders, investors, potential investors and other bona fide consultants or advisers (with respect to this Lease only); provided such third parties agree to be bound by this Section or (z) to bona fide prospective assignees or subtenants of this Lease; provided they agree in writing to be bound by this Section.

38. Notices . Except as otherwise stated in this Lease, any notice, consent, demand, invoice, statement or other communication required or permitted to be given hereunder shall be in writing and shall be given by (a) personal delivery, (b) overnight delivery with a reputable international overnight delivery service, such as FedEx, or (c) email transmission, so long as such transmission is followed within one (1) business day by delivery utilizing one of the methods described in Subsection 38(a) or (b), provided that, for purposes of this Subsection 38(c), if delivery utilizing one of the other methods described in Subsection 38(a) or (b) is not reasonably practicable due to an event of Force Majeure (as defined below), then such requirement shall be waived for deliveries by email transmission so long as either the receiving party responds to the sending party confirming receipt of the applicable email transmission, or the sending party receives other electronic confirmation that the email transmission was received and read by the receiving party, such as a "read receipt" notice.. Any such notice, consent, demand, invoice, statement or other communication shall be deemed delivered (x) upon receipt, if given in accordance with Subsection 38(a); (y) one (1) business day after deposit with a reputable international overnight delivery service, if given in accordance with Subsection 38(b); or (z) upon transmission, if given in accordance with Subsection 38(c). Except as otherwise stated in this Lease, any notice, consent, demand, invoice, statement or other communication required or permitted to be given pursuant to this Lease shall be addressed to Tenant at the Premises, or to Landlord or Tenant at the addresses shown in Sections 2.9 and 2.10 or 2.11, respectively. Either party may, by notice to the other given pursuant to this Section, specify additional or different addresses for notice purposes.

39. Miscellaneous.

39.1. Landlord reserves the right to change the name of the Building or the Premises in its sole discretion.

39.2. To induce Landlord to enter into this Lease, Tenant agrees that it shall furnish to Landlord, from time to time, within ten (10) business days after receipt of Landlord's written request, the most recent year-end unconsolidated financial statements reflecting Tenant's current financial condition audited by a nationally recognized accounting firm. Tenant shall, within ninety (90) days after the end of Tenant's financial year, furnish Landlord with a certified copy of Tenant's year-end unconsolidated financial statements for the previous year audited by a nationally recognized accounting firm. Tenant represents and warrants that all financial



statements, records and information furnished by Tenant to Landlord in connection with this Lease are true, correct and complete in all respects. If audited financials are not otherwise prepared, unaudited financials complying with generally accepted accounting principles and certified by the chief financial officer of Tenant as true, correct and complete in all respects shall suffice for purposes of this Section. If Tenant fails to deliver to Landlord any financial statement within the time period required under this Section, then Tenant shall be required to pay to Landlord an administrative fee equal to One Thousand Dollars (\$1,000) within five (5) business days after receiving written notice from Landlord advising Tenant of such failure (provided, however, that Landlord's acceptance of such fee shall not prevent Landlord from pursuing any other rights or remedies under this Lease, at law or in equity). The provisions of this Section shall not apply at any time while Tenant is a corporation whose shares are traded on any nationally recognized stock exchange.

39.3. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or option for a lease, and shall not be effective as a lease or otherwise until execution by and delivery to both Landlord and Tenant.

39.4. The terms of this Lease are intended by the parties as a final, complete and exclusive expression of their agreement with respect to the terms that are included herein, and may not be contradicted or supplemented by evidence of any other prior or contemporaneous agreement.

39.5. Neither party shall record this Lease.

39.6. Where applicable in this Lease, the singular includes the plural and the masculine or neuter includes the masculine, feminine and neuter. The words "include," "includes," "included" and "including" mean "'include,' etc., without limitation." The word "shall" is mandatory and the word "may" is permissive. The word "business day" means a calendar day other than any national or local holiday on which federal government agencies in the County of Mercer are closed for business, or any weekend. The section headings of this Lease are not a part of this Lease and shall have no effect upon the construction or interpretation of any part of this Lease. Landlord and Tenant have each participated in the drafting and negotiation of this Lease, and the language in all parts of this Lease shall be in all cases construed as a whole according to its fair meaning and not strictly for or against either Landlord or Tenant.

39.7. Except as otherwise expressly set forth in this Lease, each party shall pay its own costs and expenses incurred in connection with this Lease and such party's performance under this Lease; provided that, if either party commences an action, proceeding, demand, claim, action, cause of action or suit against the other party arising from or in connection with this Lease, then the substantially prevailing party shall be reimbursed by the other party for all reasonable costs and expenses, including reasonable attorneys' fees and expenses, incurred by the substantially prevailing party in such action, proceeding, demand, claim, action, cause of action or suit, and in any appeal in connection therewith (regardless of whether the applicable action, proceeding, demand, claim, action, cause of action, suit or appeal is voluntarily withdrawn or dismissed). In addition, Landlord shall, upon demand, be entitled to all reasonable attorneys' fees and all other reasonable costs incurred in the preparation and service of any notice or demand hereunder, regardless of whether a legal action is subsequently commenced, or

incurred in connection with any contested matter or other proceeding in bankruptcy court concerning this Lease.

39.8. Time is of the essence with respect to the performance of every provision of this Lease.

39.9. Each provision of this Lease performable by Tenant shall be deemed both a covenant and a condition.

39.10. Notwithstanding anything to the contrary contained in this Lease, Tenant's obligations under this Lease are independent and shall not be conditioned upon performance by Landlord.

39.11. Any provision of this Lease that shall prove to be invalid, void or illegal shall in no way affect, impair or invalidate any other provision hereof, and all other provisions of this Lease shall remain in full force and effect and shall be interpreted as if the invalid, void or illegal provision did not exist.

39.12. Each of the covenants, conditions and agreements herein contained shall inure to the benefit of and shall apply to and be binding upon the parties hereto and their respective heirs; legatees; devisees; executors; administrators; and permitted successors and assigns. This Lease is for the sole benefit of the parties and their respective heirs, legatees, devisees, executors, administrators and permitted successors and assigns, and nothing in this Lease shall give or be construed to give any other person or entity any legal or equitable rights. Nothing in this Section shall in any way alter the provisions of this Lease restricting assignment or subletting.

39.13. This Lease shall be governed by, construed and enforced in accordance with the laws of the state in which the Premises are located, without regard to such state's conflict of law principles.

39.14. Tenant guarantees, warrants and represents that the individual or individuals signing this Lease have the power, authority and legal capacity to sign this Lease on behalf of and to bind all entities, corporations, partnerships, limited liability companies, joint venturers or other organizations and entities on whose behalf such individual or individuals have signed.

39.15. This Lease may be executed in one or more counterparts, each of which, when taken together, shall constitute one and the same document.

39.16. No provision of this Lease may be modified, amended or supplemented except by an agreement in writing signed by Landlord and Tenant.

39.17. No waiver of any term, covenant or condition of this Lease shall be binding upon Landlord unless executed in writing by Landlord. The waiver by Landlord of any breach or default of any term, covenant or condition contained in this Lease shall not be deemed to be a waiver of any preceding or subsequent breach or default of such term, covenant or condition or any other term, covenant or condition of this Lease.

39.18. To the extent permitted by Applicable Laws, the parties waive trial by jury in any action, proceeding or counterclaim brought by the other party hereto related to matters arising from or in any way connected with this Lease; the relationship between Landlord and Tenant; Tenant's use or occupancy of the Premises; or any claim of injury or damage related to this Lease or the Premises.

39.19. A facsimile, electronic or portable document format (PDF) signature on this Lease or any other document required or permitted by this Lease to be delivered by Landlord or Tenant shall be equivalent to, and have the same force and effect as, an original signature.

39.20. For purposes of this Lease, "Force Majeure" means accidents; breakage; casualties (to the extent not caused by the party claiming Force Majeure); Severe Weather Conditions (as defined below); physical natural disasters (but excluding weather conditions that are not Severe Weather Conditions); strikes, lockouts or other labor disturbances or labor disputes (other than labor disturbances and labor disputes resulting solely from the acts or omissions of the party claiming Force Majeure); acts of terrorism; riots or civil disturbances; wars or insurrections; plagues, epidemics, pandemics, or public health crises (including regulations, actions or delays by Governmental Authorities resulting from any such plague, epidemic, pandemic or public health crisis); shortages of materials (which shortages are not unique to the party claiming Force Majeure); regulations, moratoria or other actions, inactions or delays by Governmental Authorities, provided that any delay by a Governmental Authority in issuing any required permit or approval is not caused by the failure of the party claiming Force Majeure to timely submit a complete application for such permit or approval in compliance with Applicable Laws; failures by third parties to deliver gas, oil or another suitable fuel supply, or inability of the party claiming Force Majeure, by exercise of reasonable diligence, to obtain gas, oil or another suitable fuel; or other causes beyond the reasonable control of the party claiming that Force Majeure has occurred. "Severe Weather Conditions" means weather conditions that are materially worse than those that would be reasonably anticipated for the Property at the applicable time based on historic meteorological records. Notwithstanding anything in this Lease to the contrary, events of Force Majeure shall excuse timely performance of a party hereunder (other than either party's obligation to pay any amounts hereunder, which shall not be excused by Force Majeure) for a period equal to the delay caused thereby and, therefore, if this Lease specifies a time period for performance of an obligation of either party, that time period shall be extended by the period of any delay in such party's performance caused by an event of Force Majeure. Each party claiming any delay as a result of Force Majeure shall notify the other party in writing within ten (10) business days after it acquires actual knowledge of the event constituting an event of Force Majeure, which written notice shall state in reasonable detail the nature of such event, the reason(s) that such event constitutes an event of Force Majeure, and the manner in which such event has or will delay performance of the claiming party's obligations hereunder.

40. Rooftop Installation Area.

40.1. Tenant may use certain areas of the roof reasonably approved by Landlord (the "Rooftop Installation Area") solely to operate, maintain, repair and replace rooftop antennae, mechanical equipment, communications antennas and other equipment installed by Tenant in the Rooftop Installation Area in accordance with this Article ("Tenant's Rooftop Equipment").

Tenant's Rooftop Equipment shall be only for Tenant's use of the Premises for the Permitted Use.

40.2. Tenant shall install Tenant's Rooftop Equipment at its sole cost and expense, at such times and in such manner as Landlord may reasonably designate, and in accordance with this Article and the applicable provisions of this Lease regarding Alterations. Tenant's Rooftop Equipment and the installation thereof shall be subject to Landlord's prior written approval, which approval shall not be unreasonably withheld. Among other reasons, Landlord may withhold approval if the installation or operation of Tenant's Rooftop Equipment could reasonably be expected to damage the structural integrity of the Building or to transmit vibrations or noise or cause other adverse effects beyond the Premises to an extent not customary in first class laboratory buildings, unless Tenant implements measures that are acceptable to Landlord in its reasonable discretion to avoid any such damage or transmission.

40.3. Tenant shall comply with any roof or roof-related warranties. Tenant shall obtain a letter from Landlord's roofing contractor within thirty (30) days after completion of any Tenant work on the rooftop stating that such work did not affect any such warranties. Tenant, at its sole cost and expense, shall inspect the Rooftop Installation Area at least annually, and correct any loose bolts, fittings or other appurtenances and repair any damage to the roof arising from the installation or operation of Tenant's Rooftop Equipment. Tenant shall not permit the installation, maintenance or operation of Tenant's Rooftop Equipment to violate any Applicable Laws or constitute a nuisance. Tenant shall pay Landlord within thirty (30) days after demand (a) all applicable taxes, charges, fees or impositions imposed on Landlord by Governmental Authorities as the result of Tenant's use of the Rooftop Installation Areas in excess of those for which Landlord would otherwise be responsible for the use or installation of Tenant's Rooftop Equipment and (b) the amount of any increase in Landlord's insurance premiums as a result of the installation of Tenant's Rooftop Equipment.

40.4. If Tenant's Equipment (a) causes physical damage to the structural integrity of the Building or (b) interferes with any telecommunications, mechanical or other systems located at or near or servicing the Premises that were installed prior to the installation of Tenant's Rooftop Equipment, in each case in excess of that permissible under Federal Communications Commission regulations, then Tenant shall cooperate with Landlord to determine the source of the damage or interference and promptly repair such damage and eliminate such interference, in each case at Tenant's sole cost and expense, within ten (10) days after receipt of notice of such damage or interference (which notice may be oral; provided that Landlord also delivers to Tenant written notice of such damage or interference within twenty-four (24) hours after providing oral notice).

40.5. Landlord reserves the right to cause Tenant to relocate Tenant's Rooftop Equipment to comparably functional space on the roof or in the penthouse of the Building by giving Tenant prior written notice thereof. Landlord agrees to pay the reasonable costs thereof. Tenant shall arrange for the relocation of Tenant's Rooftop Equipment within sixty (60) days after receipt of Landlord's notification of such relocation. In the event Tenant fails to arrange for relocation within such sixty (60)-day period, Landlord shall have the right to arrange for the relocation of Tenant's Rooftop Equipment in a manner that does not unnecessarily interrupt or interfere with Tenant's use of the Premises for the Permitted Use.

41. Option to Extend Term. Tenant shall have the option (“Option”) to extend the Term by five (5) years as to the entire Premises (and no less than the entire Premises) upon the following terms and conditions. Any extension of the Term pursuant to the Option shall be on all the same terms and conditions as this Lease, except as follows:

41.1. Base Rent at the commencement of the Option term shall equal the then-current fair market value for comparable office and laboratory space in the Princeton, New Jersey market of comparable age, quality, level of finish and proximity to amenities and public transit, and containing the systems and improvements present in the Premises as of the date that Tenant gives Landlord written notice of Tenant’s election to exercise the Option (“FMV”), and shall be further increased on each annual anniversary of the Option term commencement date by three percent (3%). Tenant may, no more than fifteen (15) months prior to the date the Term is then scheduled to expire, request Landlord’s estimate of the FMV for the Option term. Landlord shall, within fifteen (15) days after receipt of such request, give Tenant a written proposal of such FMV. If Tenant gives written notice to exercise the Option, such notice shall specify whether Tenant accepts Landlord’s proposed estimate of FMV. If Tenant does not accept the FMV, then the parties shall endeavor to agree upon the FMV, taking into account all relevant factors, including (a) the size of the Premises, (b) the length of the Option term, (c) rent in comparable buildings in the relevant market, including concessions offered to new tenants, such as free rent, tenant improvement allowances and moving allowances, (d) Tenant’s creditworthiness and (e) the quality and location of the Premises. In the event that the parties are unable to agree upon the FMV within thirty (30) days after Tenant notifies Landlord that Tenant is exercising the Option, then either party may request that the same be determined as follows: a senior officer of a nationally recognized leasing brokerage firm with local knowledge of the Princeton, New Jersey laboratory/research and development leasing market (the “Baseball Arbitrator”) shall be selected and paid for jointly by Landlord and Tenant. If Landlord and Tenant are unable to agree upon the Baseball Arbitrator, then the same shall be designated by the local chapter of the Judicial Arbitration and Mediation Services or any successor organization thereto (the “JAMS”). The Baseball Arbitrator selected by the parties or designated by JAMS shall (y) have at least ten (10) years’ experience in the leasing of laboratory/research and development space in the Princeton, New Jersey market and (z) not have been employed or retained by either Landlord or Tenant or any affiliate of either for a period of at least ten (10) years prior to appointment pursuant hereto. Each of Landlord and Tenant shall submit to the Baseball Arbitrator and to the other party its determination of the FMV. The Baseball Arbitrator shall grant to Landlord and Tenant a hearing and the right to submit evidence. The Baseball Arbitrator shall determine which of the two (2) FMV determinations more closely represents the actual FMV. The arbitrator may not select any other FMV for the Premises other than one submitted by Landlord or Tenant. The FMV selected by the Baseball Arbitrator shall be binding upon Landlord and Tenant and shall serve as the basis for determination of Base Rent payable for the Option term. If, as of the commencement date of the Option term, the amount of Base Rent payable during the Option term shall not have been determined, then, pending such determination, Tenant shall pay Base Rent equal to the Base Rent payable with respect to the last year of the then-current Term. After the final determination of Base Rent payable for the Option term, the parties shall promptly execute a written amendment to this Lease specifying the amount of Base Rent to be paid during the Option term. Any failure of the parties to execute such amendment shall not affect the validity of the FMV determined pursuant to this Section.

41.2. The Option is not assignable separate and apart from this Lease except in the event of an Exempt Transfer.

41.3. The Option is conditional upon Tenant giving Landlord written notice of its election to exercise the Option at least twelve (12) months prior to the end of the expiration of the then-current Term. Time shall be of the essence as to Tenant's exercise of the Option. Tenant assumes full responsibility for maintaining a record of the deadlines to exercise the Option. Tenant acknowledges that it would be inequitable to require Landlord to accept any exercise of the Option after the date provided for in this Section.

41.4. Notwithstanding anything contained in this Article to the contrary, Tenant shall not have the right to exercise the Option:

(a) During the time commencing from the date Landlord delivers to Tenant a written notice that Tenant is in default under any provisions of this Lease and continuing until Tenant has cured the specified default to Landlord's reasonable satisfaction; or

(b) At any time after any Default as described in Article 30 of the Lease (provided, however, that, for purposes of this Section 41.4(b), Landlord shall not be required to provide Tenant with notice of such Default) and continuing until Tenant cures any such Default, if such Default is susceptible to being cured; or

(c) In the event that Tenant has defaulted in the performance of its obligations under this Lease two (2) or more times during the twelve (12)-month period immediately prior to the date that Tenant intends to exercise the Option, whether or not Tenant has cured such defaults.

41.5. The period of time within which Tenant may exercise the Option shall not be extended or enlarged by reason of Tenant's inability to exercise such Option because of the provisions of Section 41.4.

41.6. All of Tenant's rights under the provisions of the Option shall terminate and be of no further force or effect even after Tenant's due and timely exercise of the Option if, after such exercise, but prior to the commencement date of the new term, (a) Tenant fails to pay to Landlord a monetary obligation of Tenant for a period of twenty (20) days after written notice from Landlord to Tenant, (b) Tenant fails to commence to cure a default (other than a monetary default) within thirty (30) days after the date Landlord gives notice to Tenant of such default or (c) Tenant has defaulted under this Lease two (2) or more times and a service or late charge under Section 30.1 has become payable for any such default, whether or not Tenant has cured such defaults.

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IN WITNESS WHEREOF, the parties hereto have executed this Lease as of the date first above written.

LANDLORD:

BMR-ONE RESEARCH WAY LLC,  
a Delaware limited liability company

By: /s/ Colleen OConnor  
Name: Colleen OConnor  
Title: Vice President, East Coast and U.K. Markets

TENANT:

PMV PHARMACEUTICALS, INC.,  
a Delaware corporation

By: /s/ Winston Kung  
Name: Winston Kung  
Title: Chief Operating Officer and Chief Financial Officer

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**EXHIBIT A**

**PREMISES**

A-1

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**EXHIBIT A-1**

**PROPERTY**

A-1-1

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## EXHIBIT B

### WORK LETTER

This Work Letter (this "Work Letter") is made and entered into as of the \_\_\_\_ day of December, 2020, by and between BMR-ONE RESEARCH WAY LLC, a Delaware limited liability company ("Landlord"), and PMV PHARMACEUTICALS, INC., a Delaware corporation ("Tenant"), and is attached to and made a part of that certain Lease dated as of December \_\_\_\_, 2020 (as the same may be amended, amended and restated, supplemented or otherwise modified from time to time, the "Lease"), by and between Landlord and Tenant for the Premises located at One Research Way, Princeton, New Jersey. All capitalized terms used but not otherwise defined herein shall have the meanings given them in the Lease.

#### 1. General Requirements.

##### 1.1. Authorized Representatives.

(a) Landlord designates, as Landlord's authorized representative ("Landlord's Authorized Representative"), (i) Joe Imparato as the person authorized to initial plans, drawings, approvals and to sign change orders pursuant to this Work Letter and (ii) an officer of Landlord as the person authorized to sign any amendments to this Work Letter or the Lease. Tenant shall not be obligated to respond to or act upon any such item until such item has been initialed or signed (as applicable) by the appropriate Landlord's Authorized Representative. Landlord may change either Landlord's Authorized Representative upon one (1) business day's prior written notice to Tenant.

(b) Tenant designates Austin Barrett ("Tenant's Authorized Representative") as the person authorized to initial and sign all plans, drawings, change orders and approvals pursuant to this Work Letter. Landlord shall not be obligated to respond to or act upon any such item until such item has been initialed or signed (as applicable) by Tenant's Authorized Representative. Tenant may change Tenant's Authorized Representative upon one (1) business day's prior written notice to Landlord.

1.2. Schedule. The schedule for design and development of the Tenant Improvements, including the time periods for preparation and review of construction documents, approvals and performance, shall be in accordance with a schedule to be prepared by Tenant (the "Schedule"). Tenant shall prepare the Schedule so that it is a reasonable schedule for the completion of the Tenant Improvements. The Schedule shall clearly identify all activities requiring Landlord participation. As soon as the Schedule is completed, Tenant shall deliver the same to Landlord for Landlord's approval, which approval shall not be unreasonably withheld, conditioned or delayed. Such Schedule shall be approved or disapproved by Landlord within ten (10) business days after delivery to Landlord. Landlord's failure to respond within such ten (10) business day period shall be deemed approval by Landlord. If Landlord disapproves the Schedule, then Landlord shall notify Tenant in writing of its objections to such Schedule, and the parties shall confer and negotiate in good faith to reach agreement on the Schedule. The Schedule shall be subject to adjustment as mutually agreed upon in writing by the parties, or as provided in this Work Letter.

1.3. Tenant's Architects, Contractors and Consultants. The architect, engineering consultants, design team, general contractor and subcontractors responsible for the construction of the Tenant Improvements shall be selected by Tenant and approved by Landlord, which approval Landlord shall not unreasonably withhold, condition or delay, and Landlord may refuse to use any architects, consultants, contractors, subcontractors or material suppliers that Landlord reasonably believes could cause labor disharmony or may not have sufficient experience, in Landlord's reasonable opinion, to perform work in an occupied Class "A" laboratory research building and in lab areas. Landlord hereby approves Vanderweil Engineers as Tenant's engineer, and SGA as Tenant's architect, for the Tenant Improvements. All Tenant contracts related to the Tenant Improvements shall provide that Tenant may assign such contracts and any warranties with respect to the Tenant Improvements to Landlord at any time.

2. Tenant Improvements. All Tenant Improvements shall be performed by Tenant's contractor, at Tenant's sole cost and expense (subject to Landlord's obligations with respect to any portion of the TI Allowance and in accordance with the Approved Plans (as defined below), the Lease and this Work Letter. To the extent that the total projected cost of the Tenant Improvements (as projected by Landlord) exceeds the TI Allowance (such excess, the "Excess TI Costs"), Tenant shall pay the costs of the Tenant Improvements as such costs become due, and Landlord shall reimburse Tenant (or pay directly to Tenant's contractor) on a pari passu basis, in the proportion of Excess TI Costs payable by Tenant to the TI Allowance payable by Landlord. If the cost of the Tenant Improvements (as projected by Landlord) increases over Landlord's initial projection, Tenant shall promptly notify Landlord, and Landlord's payment of the TI Allowance shall be on an adjusted pari passu basis based on the additional Excess TI Costs. All material and equipment furnished by Tenant or its contractors as the Tenant Improvements shall be new or "like new;" the Tenant Improvements shall be performed in a first-class, workmanlike manner; and the quality of the Tenant Improvements shall be of a nature and character not less than the Building Standard, as set forth in Exhibit B-2. Tenant shall take, and shall require its contractors to take, commercially reasonable steps to protect the Premises during the performance of any Tenant Improvements, including covering or temporarily removing any window coverings so as to guard against dust, debris or damage. All Tenant Improvements shall be performed in accordance with Article 16 of the Lease; provided that, notwithstanding anything in the Lease or this Work Letter to the contrary, in the event of a conflict between this Work Letter and Article 16 of the Lease, the terms of this Work Letter shall govern.

2.1. Work Plans. Tenant shall prepare and submit to Landlord for approval schematics covering the Tenant Improvements prepared in conformity with the applicable provisions of this Work Letter (the "Draft Schematic Plans"). Tenant acknowledges that any vivarium to be constructed as part of the Tenant Improvements shall not exceed 5,000 rentable square feet unless otherwise approved by Landlord. Any such vivarium shall be in a location approved by Landlord in its sole and reasonable discretion, and shall use disposable cages. The Draft Schematic Plans shall contain sufficient information and detail to accurately describe the proposed design to Landlord and such other information as Landlord may reasonably request. Landlord shall notify Tenant in writing within ten (10) business days after receipt of the Draft Schematic Plans whether Landlord approves or objects to the Draft Schematic Plans and of the manner, if any, in which the Draft Schematic Plans are unacceptable. Landlord's failure to respond within such ten (10) business day period shall be deemed approval by Landlord. If

Landlord reasonably objects to the Draft Schematic Plans, then Tenant shall revise the Draft Schematic Plans and cause Landlord's objections to be remedied in the revised Draft Schematic Plans. Tenant shall then resubmit the revised Draft Schematic Plans to Landlord for approval, such approval not to be unreasonably withheld, conditioned or delayed. Landlord's approval of or objection to revised Draft Schematic Plans and Tenant's correction of the same shall be in accordance with this Section until Landlord has approved the Draft Schematic Plans in writing or been deemed to have approved them. The iteration of the Draft Schematic Plans that is approved or deemed approved by Landlord without objection shall be referred to herein as the "Approved Schematic Plans."

2.2. Construction Plans. Tenant shall prepare final plans and specifications for the Tenant Improvements that (a) are consistent with and are logical evolutions of the Approved Schematic Plans and (b) incorporate any other Tenant-requested (and Landlord-approved) Changes (as defined below). As soon as such final plans and specifications ("Construction Plans") are completed, Tenant shall deliver the same to Landlord for Landlord's approval, which approval shall not be unreasonably withheld, conditioned or delayed. All such Construction Plans shall be submitted by Tenant to Landlord in electronic .pdf, CADD and full-size hard copy formats, and shall be approved or disapproved by Landlord within ten (10) business days after delivery to Landlord. Landlord's failure to respond within such ten (10) business day period shall be deemed approval by Landlord. If the Construction Plans are disapproved by Landlord, then Landlord shall notify Tenant in writing of its objections to such Construction Plans, and the parties shall confer and negotiate in good faith to reach agreement on the Construction Plans. Promptly after the Construction Plans are approved by Landlord and Tenant, two (2) copies of such Construction Plans shall be initialed and dated by Landlord and Tenant, and Tenant shall promptly submit such Construction Plans to all appropriate Governmental Authorities for approval. The Construction Plans so approved, and all change orders specifically permitted by this Work Letter, are referred to herein as the "Approved Plans."

2.3. Changes to the Tenant Improvements. Any changes to the Approved Plans (each, a "Change") shall be requested and instituted in accordance with the provisions of this Article 2 and shall be subject to the written approval of the non-requesting party in accordance with this Work Letter.

(a) Change Request. Either Landlord or Tenant may request Changes after Landlord approves the Approved Plans by notifying the other party thereof in writing in substantially the same form as the AIA standard change order form (a "Change Request"), which Change Request shall detail the nature and extent of any requested Changes, including (a) the Change, (b) the party required to perform the Change and (c) any modification of the Approved Plans and the Schedule, as applicable, necessitated by the Change. If the nature of a Change requires revisions to the Approved Plans, then the requesting party shall be solely responsible for the cost and expense of such revisions and any increases in the cost of the Tenant Improvements as a result of such Change. Change Requests shall be signed by the requesting party's Authorized Representative.

(b) Approval of Changes. All Change Requests shall be subject to the other party's prior written approval, which approval shall not be unreasonably withheld, conditioned or delayed. The non-requesting party shall have five (5) business days after receipt of a Change Request to notify the requesting party in writing of the non-requesting party's decision either to approve or object to the Change Request. The non-requesting party's failure to respond within such five (5) business day period shall be deemed approval by the non-requesting party.

2.4. Preparation of Estimates. Tenant shall, before proceeding with any Change, using its best efforts, prepare as soon as is reasonably practicable (but in no event more than seven (7) days after delivering a Change Request to Landlord or receipt of a Change Request) an estimate of the increased costs or savings that would result from such Change, as well as an estimate of such Change's effects on the Schedule. Landlord shall have seven (7) days after receipt of such information from Tenant to (a) in the case of a Tenant-initiated Change Request, approve or reject such Change Request in writing, or (b) in the case of a Landlord-initiated Change Request, notify Tenant in writing of Landlord's decision either to proceed with or abandon the Landlord-initiated Change Request.

2.5. Quality Control Program; Coordination. Tenant shall provide Landlord with information regarding the following (together, the "QCP"): (a) Tenant's general contractor's quality control program and (b) evidence of subsequent monitoring and action plans. The QCP shall be subject to Landlord's reasonable review and approval and shall specifically address the Tenant Improvements. Tenant shall ensure that the QCP is regularly implemented on a scheduled basis and shall provide Landlord with reasonable prior notice and access to attend all inspections and meetings between Tenant and its general contractor. At the conclusion of the Tenant Improvements, Tenant shall deliver the quality control log to Landlord, which shall include all records of quality control meetings and testing and of inspections held in the field, including inspections relating to concrete, steel roofing, piping pressure testing and system commissioning.

3. Completion of Tenant Improvements. Tenant, at its sole cost and expense (except for the TI Allowance), shall perform and complete the Tenant Improvements in all respects (a) in substantial conformance with the Approved Plans, (b) otherwise in compliance with provisions of the Lease and this Work Letter and (c) in accordance with Applicable Laws, the requirements of Tenant's insurance carriers, the requirements of Landlord's insurance carriers (to the extent Landlord provides its insurance carriers' requirements to Tenant) and the board of fire underwriters having jurisdiction over the Premises. The Tenant Improvements shall be deemed completed at such time as Tenant shall furnish to Landlord (t) evidence satisfactory to Landlord that (i) all Tenant Improvements have been completed and paid for in full (which shall be evidenced by the architect's certificate of completion and the general contractor's and each subcontractor's and material supplier's final unconditional waivers and releases of liens, each in a form acceptable to Landlord and complying with Applicable Laws, and a Certificate of Substantial Completion in the form of the American Institute of Architects document G704, executed by the project architect and the general contractor, together with a statutory notice of substantial completion from the general contractor), (ii) all Tenant Improvements have been accepted by Landlord, (iii) any and all liens related to the Tenant Improvements have either been discharged of record (by payment, bond, order of a court of competent jurisdiction or otherwise)

or waived by the party filing such lien and (iv) no security interests relating to the Tenant Improvements are outstanding, (u) all certifications and approvals with respect to the Tenant Improvements that may be required from any Governmental Authority and any board of fire underwriters or similar body for the use and occupancy of the Premises (including a certificate of occupancy (or its substantial equivalent) for the Premises for the Permitted Use), (v) certificates of insurance required by the Lease to be purchased and maintained by Tenant, (w) an affidavit from Tenant's architect certifying that all work performed in, on or about the Premises is in accordance with the Approved Plans, (x) complete "as built" drawing print sets, project specifications and shop drawings and electronic CADD files on disc (showing the Tenant Improvements as an overlay on the Building "as built" plans (provided that Landlord provides the Building "as-built" plans provided to Tenant) of all contract documents for work performed by their architect and engineers in relation to the Tenant Improvements, (y) a commissioning report prepared by a licensed, qualified commissioning agent hired by Tenant and approved by Landlord for all new or affected mechanical, electrical and plumbing systems (which report Landlord may hire a licensed, qualified commissioning agent to peer review, and whose reasonable recommendations Tenant's commissioning agent shall perform and incorporate into a revised report) and (z) such other "close out" materials as Landlord reasonably requests consistent with Landlord's own requirements for its contractors, such as copies of manufacturers' warranties, operation and maintenance manuals and the like.

#### 4. Insurance.

4.1. Property Insurance. At all times during the period beginning with commencement of construction of the Tenant Improvements and ending with final completion of the Tenant Improvements, Tenant shall maintain, or cause to be maintained (in addition to the insurance required of Tenant pursuant to the Lease), property insurance insuring Landlord and the Landlord Parties, as their interests may appear. Such policy shall, on a completed replacement cost basis for the full insurable value at all times, insure against loss or damage by fire, vandalism and malicious mischief and other such risks as are customarily covered by the so-called "broad form extended coverage endorsement" upon all Tenant Improvements and the general contractor's and any subcontractors' machinery, tools and equipment, all while each forms a part of, or is contained in, the Tenant Improvements or any temporary structures on the Premises, or is adjacent thereto; provided that, for the avoidance of doubt, insurance coverage with respect to the general contractor's and any subcontractors' machinery, tools and equipment shall be carried on a primary basis by such general contractor or the applicable subcontractor(s). Tenant agrees to pay any deductible, and Landlord is not responsible for any deductible, for a claim under such insurance.

4.2. Workers' Compensation Insurance. At all times during the period of construction of the Tenant Improvements, Tenant shall, or shall cause its contractors or subcontractors to, maintain statutory workers' compensation insurance as required by Applicable Laws.

4.3. Waivers of Subrogation. Any insurance provided pursuant to this Article shall waive subrogation against the Landlord Parties and Tenant shall hold harmless and indemnify the Landlord Parties for any loss or expense incurred as a result of a failure to obtain such waivers of subrogation from insurers.

5. Liability. Tenant assumes sole responsibility and liability for any and all injuries or the death of any persons, including Tenant's contractors and subcontractors and their respective employees, agents and invitees, and for any and all damages to property arising from any act or omission on the part of Tenant, Tenant's contractors or subcontractors, or their respective employees, agents and invitees in the prosecution of the Tenant Improvements. Tenant agrees to Indemnify the Landlord Indemnitees from and against all Claims due to, because of or arising from any and all such injuries, death or damage, whether real or alleged, and Tenant and Tenant's contractors and subcontractors shall assume and defend at their sole cost and expense all such Claims; provided, however, that nothing contained in this Work Letter shall be deemed to Indemnify Landlord from or against liability to the extent arising directly from Landlord's negligence or willful misconduct. Any deficiency in design or construction of the Tenant Improvements shall be solely the responsibility of Tenant, notwithstanding the fact that Landlord may have approved of the same in writing.

6. TI Allowance.

6.1. Application of TI Allowance. Landlord shall contribute the TI Allowance toward the costs and expenses incurred in connection with the performance of the Tenant Improvements, in accordance with Article 4 of the Lease. If the entire TI Allowance is not applied toward or reserved for the costs of the Tenant Improvements, then Tenant shall not be entitled to a credit of such unused portion of the TI Allowance. If the entire Excess TI Costs advanced by Tenant to Landlord are not applied toward the costs of the Tenant Improvements, then Landlord shall promptly return such excess to Tenant following completion of the Tenant Improvements. Tenant may apply the TI Allowance for the payment of construction and other costs in accordance with the terms and provisions of the Lease.

6.2. Approval of Budget for the Tenant Improvements. Notwithstanding anything to the contrary set forth elsewhere in this Work Letter or the Lease, Landlord shall not have any obligation to expend any portion of the TI Allowance until Landlord and Tenant shall have approved in writing the budget for the Tenant Improvements (the "Approved Budget"). Prior to Landlord's approval of the Approved Budget, Tenant shall pay all of the costs and expenses incurred in connection with the Tenant Improvements as they become due. Landlord shall not be obligated to reimburse Tenant for costs or expenses relating to the Tenant Improvements that exceed the amount of the TI Allowance. Landlord shall not unreasonably withhold, condition or delay its approval of any budget for Tenant Improvements that is proposed by Tenant.

6.3. Fund Requests. Upon submission by Tenant to Landlord as of or prior to the TI Deadline of (a) a statement (a "Fund Request") setting forth the total amount of the TI Allowance requested, (b) a summary of the Tenant Improvements performed using AIA standard form Application for Payment (G 702) executed by the general contractor and by the architect, (c) invoices from the general contractor, the architect, and any subcontractors, material suppliers and other parties requesting payment with respect to the amount of the TI Allowance then being requested, and (d) unconditional lien releases from the general contractor and each subcontractor and material supplier with respect to previous payments made by either Landlord or Tenant for the Tenant Improvements in a form acceptable to Landlord and complying with Applicable Laws each in a form acceptable to Landlord and complying with Applicable Laws, then Landlord shall,

within thirty (30) days following receipt by Landlord of a Fund Request and the accompanying materials required by this Section, pay to (as elected by Landlord) the applicable contractors, subcontractors and material suppliers or Tenant (for reimbursement for payments made by Tenant to such contractors, subcontractors or material suppliers either prior to Landlord's approval of the Approved TI Budget or as a result of Tenant's decision to pay for the Tenant Improvements itself and later seek reimbursement from Landlord in the form of one lump sum payment in accordance with the Lease and this Work Letter), the amount of Tenant Improvement costs set forth in such Fund Request or Landlord's pari passu share thereof if Excess TI Costs exist based on the Approved Budget; provided, however, that Landlord shall not be obligated to make any payments under this Section until the budget for the Tenant Improvements is approved in accordance with Section 6.2, and any Fund Request under this Section shall be submitted as of or prior to the TI Deadline and shall be subject to the payment limits set forth in Section 6.2 above and Article 4 of the Lease. Notwithstanding anything in this Section to the contrary, Tenant shall not submit a Fund Request after the TI Deadline or more often than every thirty (30) days. Any additional Fund Requests submitted by Tenant after the TI Deadline or more often than every thirty (30) days shall be void and of no force or effect.

6.4. Accrual Information. In addition to the other requirements of this Section 6, Tenant shall, no later than the second (2<sup>nd</sup>) business day of each month until the Tenant Improvements are complete, provide Landlord with an estimate of (a) the percentage of design and other soft cost work that has been completed, (b) design and other soft costs spent through the end of the previous month, both from commencement of the Tenant Improvements and solely for the previous month, (c) the percentage of construction and other hard cost work that has been completed, (d) construction and other hard costs spent through the end of the previous month, both from commencement of the Tenant Improvements and solely for the previous month, and (e) the date of Substantial Completion of the Tenant Improvements.

7. Miscellaneous.

7.1. Incorporation of Lease Provisions. Sections 39.6 through 39.19 of the Lease are incorporated into this Work Letter by reference, and shall apply to this Work Letter in the same way that they apply to the Lease.

7.2. General. Except as otherwise set forth in the Lease or this Work Letter, this Work Letter shall not apply to improvements performed in any additional premises added to the Premises at any time or from time to time, whether by any options under the Lease or otherwise; or to any portion of the Premises or any additions to the Premises in the event of a renewal or extension of the original Term, whether by any options under the Lease or otherwise, unless the Lease or any amendment or supplement to the Lease expressly provides that such additional premises are to be delivered to Tenant in the same condition as the initial Premises.

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IN WITNESS WHEREOF, Landlord and Tenant have executed this Work Letter to be effective on the date first above written.

LANDLORD:

BMR-ONE RESEARCH WAY LLC,  
a Delaware limited liability company

By: /s/ Colleen OConnor  
Name: Colleen OConnor  
Title: Vice President, East Coast and U.K. Markets

TENANT:

PMV PHARMACEUTICALS, INC.,  
a Delaware corporation

By: /s/ Winston Kung  
Name: Winston Kung  
Title: Chief Operating Officer and Chief Financial Officer

## EXHIBIT B-1

### TENANT WORK INSURANCE SCHEDULE

1. Types of Coverage. Tenant shall maintain or cause Tenant's contractors performing construction or renovation work to maintain such insurance as shall protect it from the claims set forth below that may arise out of or result from any Tenant Work, whether such Tenant Work is completed by Tenant or by any Tenant contractors or by any person directly or indirectly employed by Tenant or any Tenant contractors, or by any person for whose acts Tenant or any Tenant contractors may be liable:

a. Commercial General Liability. Commercial general liability insurance written on the ISO form CG 00 01 or equivalent, including products and completed operations, on an occurrence basis. Such coverage shall apply to all Tenant Work done by Tenant's contractors and subcontractors of all tiers and provide insurance against personal injury, wrongful death, and property damage (other than to the Tenant Work itself). The policy shall include contractual liability coverage sufficient to address the obligations of the Lease and the Tenant Work. This insurance policy shall include Landlord Parties as additional insureds with endorsements equivalent to ISO CG 20 10 04/13 for ongoing operations, and to ISO CG 20 37 04/13 for completed operations. This policy shall be primary and noncontributory with respect to any other insurance available to an additional insured. The policy shall include endorsement ISO CG 24 04 or its equivalent, a waiver of subrogation in favor of the Landlord Parties. Tenant contractors' Commercial General Liability Insurance shall include premises/operations (including explosion, collapse and underground coverage if such Tenant Work involves any underground work), elevators, independent contractors, products and completed operations, and blanket contractual liability on all written contracts, all including broad form property damage coverage. Coverage for completed operations must be maintained through the applicable statute of repose period following completion of the Tenant Work.

b. Business Automobile Liability Insurance. Business Automobile Liability Insurance on an "occurrence" form covering any or all autos (including owned, hired, leased and non-owned vehicles) used by or on behalf of the insured, and providing insurance for bodily injury and property damage. The policy shall include coverage for loading and unloading activities. This policy shall include the Landlord Parties as additional insureds, with endorsements.

c. Workers' Compensation and Employer's Liability Insurance. For all operations, Workers' Compensation insurance in compliance with statutory limits for the Workers' Compensation Laws of the state in which the Premises are located, and an Employer's Liability limit of not less than \$1,000,000 each accident.

d. Contractors' Pollution Liability. Contractors and subcontractors handling, removing or treating Hazardous Materials shall maintain pollution liability insurance. Such coverage shall include bodily injury, sickness, disease, death or mental anguish or shock sustained by any person; property damage or environmental damage, including physical injury to or destruction of tangible property (including the resulting loss of use thereof), contractual liability coverage to cover liability arising out of cleanup, removal, storage or handling of

hazardous or toxic chemicals, materials or substances, or any other pollutants (including mold, asbestos or asbestos-containing materials); and defense costs, charges and expenses incurred in the investigation, adjustment or defense of claims for such damages. Claims-made coverage is permitted, provided that the policy retroactive date is continuously maintained prior to the commencement of the Tenant Work. This policy shall include the Landlord Parties as additional insureds, with endorsements.

e. Professional Liability (Errors and Omissions). Contractors and subcontractors of any tier performing Tenant Work that includes any professional services, including design, architecture, engineering, testing, surveying or design/build services shall provide and maintain professional liability insurance. Coverage shall be maintained following completion of the Tenant Work through the applicable statute of repose of the state in which the Premises are located.

2. Minimum Limits of Insurance. All coverage types as defined above to be procured by Tenant's general contractor and designer for any Tenant Work shall be written for limits of insurance not less than:

Coverage	Cost of Work	Minimum Limits of Insurance
a. Commercial General Liability * Limits may be met by use of excess and/or umbrella liability insurance, <u>provided</u> that such coverage is at least as broad as the primary coverages required herein	<\$200 million	\$100 million per occurrence, general aggregate, and products and completed operations aggregate
	<\$100 million	\$50 million per occurrence, general aggregate, and products and completed operations aggregate
	<\$50 million	\$25 million per occurrence, general aggregate, and products and completed operations aggregate
	<\$25 million	\$10 million per occurrence, general aggregate, and products and completed operations aggregate
	<\$10 million	\$5 million per occurrence, general aggregate, and products and completed operations aggregate
	<\$5 million	\$2 million per occurrence, general aggregate, and products and completed operations aggregate
b. Commercial Automobile Liability * Limits may be met by use of excess and/or umbrella liability insurance, <u>provided</u> that such coverage is at least as broad as the primary coverages required herein	≥\$25 million	\$25 million combined single limit
	<\$25 million	\$10 million combined single limit
	<\$10 million	\$5 million combined single limit
	<\$5 million	\$2 million combined single limit

Coverage	Cost of Work	Minimum Limits of Insurance
c.Workers' Compensation	At all times	As required by Applicable Laws
d.Contractor's Pollution Liability	At all times	\$2 million per location and \$4 million aggregate
e. Professional Liability (Errors and Omissions)	<\$200 million	\$10 million per project and in the aggregate
	<\$75 million	\$5 million per project and in the aggregate
	<\$25 million	\$2 million per project and \$4 million aggregate
	<\$10 million	\$1 million per project and \$2 million aggregate

3. Notice of Cancellation. The foregoing policies shall contain a provision that coverages afforded under the policies shall not be canceled or not renewed until at least thirty (30) days' prior written notice has been given to the Landlord.
4. Evidence of Insurance. Certificates of insurance, including required endorsements showing such coverages to be in force, shall be provided to Landlord prior to the commencement of any Tenant Work and prior to each renewal.
5. Insurer Ratings. The minimum A.M. Best's rating of each insurer shall be A-VII.
6. Additional Insureds. The policies shall name Landlord Parties as additional insureds to the extent required by the Lease, the Work Letter or this Exhibit.
7. Waiver of Subrogation. Tenant, contractors and subcontractors, and each of their respective insurers shall provide waivers of subrogation in favor of the Landlord Parties with respect to all insurance required by the Lease, the Work Letter or this Exhibit.
8. Tenant's Contractors. Tenant shall require all other persons, firms and corporations engaged or employed by Tenant in connection with the performance of Tenant Work to carry and maintain coverages with limits not less than those required by this Exhibit. Tenant's contractors' and subcontractors' insurance compliance, including any coverage exceptions, shall be Tenant's responsibility. Tenant shall incorporate these insurance requirements by reference within any contract executed by Tenant and its contractors. Tenant shall obtain and verify the accuracy of certificates of insurance evidencing required coverage prior to permitting its contractors, subcontractors (of any tier), suppliers and agents from performing any Tenant Work or services at the Premises. Tenant shall furnish original certificates of insurance with additional insured endorsements from Tenant's contractors, subcontractors (of any tier), suppliers and agents as evidence thereof, as Landlord may reasonably request.
9. No Limit of Liability. It is expressly acknowledged and agreed that the insurance policies and limits required hereunder shall not limit the liability of Tenant or its contractors or subcontractors, and that Landlord makes no representation that these types or amounts of insurance are sufficient or adequate to protect Tenant or its contractors' or subcontractors'

interests or liabilities, but are merely minimums. Any insurance carried by Landlord shall be secondary and non-contributory to that carried by Tenant and/or its contractors or subcontractors.

B-1-4

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**EXHIBIT B-2**  
**BUILDING STANDARDS**

B-2-1

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**EXHIBIT C**

**ACKNOWLEDGEMENT OF TERM COMMENCEMENT DATE  
AND TERM EXPIRATION DATE**

THIS ACKNOWLEDGEMENT OF TERM COMMENCEMENT DATE AND TERM EXPIRATION DATE is entered into as of [\_\_\_\_], 20[\_\_\_], with reference to that certain Lease (the “Lease”) dated as of [\_\_\_\_], 20[\_\_\_], by PMV PHARMACEUTICALS, INC., a Delaware corporation (“Tenant”), in favor of BMR-ONE RESEARCH WAY LLC, a Delaware limited liability company (“Landlord”). All capitalized terms used herein without definition shall have the meanings ascribed to them in the Lease.

Tenant hereby confirms the following:

1. Tenant accepted possession of the Premises for construction of improvements or the installation of personal or other property on [\_\_\_\_], 20[\_\_\_], and for use in accordance with the Permitted Use on [\_\_\_\_], 20[\_\_\_]. Tenant first occupied the Premises for the Permitted Use on [\_\_\_\_], 20[\_\_\_].
2. The Premises are in good order, condition and repair.
3. The Tenant Improvements are Substantially Complete.
4. All conditions of the Lease to be performed by Landlord as a condition to the full effectiveness of the Lease have been satisfied, and Landlord has fulfilled all of its duties in the nature of inducements offered to Tenant to lease the Premises.
5. In accordance with the provisions of Article 4 of the Lease, the Term Commencement Date is [\_\_\_\_], 20[\_\_\_], and, unless the Lease is terminated prior to the Term Expiration Date pursuant to its terms, the Term Expiration Date shall be May 31, 2032.
6. The Lease is in full force and effect, and the same represents the entire agreement between Landlord and Tenant concerning the Premises[, except [\_\_\_\_]].
7. Tenant has no existing defenses against the enforcement of the Lease by Landlord, and there exist no offsets or credits against Rent owed or to be owed by Tenant.
8. The obligation to pay Rent is presently in effect and all Rent obligations on the part of Tenant under the Lease commenced to accrue on [\_\_\_\_], 20[\_\_\_], with Base Rent payable on the dates and amounts set forth in the chart below:

<b><u>Dates</u></b>	<b><u>Approximate Square Feet of Rentable Area</u></b>	<b><u>Base Rent per Square Foot of Rentable Area</u></b>	<b><u>Monthly Base Rent</u></b>	<b><u>Annual Base Rent</u></b>
[ ]/[ ]/[ ]- [ ]/[ ]/[ ]	[ ]	[\$____] annually	[ ]	[ ]

9. The undersigned Tenant has not made any prior assignment, transfer, hypothecation or pledge of the Lease or of the rents thereunder or sublease of the Premises or any portion thereof.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

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IN WITNESS WHEREOF, Tenant has executed this Acknowledgment of Term Commencement Date and Term Expiration Date as of the date first written above.

TENANT:

PMV PHARMACEUTICALS, INC.,  
a Delaware corporation

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

**EXHIBIT D**

[Intentionally Omitted]

D-1

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**EXHIBIT E**

**FORM OF LETTER OF CREDIT**

[On letterhead or L/C letterhead of Issuer]

**LETTER OF CREDIT**

Date: \_\_\_\_\_, 20\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
(the "Beneficiary")

Attention: \_\_\_\_\_  
L/C. No.: \_\_\_\_\_  
Loan No. : \_\_\_\_\_

Ladies and Gentlemen:

We establish in favor of Beneficiary our irrevocable and unconditional Letter of Credit numbered as identified above (the "L/C") for an aggregate amount of \$\_\_\_\_\_, expiring at \_\_:00 p.m. on \_\_\_\_\_ or, if such day is not a Banking Day, then the next succeeding Banking Day (such date, as extended from time to time, the "Expiry Date"). "Banking Day" means a weekday except a weekday when commercial banks in \_\_\_\_\_ are authorized or required to close.

We authorize Beneficiary to draw on us (the "Issuer") for the account of \_\_\_\_\_ (the "Account Party"), under the terms and conditions of this L/C.

Funds under this L/C are available by presenting the following documentation (the "Drawing Documentation"): (a) the original L/C and (b) a sight draft substantially in the form of Attachment 1, with blanks filled in and bracketed items provided as appropriate. No other evidence of authority, certificate, or documentation is required.

Drawing Documentation must be presented at Issuer's office at \_\_\_\_\_ on or before the Expiry Date by personal presentation, courier or messenger service, or fax. Presentation by fax shall be effective upon electronic confirmation of transmission as evidenced by a printed report from the sender's fax machine. After any fax presentation, but not as a condition to its effectiveness, Beneficiary shall with reasonable promptness deliver the original Drawing Documentation by any other means. Issuer will on request issue a receipt for Drawing Documentation.

We agree, irrevocably, and irrespective of any claim by any other person, to honor drafts drawn under and in conformity with this L/C, within the maximum amount of this L/C, presented

to us on or before the Expiry Date, provided we also receive (on or before the Expiry Date) any other Drawing Documentation this L/C requires.

We shall pay this L/C only from our own funds by check or wire transfer, in compliance with the Drawing Documentation.

If Beneficiary presents proper Drawing Documentation to us on or before the Expiry Date, then we shall pay under this L/C at or before the following time (the "Payment Deadline"): (a) if presentment is made at or before noon of any Banking Day, then the close of such Banking Day; and (b) otherwise, the close of the next Banking Day. We waive any right to delay payment beyond the Payment Deadline. If we determine that Drawing Documentation is not proper, then we shall so advise Beneficiary in writing, specifying all grounds for our determination, within one Banking Day after the Payment Deadline.

Partial drawings are permitted. This L/C shall, except to the extent reduced thereby, survive any partial drawings.

We shall have no duty or right to inquire into the validity of or basis for any draw under this L/C or any Drawing Documentation. We waive any defense based on fraud or any claim of fraud.

The Expiry Date shall automatically be extended by one year (but never beyond \_\_\_\_\_ (the "Outside Date")) unless, on or before the date 90 days before any Expiry Date, we have given Beneficiary notice that the Expiry Date shall not be so extended (a "Nonrenewal Notice"). We shall promptly upon request confirm any extension of the Expiry Date under the preceding sentence by issuing an amendment to this L/C, but such an amendment is not required for the extension to be effective. We need not give any notice of the Outside Date.

Beneficiary may from time to time without charge transfer this L/C, in whole but not in part, to any transferee (the "Transferee"). Issuer shall look solely to Account Party for payment of any fee for any transfer of this L/C. Such payment is not a condition to any such transfer. Beneficiary or Transferee shall consummate such transfer by delivering to Issuer the original of this L/C and a Transfer Notice substantially in the form of Attachment 2, purportedly signed by Beneficiary, and designating Transferee. Issuer shall promptly reissue or amend this L/C in favor of Transferee as Beneficiary. Upon any transfer, all references to Beneficiary shall automatically refer to Transferee, who may then exercise all rights of Beneficiary. Issuer expressly consents to any transfers made from time to time in compliance with this paragraph.

Any notice to Beneficiary shall be in writing and delivered by hand with receipt acknowledged or by overnight delivery service such as FedEx (with proof of delivery) at the above address, or such other address as Beneficiary may specify by written notice to Issuer. A copy of any such notice shall also be delivered, as a condition to the effectiveness of such notice, to: \_\_\_\_\_ (or such replacement as Beneficiary designates from time to time by written notice).

No amendment that adversely affects Beneficiary shall be effective without Beneficiary's written consent.

This L/C is subject to and incorporates by reference: (a) the International Standby Practices 98 (“ISP 98”); and (b) to the extent not inconsistent with ISP 98, Article 5 of the Uniform Commercial Code of the State of New York.

Very truly yours,

[Issuer Signature]

**ATTACHMENT 1 TO EXHIBIT E**

**FORM OF SIGHT DRAFT**

[BENEFICIARY LETTERHEAD]

TO:

[Name and Address of Issuer]

**SIGHT DRAFT**

AT SIGHT, pay to the Order of \_\_\_\_\_, the sum of \_\_\_\_\_ United States Dollars (\$\_\_\_\_\_).  
Drawn under [Issuer] Letter of Credit No. \_\_\_\_\_ dated \_\_\_\_\_.

[Issuer is hereby directed to pay the proceeds of this Sight Draft solely to the following account: \_\_\_\_\_.]

[Name and signature block, with signature or purported signature of Beneficiary]

Date: \_\_\_\_\_

**ATTACHMENT 2 TO EXHIBIT E**

**FORM OF TRANSFER NOTICE**

[BENEFICIARY LETTERHEAD]

TO:

[Name and Address of Issuer] (the "Issuer")

**TRANSFER NOTICE**

By signing below, the undersigned, Beneficiary (the "Beneficiary") under Issuer's Letter of Credit No. \_\_\_\_\_ dated \_\_\_\_\_ (the "L/C"), transfers the L/C to the following transferee (the "Transferee"):

[Transferee Name and Address]

The original L/C is enclosed. Beneficiary directs Issuer to reissue or amend the L/C in favor of Transferee as Beneficiary. Beneficiary represents and warrants that Beneficiary has not transferred, assigned, or encumbered the L/C or any interest in the L/C, which transfer, assignment, or encumbrance remains in effect.

[Name and signature block, with signature or purported signature of Beneficiary]

Date: \_\_\_\_\_]

## EXHIBIT F

### RULES AND REGULATIONS

NOTHING IN THESE RULES AND REGULATIONS (“RULES AND REGULATIONS”) SHALL SUPPLANT ANY PROVISION OF THE LEASE. IN THE EVENT OF A CONFLICT OR INCONSISTENCY BETWEEN THESE RULES AND REGULATIONS AND THE LEASE, THE LEASE SHALL PREVAIL.

1. Except as specifically provided in the Lease, no sign, placard, picture, advertisement, name or notice shall be installed or displayed on any part of the outside of the Premises without Landlord’s prior written consent. Landlord shall have the right to remove, at Tenant’s sole cost and expense and without notice, any sign installed or displayed in violation of this rule.
2. If Landlord objects in writing to any curtains, blinds, shades, screens, hanging plants or other similar objects attached to or used in connection with any window or door of the Premises or placed on any windowsill, and (a) such window, door or windowsill is visible from the exterior of the Premises and (b) such curtain, blind, shade, screen, hanging plant or other object is not included in plans approved by Landlord, then Tenant shall promptly remove such curtains, blinds, shades, screens, hanging plants or other similar objects at its sole cost and expense.
3. Tenant shall not place a load upon any floor of the Premises that exceeds the load per square foot that (a) such floor was designed to carry or (b) is allowed by Applicable Laws.
4. Tenant shall not use any method of HVAC other than that shown in the Tenant Improvement plans.
5. Tenant shall not install any radio, television or other antennae; cell or other communications equipment; or other devices on the roof or exterior walls of the Premises except in accordance with the Lease. Tenant shall not interfere with radio, television or other digital or electronic communications at the Premises or elsewhere.
6. Tenant shall store all of its trash, garbage and Hazardous Materials in receptacles within its Premises or in receptacles designated by Landlord outside of the Premises. Tenant shall not place in any such receptacle any material that cannot be disposed of in the ordinary and customary manner of trash, garbage and Hazardous Materials disposal. Tenant shall be responsible, at its sole cost and expense, for Tenant’s removal of its trash, garbage and Hazardous Materials.
7. The Premises shall not be used for lodging or for any improper, immoral or objectionable purpose. No cooking shall be done or permitted in the Premises; provided, however, that Tenant may use (a) equipment approved in accordance with the requirements of insurance policies that Landlord or Tenant is required to purchase and maintain pursuant to the Lease for brewing coffee, tea, hot chocolate and similar beverages, (b) microwave ovens for employees’ use and (c) equipment shown on Tenant Improvement plans approved by Landlord; provided, further, that any such equipment and microwave ovens are used in accordance with Applicable Laws.



8. Tenant shall not, without Landlord's prior written consent, use the name of the Premises, if any, in connection with or in promoting or advertising Tenant's business except as Tenant's address.
9. Tenant shall comply with all safety, fire protection and evacuation procedures and regulations established by Landlord or any Governmental Authority.
10. Tenant assumes any and all responsibility for protecting the Premises from theft, robbery and pilferage, which responsibility includes keeping doors locked and other means of entry to the Premises closed.
11. Tenant shall not modify any locks to the Premises without Landlord's prior written consent, which consent Landlord shall not unreasonably withhold, condition or delay. Tenant shall furnish Landlord with copies of keys, pass cards or similar devices for locks to the Premises.
12. Tenant shall cooperate and participate in all reasonable security programs affecting the Premises.
13. Tenant shall not permit any animals in the Premises, other than for service animals or for use in laboratory experiments.
14. The water and wash closets and other plumbing fixtures shall not be used for any purposes other than those for which they were constructed, and no sweepings, rubbish, rags or other substances shall be deposited therein.
15. Discharge of industrial sewage shall only be permitted if Tenant, at its sole expense, first obtains all necessary permits and licenses therefor from all applicable Governmental Authorities.
16. Smoking and the use of smokeless tobacco products, electronic smoking devices (e.g., e-cigarettes) and nicotine products is prohibited inside the Building, except in designated outdoor areas of the Premises (if any).
17. Tenant shall comply with all orders, requirements and conditions now or hereafter imposed by Applicable Laws or Landlord ("Waste Regulations") regarding the collection, sorting, separation and recycling of waste products, garbage, refuse and trash generated by Tenant (collectively, "Waste Products"), including (without limitation) the separation of Waste Products into receptacles reasonably approved by Landlord and the removal of such receptacles in accordance with any collection schedules prescribed by Waste Regulations.
18. Tenant, at Tenant's sole cost and expense, shall enter into an extermination contract with an exterminator reasonably approved by Landlord, which shall provide for monthly inspections of the Premises, and, if necessary or recommended, monthly exterminations of the Premises to Landlord's reasonable satisfaction and shall cause all portions of the Premises used for the storage, preparation, service or consumption of food or beverages to be cleaned daily in a manner reasonably satisfactory to Landlord, and to be treated against infestation by insects, rodents and other vermin and pests whenever there is evidence of any infestation. Tenant shall not permit any person to enter the Premises for the purpose of providing such extermination

services, unless such persons have been approved by Landlord. If requested by Landlord, Tenant shall, at Tenant's sole cost and expense, store any refuse generated in the Premises by the consumption of food or beverages in a cold box or similar facility.

19. Electric vehicles may be charged using only electric vehicle charging stations installed for that purpose, and no other electrical outlets or connections at the Project may be used for charging vehicles of any kind.

20. Firearms and any other items intended for use as weapons are not permitted in the Building(s) or at the Project.

Landlord may waive any one or more of these Rules and Regulations for the benefit of Tenant, but no such waiver by Landlord shall be construed as a waiver of such Rules and Regulations in favor of Tenant, nor prevent Landlord from thereafter enforcing any such Rules and Regulations against Tenant. These Rules and Regulations are in addition to, and shall not be construed to in any way modify or amend, in whole or in part, the terms covenants, agreements and conditions of the Lease. Landlord reserves the right to make such other and reasonable additional rules and regulations as, in its judgment, may from time to time be needed for safety and security, the care and cleanliness of the Premises, or the preservation of good order therein; provided, however, that Tenant shall not be obligated to adhere to such additional rules or regulations until Landlord has provided Tenant with written notice thereof. Tenant agrees to abide by these Rules and Regulations and any such additional rules and regulations issued or adopted by Landlord. Tenant shall be responsible for the observance of these Rules and Regulations by all Tenant Parties.

## COVID-19 RULES AND REGULATIONS

To help minimize the spread of the COVID-19 virus and maintain a safe and healthy work environment, Landlord has instituted the below rules and regulations (the “COVID-19 Rules and Regulations”) as part of the Rules and Regulations. The COVID-19 Rules and Regulations are in effect until further notice from Landlord.

1. Individuals may not enter the Building/Property/Project if they are sick or experiencing flu-like symptoms.
2. Individuals who have been ill or have displayed flu-like symptoms must follow all recommendations of the Centers for Disease Control (CDC) for symptomatic individuals prior to returning to the Building/Property/Project.
3. Individuals who have been exposed to a known COVID-19-infected individual should not return to the Building/Property/Project until 14 days after their most recent exposure to that infected individual.
4. In Common Areas, including elevators and parking garages, individuals must wear face coverings or masks, practice social distancing, and maintain six feet of separation from others as much as possible.
5. Group gatherings are not allowed in Common Areas at this time.
6. Tenants must adhere to signage posted throughout the Building/Property/Project, including related to amenity closures or restrictions.
7. Individuals must clean up after themselves, wash hands frequently, and not leave trash or other personal items in Common Areas.
8. Tenants must develop a COVID-19 remediation response plan for their Premises and share that plan with the Landlord. Additionally, tenants must share their re-emergence plan with Landlord and continue to provide Landlord with updates as their plan evolves.
9. Tenants shall monitor evolving CDC, state and local governmental guidelines, and educate their employees about new guidance and information, as needed.
10. Tenants must promptly report known COVID-19 cases that have occurred at the Building/Property/Project to Landlord, but Tenant shall not be obligated to identify the name of the individual due to privacy or Applicable Laws.

**EXHIBIT G**

[Intentionally Omitted]

G-1

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**EXHIBIT H**  
**TENANT'S PROPERTY**

None.

H-1

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**EXHIBIT I**

**FORM OF ESTOPPEL CERTIFICATE**

To: BMR-ONE RESEARCH WAY LLC  
4570 Executive Drive, Suite 400  
San Diego, California 92121  
Attention: Legal Department

BioMed Realty, L.P.  
4570 Executive Drive, Suite 400  
San Diego, California 92121

Re: One Research Way (the "Premises") at One Research Way, Princeton, New Jersey (the "Property")

The undersigned tenant ("Tenant") hereby certifies to you as follows:

1. Tenant is a tenant at the Property under a lease (the "Lease") for the Premises dated as of [\_\_\_\_], 20[\_\_\_]. The Lease has not been cancelled, modified, assigned, extended or amended [except as follows: [\_\_\_\_]], and there are no other agreements, written or oral, affecting or relating to Tenant's lease of the Premises or any other space at the Property. The lease term expires on [\_\_\_\_], 20[\_\_\_].
2. Tenant took possession of the Premises, currently consisting of [\_\_\_\_] square feet, on [\_\_\_\_], 20[\_\_\_], and commenced to pay rent on [\_\_\_\_], 20[\_\_\_]. Tenant has full possession of the Premises, has not assigned the Lease or sublet any part of the Premises, and does not hold the Premises under an assignment or sublease[, except as follows: [\_\_\_\_]].
3. All base rent, rent escalations and additional rent under the Lease have been paid through [\_\_\_\_], 20[\_\_\_]. There is no prepaid rent[, except \$[\_\_\_\_]][, and the amount of security deposit is \$[\_\_\_\_] [in cash][OR][in the form of a letter of credit]]. Tenant currently has no right to any future rent abatement under the Lease.
4. Base rent is currently payable in the amount of \$[\_\_\_\_] per month.
5. Tenant is currently paying estimated payments of additional rent of \$[\_\_\_\_] per month on account of real estate taxes, insurance, management fees and maintenance expenses.
6. All work to be performed for Tenant under the Lease has been performed as required under the Lease and has been accepted by Tenant[, except [\_\_\_\_]], and all allowances to be paid to Tenant, including allowances for tenant improvements, moving expenses or other items, have been paid.
7. The Lease is in full force and effect, free from default and free from any event that could become a default under the Lease, and Tenant has no claims against the landlord or offsets or defenses against rent, and there are no disputes with the landlord. Tenant has received no notice

of prior sale, transfer, assignment, hypothecation or pledge of the Lease or of the rents payable thereunder[, except [\_\_\_\_\_]].

8. Tenant has no rights or options to purchase the Property.

9. To Tenant's knowledge, no hazardous wastes have been generated, treated, stored or disposed of by or on behalf of Tenant in, on or around the Premises in violation of any environmental laws.

10. The undersigned has executed this Estoppel Certificate with the knowledge and understanding that [INSERT NAME OF LANDLORD, PURCHASER OR LENDER, AS APPROPRIATE] or its assignee is [acquiring the Property/making a loan secured by the Property] in reliance on this certificate and that the undersigned shall be bound by this certificate. The statements contained herein may be relied upon by [INSERT NAME OF PURCHASER OR LENDER, AS APPROPRIATE], BMR-One Research Way LLC, BioMed Realty, L.P., [BRE Edison L.P.][OR][BRE Edison II LP], and any [other ]mortgagee of the Property and their respective successors and assigns.

Any capitalized terms not defined herein shall have the respective meanings given in the Lease.

Dated this [\_\_\_\_] day of [\_\_\_\_\_], 20[\_\_\_\_].

PMV PHARMACEUTICALS, INC.,  
a Delaware corporation

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

**EXHIBIT J**

**FORRESTAL CENTER SIGNAGE CRITERIA**

[See Attached]

J-1



**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-249094) pertaining to the 2013 Equity Incentive Plan, 2020 Equity Incentive Plan and 2020 Employee Stock Purchase Plan of PMV Pharmaceuticals, Inc. of our report dated March 3, 2021, with respect to the financial statements of PMV Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania  
March 3, 2021

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO  
EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David H. Mack, certify that:

1. I have reviewed this Annual Report on Form 10-K of PMV Pharmaceuticals, 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 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) 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
  - (c) 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 3, 2021

PMV PHARMACEUTICALS, INC.

By: /s/ David H. Mack  
Name: David H. Mack, Ph.D.  
Title: Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO  
EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Winston Kung, certify that:

1. I have reviewed this Annual Report on Form 10-K of PMV Pharmaceuticals, 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 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) 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
  - (c) 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 3, 2021

PMV PHARMACEUTICALS, INC.

By: /s/ Winston Kung  
Name: Winston Kung  
Title: Chief Operating Officer and  
Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO  
18 U.S.C SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of PMV Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David H. Mack, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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 3, 2021

PMV PHARMACEUTICALS, INC.

By: /s/ David H. Mack  
Name: David H. Mack, Ph.D.  
Title: Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO  
18 U.S.C SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of PMV Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Winston Kung, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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 3, 2021

PMV PHARMACEUTICALS, INC.

By: /s/ Winston Kung  
Name: Winston Kung  
Title: Chief Operating Officer and  
Chief Financial Officer  
(Principal Financial Officer)