

As confidentially submitted to the Securities and Exchange Commission on July 31, 2020.
 This Amendment No. 1 to the draft registration statement has not been publicly filed with the Securities and Exchange Commission
 and all information herein remains strictly confidential.

Registration No. 333-

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

FORM S-1
 REGISTRATION STATEMENT
 Under
 The Securities Act of 1933

PMV PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware
 (State or other jurisdiction of
 incorporation or organization)

2834
 (Primary Standard Industrial
 Classification Code Number)

46-3218129
 (I.R.S. Employer
 Identification Number)

8 Clarke Drive, Suite 3
 Cranbury, NJ 08512
 (609) 642-6670

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

David H. Mack, Ph.D.
 President and Chief Executive Officer
 8 Clarke Drive, Suite 3
 Cranbury, NJ 08512
 (609) 642-6670

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

Copies to:

Kenneth A. Clark
 Tony Jeffries
 Megan J. Baier
 Wilson Sonsini Goodrich & Rosati, P.C.
 650 Page Mill Road
 Palo Alto, CA 94304
 (650) 493-9300

Winston Kung
 Chief Operating Officer and
 Chief Financial Officer
 PMV Pharmaceuticals, Inc.
 8 Clarke Drive, Suite 3
 Cranbury, NJ 08512
 (609) 642-6670

Brian Cuneo
 Nathan Ajiashvili
 Richard Kim
 Latham & Watkins LLP
 140 Scott Drive
 Menlo Park, CA 94025
 (650) 328-4600

**Approximate date of commencement of proposed sale to the public:
 As soon as practicable after the effective date of this Registration Statement.**

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price ⁽¹⁾⁽²⁾	Amount of Registration Fee
Common Stock \$0.00001 par value per share	\$	\$

(1) Includes offering price of any additional shares of common stock that the underwriters have the option to purchase.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

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

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

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION, DATED _____, 2020

Shares



Common Stock

This is an initial public offering of shares of common stock of PMV Pharmaceuticals, Inc. All of the _____ shares of common stock are being sold by the company.

Prior to this offering, there has been no public market for our common stock. We estimate that the initial public offering price of our common stock will be between \$ _____ and \$ _____ per share. We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "PMVP."

We are an "emerging growth company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced reporting requirements for this prospectus and may elect to do so in future filings.

Investing in our common stock involves a high degree of risk. Before buying any shares, you should read carefully the discussion of the material risks of investing in our common stock under the heading "[Risk Factors](#)" starting on page 12 of this prospectus.

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

	Per Share	Total
Initial public offering price	\$ _____	\$ _____
Underwriting discounts and commissions ⁽¹⁾	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

⁽¹⁾ See the section titled "Underwriting" beginning on page 196 for additional information regarding compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional _____ shares of common stock from us at the initial public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares against payment in New York, New York on _____, 2020.

Goldman Sachs & Co. LLC

BofA Securities

Cowen

Evercore ISI

Prospectus dated _____, 2020.

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Through and including _____, 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

We and the underwriters have not authorized anyone to provide you any information other than that contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: we have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

TRADEMARKS

We use the name “PMV Pharma,” the “PMV Pharma” logo and other marks as unregistered trademarks in the United States and other countries. This prospectus 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 prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ 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.

MARKET AND INDUSTRY DATA

This prospectus contains estimates, projections and other information concerning our industry, our business and the potential markets for our product candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained the industry, market and similar data set forth in this prospectus from our internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies.

While we believe that the data we use from third parties is reliable, we have not separately verified these data. This information, to the extent it contains estimates or projections, involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates or projections. The industry in which we operate is subject to risks and uncertainties due to a variety of factors, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in these publications and reports.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read the entire prospectus carefully, especially "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and the related notes, before deciding to buy shares of our common stock. Unless the context requires otherwise, references in this prospectus to "PMV Pharmaceuticals," "the Company," "we," "us" and "our" refer to PMV Pharmaceuticals, Inc.

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.

We believe that we have designed our lead product candidate, PC14586, 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. We are initially pursuing a tumor-agnostic development strategy and plan to submit our investigational new drug application, or IND, for PC14586 and start a Phase 1/2 clinical trial in the second half of 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. We cannot guarantee that the U.S. Food and Drug Administration, or 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. We expect to advance our next program, targeting p53R273H mutations, into lead optimization in the second half of 2020. We own worldwide commercial rights to all of our programs. 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.

Potential of Precision Medicine in p53

Cancer is a genetic disease that results from changes in a person’s DNA that causes cells to grow and divide uncontrollably. Recent advances in genetic sequencing and a better understanding of mutations that drive cancers have facilitated the development of precise, gene- and protein-specific drugs known as targeted therapies. There are multiple tumor-agnostic product approvals that are based on a genetic mutation that defines the cancer, as opposed to the tumor type.

The p53 gene provides instructions for the production of tumor suppression protein p53. 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. The p53 gene is the most widely mutated gene in human cancers and to date, more than 25,000 unique p53 mutations have been discovered. 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.

Therefore, we believe that the best way to address p53-driven cancers is by targeting individual p53 mutations using a precision oncology approach. Diagnostic tests are currently used by physicians in their practice to identify cancer patients with p53 mutations. We believe that identifying the p53 gene mutation and structurally correcting the specific mutant p53 protein to restore wild-type p53 activity can potentially serve as the basis of treatment for patients with these mutations.

Our Approach

We believe our novel approach to reactivate the p53 function through structural correction of the mutant p53 protein to wild-type represents a therapeutic strategy to target p53. Decades of research on p53 have unveiled its potential as a precision oncology target. Mutations in the p53 gene can give rise to mutant p53 proteins with different conformational structures. As a result, we are developing oral small molecule therapies that selectively target a specific mutant p53 protein while sparing wild-type p53. Our innovation engine is composed 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 scientific advisory board, or 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 the mutated p53 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 Macrophage Inhibitory Cytokine-1, or 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 therapeutic programs for translation to the clinic.

Our PC14586 Program

Our lead product candidate, PC14586, is designed to be an orally available small molecule that structurally corrects a mutant p53 protein with the Y220C mutation and restores wild-type p53 function. The Y220C mutation is associated with 1.0-1.5% of all cancers, including breast, NSCLC, colorectal, pancreatic and ovarian cancers. There are currently no drugs 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 selectively bind to the crevice created by the p53 Y220C mutation and restore the wild-type p53 protein structure and tumor suppressing function. In preclinical studies, we have demonstrated that PC14586 rapidly converts the large protein pool of mutant p53 Y220C protein to wild-type structure. 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.

PC14586 also exhibited profound single-agent anti-tumor activity in mouse models. We created a human p53 knock-in, or HUPKI, mouse that expresses a p53 protein with the human p53 DNA binding domain and the 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 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.

PC14586 administered as a single-agent demonstrated regression in tumors that express the p53 Y220C mutation in the syngeneic mouse model. PC14586 also exhibited anti-tumor activity in combination with anti-PD-1 therapy in syngeneic mouse models with the human p53 Y220C mutation.

We are initially pursuing a tumor-agnostic development strategy and plan to submit our IND for PC14586 and start a Phase 1/2 clinical trial in the second half of 2020.

Our Second Program R273H

We expect to advance our next program, targeting the p53 R273H hotspot mutation, into lead optimization in the second half of 2020. R273H is the third most frequent p53 mutation and is found in approximately 4% of all p53 mutations. The R273H mutation causes a decrease in binding between the p53 protein and DNA, resulting in the p53 protein's 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 several 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.

Our History and Team

We were founded in 2013 by David Mack, Ph.D., Arnold Levine, Ph.D. and Thomas Shenk, Ph.D. Over the past seven years, 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. Our vision has been supported by leading investors, including InterWest Partners, OrbiMed Advisors, Topspin, Euclidean Capital, Nextech Invest, Viking Global Investors, Boxer Capital of Tavistock Group and Osage University Partners.

Additionally, we have assembled a management team of biopharmaceutical experts with extensive experience in drug discovery and development, with particular expertise in the discovery of small molecule oncology programs. Dr. David 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. Mr. 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. Dr. Leila Alland, 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. Dr. Deepika Jalota, Pharm.D., our Senior Vice President of Regulatory Affairs and Quality Assurance, was previously Vice President of 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 SAB, many of whom have been associated with multiple oncology product approvals.

Our Strategy

Our vision is to become a leading precision oncology company by designing, developing and commercializing small molecule therapies targeting mutant p53. 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;
- 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;
- leveraging the advantages of precision medicine and our expertise in p53 biology to pursue accelerated approval of our product candidates; and
- identifying and exploring combination therapy approaches for our product candidates.

Risks Related to Our Business

Our ability to execute on our business strategy is subject to a number of risks, which are discussed more fully in the section titled "Risk Factors." You should carefully consider these risks before making an investment in our common stock. These risks include, among others, the following:

- we have a limited operating history, have not initiated or 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;
- even if this offering is successful, we will require substantial additional capital to finance our operations;
- our discovery and preclinical 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;
- 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;
- 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 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.

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. Information contained on, or that can be accessible through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

Implications of Being an Emerging Growth Company

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act. An emerging growth company may take advantage of certain reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements in addition to any required unaudited interim financial statements, with correspondingly reduced disclosure in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations”;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have at least \$1.07 billion in annual gross revenue; (ii) the date we are deemed to be a “large accelerated filer”; (iii) the issuance, in any three-year period, by us of more than \$1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year following the fifth anniversary of this offering.

We have taken advantage of reduced reporting requirements in this prospectus and may elect to take advantage of other reduced reporting requirements in our future filings with the Securities and Exchange Commission. As a result, the information that we provide to our stockholders may be different than, and not comparable to, information presented by other public reporting companies. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would 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 we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

THE OFFERING

Common stock offered by us	shares.
Underwriters' option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of our common stock.
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	<p>We estimate that the net proceeds to us from the sale of the shares of our common stock in this offering will be approximately \$ million, or approximately \$ million if the underwriters exercise their option to purchase additional shares in full, based upon the assumed initial public offering price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We currently anticipate that we will use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term marketable securities, as follows: (1) to fund the Phase 1/2 development of PC14586; (2) to support the development of our R273H program, including lead optimization and IND-enabling studies; (3) for the development of our pipeline discovery programs; and (4) for other research and development opportunities, working capital and general corporate purposes.</p> <p>See the section titled "Use of Proceeds" for more information.</p>
Risk factors	See the section of this prospectus titled "Risk Factors" beginning on page 12 and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.
Proposed Nasdaq Global Market trading symbol	"PMVP"

The number of shares of our common stock to be outstanding after this offering is based on 164,451,912 shares of our common stock outstanding as of June 30, 2020 (including an aggregate of 120,393,150 shares of common stock issuable upon conversion of our outstanding convertible preferred stock as of June 30, 2020) and including 28,020,172 shares of our common stock issuable pursuant to the conversion of our Series D convertible preferred stock issued and sold in July 2020, and excludes the following:

- 20,653,300 shares of common stock issuable upon exercise of options to purchase shares of our common stock outstanding as of June 30, 2020, with a weighted-average exercise price of \$0.50 per share;
- _____ shares of common stock issuable upon exercise of options to purchase shares of our common stock that we granted after June 30, 2020, with a weighted-average exercise price of \$ _____ per share;
- _____ shares of common stock reserved for future issuance under our 2013 Equity Incentive Plan, as amended, or 2013 Plan, which shares will be added to the shares to be reserved under our 2020 Equity Incentive Plan, or 2020 Plan, upon its effectiveness;
- a warrant to purchase an aggregate of 56,866 shares of our Series Seed convertible preferred stock outstanding as of June 30, 2020 that will be converted into a warrant to purchase an aggregate of 56,866 shares of our common stock, with an exercise price of \$0.3517 per share, upon the completion of this offering; and
- _____ shares of common stock reserved for future issuance under our 2020 Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- no exercise of the outstanding options or warrant;
- no exercise by the underwriters of their option to purchase additional shares of common stock from us in this offering;
- the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock, which will occur immediately prior to the completion of this offering;
- the conversion of an outstanding warrant exercisable for shares of our Series Seed convertible preferred stock into a warrant exercisable for 56,866 shares of our common stock, with an exercise price of \$0.3517 per share upon the completion of this offering; and
- the filing and effectiveness of our amended and restated certificate of incorporation and the effectiveness of our amended and restated bylaws, which will occur immediately prior to the completion of this offering.

SUMMARY FINANCIAL DATA

The following tables summarize our financial data for the periods and as of the dates indicated. We have derived our summary statements of operations data for the years ended December 31, 2018 and 2019 from our audited financial statements and related notes included elsewhere in this prospectus. For interim periods, we have derived our summary statements of operations data for the six months ended June 30, 2019 and 2020 and the summary balance sheet data as of June 30, 2020 from our unaudited condensed financial statements and related notes included elsewhere in this prospectus. The unaudited condensed financial statements were prepared on a basis consistent with our audited financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future and our interim results are not necessarily indicative of our expected results for the year ending December 31, 2020. You should read the following summary financial data together with our financial statements and the related notes appearing elsewhere in this prospectus and the information in the sections titled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	<u>Year Ended December 31,</u>		<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2019</u>	<u>2019</u>	<u>2020</u>
	(unaudited)			
	(in thousands, except share and per share amounts)			
Statement of operations data:				
Operating expenses:				
Research and development	\$ 13,853	\$ 20,759	\$ 10,165	\$ 11,760
General and administrative	5,039	5,878	2,676	3,979
Total operating expenses	<u>18,892</u>	<u>26,637</u>	<u>12,841</u>	<u>15,739</u>
Loss from operations	(18,892)	(26,637)	(12,841)	(15,739)
Other income (expense):				
Interest income, net	1,341	1,301	714	563
Other income (expense)	16	(8)	—	(43)
Total other income (expense)	<u>1,357</u>	<u>1,293</u>	<u>714</u>	<u>520</u>
Loss before provision for income taxes	(17,535)	(25,344)	(12,127)	(15,219)
Provision for income taxes	3	8	2	2
Net loss	<u>\$ (17,538)</u>	<u>\$ (25,352)</u>	<u>\$ (12,129)</u>	<u>\$ (15,221)</u>
Net loss per share — basic and diluted ⁽¹⁾	\$ (1.11)	\$ (1.59)	\$ (0.76)	\$ (0.95)
Weighted-average common shares outstanding — basic and diluted ⁽¹⁾	<u>15,860,018</u>	<u>15,980,859</u>	<u>15,922,173</u>	<u>16,038,590</u>
Pro forma net loss per share attributable to common stockholders — basic and diluted (unaudited) ⁽¹⁾		<u>\$ (0.15)</u>		<u>\$ (0.09)</u>
Pro forma weighted-average number of common shares — basic and diluted (unaudited) ⁽¹⁾		<u>164,394,182</u>		<u>164,451,912</u>

⁽¹⁾ See Note 11 to our audited financial statements and Note 10 to our unaudited condensed financial statements included elsewhere in this prospectus for an explanation of the method used to calculate net loss per share, basic and diluted, pro forma net loss per share, basic and diluted, and the weighted-average number of shares used in the computation of the per share amounts.

	As of June 30, 2020	
	Actual	Pro Forma As Adjusted ⁽²⁾
Balance Sheet Data:		
Cash, cash equivalents and short-term marketable securities	\$ 86,136	\$ 156,106
Working capital ⁽³⁾	81,704	151,704
Total assets	89,102	159,042
Total liabilities	5,177	5,147
Convertible preferred stock	168,933	—
Accumulated deficit	(90,661)	(90,661)
Total stockholder's (deficit) equity	(85,008)	153,895

- (1) The pro forma balance sheet data give effect to (i) our issuance and sale in July 2020 of an aggregate of 28,020,172 shares of our Series D convertible preferred stock for gross proceeds of \$70.0 million, (ii) the automatic conversion of all outstanding shares of our convertible preferred stock, including our shares of our Series D convertible preferred stock issued in July 2020, into an aggregate of 148,413,322 shares of our common stock immediately prior to the completion of this offering and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the completion of this offering.
- (2) The pro forma as adjusted balance sheet data give further effect to our issuance and sale of _____ shares of our common stock in this offering at the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted balance sheet data is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, our pro forma as adjusted cash, cash equivalents and short-term marketable securities, working capital, total assets and total stockholders' equity by approximately \$ _____ million, assuming the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase or decrease of 1.0 million shares of common stock offered by us would increase or decrease, as applicable, our pro forma as adjusted cash, cash equivalents and short-term marketable securities, working capital, total assets and total stockholders' equity by approximately \$ _____ million, assuming the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) We define working capital as current assets less current liabilities. See our unaudited condensed financial statements included elsewhere in this prospectus and related notes for further details regarding our current assets and current liabilities.

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 prospectus, including our financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” 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.

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 initiated or 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 preclinical 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 establishing arrangements with third parties for the manufacture of initial quantities of product candidates. Our lead product candidate, PC14586, is still in preclinical development, and we haven’t yet submitted an investigational new drug application, or IND, with the U.S. Food and Drug Administration, or FDA. We have not demonstrated an ability to successfully initiate, 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

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become commercially viable. We are still in the early stages of development of our product candidates and have not yet initiated our first clinical trial. 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.

We have incurred significant net losses in each period since we commenced operations in March 2013. Our net losses were \$17.5 million and \$25.4 million for the years ended December 31, 2018 and 2019, respectively, and \$12.1 million and \$15.2 million for the six months ended June 30, 2019 and 2020, respectively. As of June 30, 2020, we had an accumulated deficit of \$90.7 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. 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 INDs for our lead product candidate and any other product candidates;
- conduct preclinical studies and 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 have not evaluated any product candidate in humans, including PC14586, our lead product candidate. As such, we face significant translational

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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:

- timely initiation and completion of our preclinical studies and clinical trials for our lead product candidate, PC14586, and 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;

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- 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. 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.

Even if this offering is successful, we will require substantial additional capital to finance our operations. 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

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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. Following this offering, 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 June 30, 2020, we had \$86.1 million in cash, cash equivalents and short-term marketable securities. We also received gross proceeds of \$70.0 million from the sale of shares of Series D convertible preferred stock in July 2020. Based on our current operating plan, we believe that the proceeds from this offering, together with our existing cash, cash equivalents and short-term marketable securities, will be sufficient to fund our operations through . Our estimate as to how long we expect the net proceeds from this offering, together with our existing cash, cash equivalents and short-term marketable securities, to be able to continue to fund our operations 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 through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Such financing may dilute our stockholders or restrict our operating activities. 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. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to future collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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 planned 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 preclinical 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 planned 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 planned 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. All of our 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;
- successful completion of preclinical studies;
- 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 initiation of clinical trials;
- 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;

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- 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 preclinical 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. At present, all of our product candidates, including our lead product candidate, PC14586, 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. As a result, we cannot be sure that we will be able to submit INDs or similar applications on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

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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 will be 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 future 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 no experience as a company in conducting clinical trials.

We have no experience as a company in conducting clinical trials. In part because of this lack of experience, we cannot be certain that our ongoing preclinical studies 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 would 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 recently entered in to a master services agreement with a CRO to lead our first-in-human planned 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 plan to work 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 on a staggered schedule, 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 following this offering 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.

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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 planned clinical trial 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 therapy, 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, as novel therapeutics, 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;

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- 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 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, Kartos Therapeutics, Novartis and Roche, including testing MDM2 inhibitors in combination with a variety of other anti-cancer agents.

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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. For additional information regarding our competition, see “Business—Competition.”

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 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 not yet initiated clinical trials for any of our product candidates, as is the case with all oncology drugs, it is likely that there may be significant side effects associated with their 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 after this offering.

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 are licensed 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 that are licensed 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 Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. 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 planned 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 proposed 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 fast track or breakthrough therapy designations for our current or future product candidates. Even if we are successful, these 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. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, 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.

All of our lead product candidates are in 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 future 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

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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, some of the clinical trials we conduct, including our planned PC14586 Phase 1/2 clinical trial, may be open-label in study design and may be 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 preclinical studies of our future 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;

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- 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 Securities and Exchange Commission 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 Securities and Exchange Commission, or 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, upon completion of this offering and 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

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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, good laboratory practice, or 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 of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may 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.

Members of the U.S. Congress and the Trump administration have expressed an intent to pass legislation or adopt executive orders to fundamentally change or repeal parts of the ACA. 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. The Trump Administration and CMS have both stated that the ruling will have no immediate effect, and 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. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, although it is unclear when or how the Supreme Court will rule. It is also unclear how other efforts to challenge, repeal or replace the ACA will impact the ACA or our business. We will continue to evaluate the effect that the ACA and its possible repeal and replacement 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.

Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The

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Trump administration has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay to third-party payors more than \$12 billion in ACA risk corridor payments that they argued were owed to them. This was appealed to the U.S. Supreme Court, who reversed the Federal Circuit's decision on April 27, 2020, and ruled that the government must make risk corridor payments.

Moreover, 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 was to remain in effect through 2029 unless additional Congressional action was taken. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which was signed into law on March 27, 2020, designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation.

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. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing

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authority. 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.

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, which will be effective as of the date of the effectiveness of the registration statement of which this prospectus forms a part, 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 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 planned 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, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA 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 July 29, 2020, we had 38 full-time employees, including 32 employees engaged in research and development. 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

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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, 2018 and 2019, we had federal NOL carryforwards of \$43.0 million and \$66.4 million, respectively. As of December 31, 2018, we had state NOL carryforwards for New Jersey, California and Massachusetts of approximately \$38.8 million, \$4.9 million and \$0.4 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. 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 \$1.7 million and \$2.2 million, respectively, as of December 31, 2018 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 this offering or subsequent 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.

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.

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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;

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- 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

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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 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 law suits 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;

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- 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 Our Common Stock and This Offering

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 following this offering is likely to 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 prospectus, 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;

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- 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 impending presidential election in the United States in 2020; 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. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not

realize any return on your investment in us and may lose some or all of your investment. 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.

We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.

Prior to this offering, no public market for shares of our common stock existed and an active trading market for our common stock may never develop or be sustained following this offering. We will determine the initial public offering price for our common stock through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration.

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. We do not currently have and may never obtain research coverage by securities or industry analysts. If no or few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. In the event we obtain securities or industry analyst coverage, 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. After this offering, we will have _____ outstanding shares of common stock, based on the number of shares outstanding as of June 30, 2020, assuming: (1) no exercise of the underwriters' option to purchase additional shares, (2) the conversion of all outstanding shares of our convertible preferred stock as of June 30, 2020 into 120,393,150 shares of common stock immediately prior to the completion of this offering and (3) the conversion of our Series D convertible preferred stock issued and sold in July 2020 into 28,020,172 shares of common stock immediately prior to the completion of this offering. This includes the shares that we sell in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Of the remaining shares, _____ shares of our common stock are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold after this offering as described in the "Shares Eligible for Future Sale" section of this prospectus. Moreover, after this offering, holders of an aggregate of _____ shares of our common stock will 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. We also intend to register all shares of common stock that we may issue under our equity incentive plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

Our executive officers, directors and the holders of substantially all of our capital stock and securities convertible into or exchangeable for our capital stock have entered into lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions described in the section titled "Underwriting," not to sell, directly or indirectly, any shares of common stock without the permission of the underwriters for a period of 180 days following the date of this prospectus. We refer to such period as the lock-up period. When the lock-up period expires, we and our securityholders subject to a lock-up agreement will be able to sell our shares in the public market. In addition, the underwriters may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. See the description of the lock-up agreement with the underwriters in the section of this prospectus titled "Shares Eligible for Future Sale" for more information. 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.

Prior to this offering, our executive officers, directors, holders of _____ % or more of our capital stock and their respective affiliates beneficially owned approximately _____ % of our voting stock and, upon the closing of this offering, that same group will beneficially own approximately _____ % of our outstanding voting stock (based on the number of shares of common stock outstanding as of July 31, 2020 assuming no exercise of the underwriters' option to purchase additional shares, no exercise of outstanding options or the warrant and no purchases of shares in this offering by any of this group), in each case assuming the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately prior to the closing of this offering. Certain of our directors are affiliated with the holders of more than _____ % of our capital stock. In particular, Arnold Oronsky, Ph.D. is an affiliate of InterWest Partners X, L.P., Peter Thompson, M.D. is an affiliate of OrbiMed Private Investments V LP and Thilo Schroeder is an affiliate Nextech V Oncology S.C.S., SIACAV-SIF,

as indicated in the “Principal Stockholders” section. These stockholders, acting together, 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 in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, 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 this prospectus and 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 initial public offering.

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

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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 this prospectus and 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 will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We will be 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 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 this offering. 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.

We expect the rules and regulations applicable to public companies 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. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. 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 have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled “Use of Proceeds,” and you will be relying on the judgment of our management regarding the application of these proceeds. You will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. Our management might not apply the net proceeds in ways that

ultimately increase or maintain the value of your investment. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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, as they will be in effect upon closing of this offering, will 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 will, 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 that will become effective upon the closing of this offering 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 that will become effective upon the closing of this offering 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 will 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 to be effective immediately prior to the completion of this offering and our indemnification agreements that we have entered into with our directors and officers will provide that:

- we will 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 will not be 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.

After this offering, we will be 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

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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.

Upon the closing of this offering, we will become 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.

After the completion of this offering, we may be at an 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

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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, including, after the closing of this offering, 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.

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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.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The initial public offering price will be substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of approximately \$ _____ per share, representing the difference between the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and our pro forma as adjusted net tangible book value per share as of June 30, 2020, after giving effect to this offering and the automatic conversion of all outstanding shares of our convertible preferred stock immediately prior to the closing of this offering. As of June 30, 2020, there were _____ shares subject to outstanding options with a weighted-average exercise price of \$ _____ per share. To the extent these outstanding securities are ultimately exercised, investors purchasing common stock in this offering will incur further dilution. See "Dilution" for a more detailed description of the dilution to new investors in the offering. For a further description of the dilution that you will experience immediately after this offering, see the section titled "Dilution."

Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and controlling stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, plans for our product candidates, planned preclinical studies and clinical trials, results of clinical trials, future research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “should,” “would,” “expect,” “plan,” “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 prospectus 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 estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our anticipated use of our existing cash, cash equivalents and short-term marketable securities and the proceeds from this offering;
- 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 application, 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 participants 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;

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- 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 special designations, such as 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;
- 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 expectations 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 prospectus and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this prospectus. 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 prospectus, 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.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the shares of our common stock in this offering will be approximately \$ million, or approximately \$ million if the underwriters exercise their option to purchase additional shares in full, based upon the assumed initial public offering price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share would increase or decrease the net proceeds to us from this offering by approximately \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares offered by us would increase or decrease the net proceeds to us from this offering by approximately \$ million, assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the initial public offering price or the number of shares by these amounts would have a material effect on our uses of the proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our common stock and facilitate our future access to the public capital markets. We currently anticipate that we will use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term marketable securities, as follows:

- approximately \$ million to fund the Phase 1/2 development of PC14586;
- approximately \$ million to support the development of our R273H product candidate, including lead optimization and IND-enabling studies;
- approximately \$ million for the development of our pipeline discovery programs; and
- the remaining proceeds, if any, for other research and development opportunities, working capital and general corporate purposes.

Based upon our current operating plan, we believe that the anticipated net proceeds from this offering, together with our existing cash, cash equivalents and short-term marketable securities, will enable us to fund our operating expenses and capital expenditure requirements through . We expect that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term marketable securities, will allow us to complete our planned Phase 1/2 trial of PC14586; however, the expected net proceeds of this offering will not be sufficient for us to complete the development and commercialization of our product candidates, and we will need to raise substantial additional capital.

The expected use of the net proceeds from the offering represents our intentions based upon our current plans and business conditions. 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. In addition, we believe opportunities may exist from time to time to expand our current business through license or acquisitions of, or investments in, complementary businesses, products or technologies. While we have no current agreements, commitments or understandings for any specific licenses, acquisitions or investments at this time, we may use a portion of the net proceeds for these purposes.

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Our management will have broad discretion over the use of the net proceeds from this offering, and our investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering. The amounts and timing of our expenditures will depend upon numerous factors including the results of our research and development efforts, the timing and success of preclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions, the amount of cash obtained through our future collaborations, if any, and any unforeseen cash needs.

Pending their uses, we plan to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have not declared or paid any cash dividends on our capital stock since our inception. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements and contractual restrictions of then-existing debt instruments and other factors that our board of directors deems relevant.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term marketable securities and capitalization as of June 30, 2020, as follows:

- on an actual basis;
- on a pro forma basis to reflect (i) our issuance and sale in July 2020 of an aggregate of 28,020,172 shares of our Series D Convertible Preferred Stock for gross proceeds of \$70.0 million, (ii) the conversion of all outstanding shares of our convertible preferred stock, including our Series D convertible preferred stock issued in July 2020, into an aggregate of 148,413,322 shares of common stock, which will occur immediately prior to the completion of this offering, and the resulting reclassification of the convertible preferred stock and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to further reflect our issuance and sale of _____ shares of common stock in this offering at the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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You should read this information in conjunction with our financial statements and the related notes (including Note 7 to our unaudited condensed financial statements as it relates to the calculation of our outstanding shares of common stock) appearing elsewhere in this prospectus, as well as the sections of this prospectus titled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of June 30, 2020		
	Actual	Pro Forma	Pro Forma as Adjusted ⁽¹⁾
	(in thousands, except per share and per share amounts) (unaudited)		
Cash, cash equivalents and short-term marketable securities	\$ 86,136	\$ 156,106	\$
Convertible preferred stock, \$0.00001 par value per share; 120,483,538 shares authorized, 120,393,150 shares issued and outstanding, actual; no shares authorized, issued or outstanding pro forma and pro forma as adjusted	168,933		
Stockholders’ equity (deficit):			
Preferred stock, \$0.00001 par value; no shares authorized, issued or outstanding, actual; shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted			
Common stock, \$0.00001 par value per share; 175,068,944 shares authorized, 16,038,590 shares issued and outstanding, actual; 201,747,258 shares authorized, 164,451,912 shares issued and outstanding, pro forma (unaudited); shares authorized, shares issued and outstanding, pro forma as adjusted (unaudited)			2
Additional paid-in capital	5,648	244,549	
Accumulated deficit	(90,661)	(90,661)	
Accumulated other comprehensive loss	5	5	
Total stockholders’ (deficit) equity	(85,008)	153,895	
Total capitalization	\$ 83,925	\$ 153,895	\$

(1) Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, our pro forma as adjusted cash, cash equivalents and short-term marketable securities, additional paid-in capital, total stockholders’ equity and total capitalization by approximately \$ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase or decrease of 1.0 million shares in the number of shares of common stock offered by us would increase or decrease, as applicable, our pro forma as adjusted cash, cash equivalents and short-term marketable securities, additional paid-in capital, total stockholders’ equity and total capitalization by approximately \$ million, assuming the assumed initial public offering price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

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The number of shares of our common stock to be outstanding after this offering is based on 164,451,912 shares of our common stock outstanding as of June 30, 2020 (including an aggregate of 120,393,150 shares of common stock issuable upon conversion of our outstanding convertible preferred stock as of June 30, 2020) and including 28,020,172 shares of our common stock issuable pursuant to the conversion of our Series D convertible preferred stock issued and sold in July 2020, and excludes the following:

- 20,653,300 shares of common stock issuable upon exercise of options to purchase shares of our common stock outstanding as of June 30, 2020, with a weighted-average exercise price of \$0.50 per share;
- shares of common stock issuable upon exercise of options to purchase shares of our common stock that we granted after June 30, 2020, with a weighted-average exercise price of \$ per share;
- shares of common stock reserved for future issuance under our 2013 Equity Incentive Plan, as amended, which shares will be added to the shares to be reserved under our 2020 Equity Incentive Plan, or 2020 Plan, upon its effectiveness;
- a warrant to purchase an aggregate of 56,866 shares of our Series Seed convertible preferred stock outstanding as of June 30, 2020 that will be converted into a warrant to purchase an aggregate of 56,866 shares of our common stock, with an exercise price of \$0.3517 per share, upon the completion of this offering; and
- shares of common stock reserved for future issuance under our 2020 Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of June 30, 2020 was approximately \$(85.0 million), or \$(5.30) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and convertible preferred stock. Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the number of shares of our common stock outstanding as of June 30, 2020.

Our pro forma net tangible book value (deficit) as of June 30, 2020 was approximately \$153.9 million, or \$0.94 per share of our common stock. Pro forma net tangible book value (deficit) represents the amount of our total tangible assets less our total liabilities. Pro forma net tangible book value (deficit) per share represents pro forma net tangible book value divided by the total number of shares of our common stock outstanding as of June 30, 2020, after giving effect to (i) the conversion of all shares of our convertible preferred stock outstanding as of June 30, 2020 into an aggregate of 120,393,150 shares of our common stock, which will occur immediately prior to the completion of this offering and (ii) the issuance and sale of 28,020,172 shares of our Series D convertible preferred stock in July 2020 for aggregate gross proceeds of approximately \$70.0 million, and the conversion of such shares into 28,020,172 shares of our common stock, which will occur immediately prior to the completion of this offering.

After giving further effect to our sale of _____ shares of common stock in this offering at the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2020 would have been approximately \$ _____ million, or \$ _____ per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$ _____ to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value per share of \$ _____ to new investors purchasing common stock in this offering.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share	\$ _____
Historical net tangible book value (deficit) per share as of June 30, 2020	\$ _____
Pro forma increase in net tangible book value (deficit) per share as of June 30, 2020	_____
Pro forma net tangible book value (deficit) per share as of June 30, 2020 Increase in pro forma net tangible book value per share attributable to new investors purchasing shares in this offering	_____
Pro forma as adjusted net tangible book value per share after this offering	_____
Dilution per share to new investors purchasing shares in this offering	\$ _____

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this

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prospectus, would increase or decrease, as applicable, the pro forma as adjusted net tangible book value per share after this offering by \$ _____ per share and the dilution to new investors purchasing common stock in this offering by \$ _____ per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase of 1.0 million shares in the number of shares offered by us would increase the pro forma as adjusted net tangible book value per share after this offering by \$ _____ and decrease the dilution per share to new investors participating in this offering by \$ _____. A decrease of 1.0 million shares in the number of shares offered by us would decrease the pro forma as adjusted net tangible book value per share after this offering by \$ _____ and increase the dilution per share to new investors participating in this offering by \$ _____, assuming the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase _____ additional shares of common stock in this offering in full at the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover of this prospectus, and assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, the pro forma as adjusted net tangible book value per share after this offering would be \$ _____ per share, and the dilution in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering would be \$ _____ per share.

The following table summarizes, on a pro forma as adjusted basis, as of June 30, 2020, the number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid and the weighted-average price per share paid by existing stockholders and by new investors in this offering at the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering		%	\$	%	\$
Investors participating in this offering					\$
Total		100%	\$	100%	

The table above assumes no exercise of the underwriters' option to purchase _____ additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to approximately _____ % of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in the offering would be increased to approximately _____ % of the total number of shares outstanding after this offering.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the total consideration paid by new investors by approximately \$ _____ million, assuming that the number of shares offered by us, as set forth on

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the cover page of this prospectus, remains the same. An increase or decrease of 1.0 million shares in the number of shares offered by us would increase or decrease, as applicable, the total consideration paid by new investors by approximately \$ million, assuming the assumed initial public offering price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, remains the same.

The number of shares of our common stock to be outstanding after this offering is based on 164,451,912 shares of our common stock outstanding as of June 30, 2020 (including an aggregate of 120,393,150 shares of common stock issuable upon conversion of our outstanding convertible preferred stock as of June 30, 2020) and including 28,020,172 shares of our common stock issuable pursuant to the conversion of our Series D convertible preferred stock issued and sold in July 2020, and excludes the following:

- 20,653,300 shares of common stock issuable upon exercise of options to purchase shares of our common stock outstanding as of June 30, 2020, with a weighted-average exercise price of \$0.50 per share;
- shares of common stock issuable upon exercise of options to purchase shares of our common stock that we granted after June 30, 2020, with a weighted-average exercise price of \$ per share;
- shares of common stock reserved for future issuance under our 2013 Equity Incentive Plan, as amended, which shares will be added to the shares to be reserved under our 2020 Equity Incentive Plan, or 2020 Plan, upon its effectiveness;
- a warrant to purchase an aggregate of 56,866 shares of our Series Seed convertible preferred stock outstanding as of June 30, 2020 that will be converted into a warrant to purchase an aggregate of 56,866 shares of our common stock, with an exercise price of \$0.3517 per share, upon the completion of this offering; and
- shares of common stock reserved for future issuance under our 2020 Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

To the extent that any outstanding options or the warrant are exercised or new options are issued under the equity benefit plans, or we issue additional shares of common stock or other securities convertible into or exercisable or exchangeable for shares of our capital stock in the future, in each case at per share prices below the price to the public in this offering, there will be further dilution to investors participating in this offering.

SELECTED FINANCIAL DATA

The following tables summarize our selected financial data for the periods and as of the dates indicated. We have derived our selected statements of operations data for the years ended December 31, 2018 and 2019 and the selected balance sheet data as of December 31, 2018 and 2019 from our audited financial statements and related notes included elsewhere in this prospectus. For interim periods, we have derived our selected statements of operations data for the six months ended June 30, 2019 and 2020 and the selected balance sheet data as of June 30, 2020 from our unaudited condensed financial statements and related notes included elsewhere in this prospectus. The unaudited condensed financial statements were prepared on a basis consistent with our audited financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future and our interim results are not necessarily indicative of our expected results for the year ending December 31, 2020. You should read the selected financial data below in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus. The selected financial data in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,		Six Months Ended June 30,	
	2018	2019	2019	2020
(in thousands, except share and per share amounts)				
Statement of operations data:				
Operating expenses:				
Research and development	\$ 13,853	\$ 20,759	\$ 10,165	\$ 11,760
General and administrative	5,039	5,878	2,676	3,979
Total operating expenses	18,892	26,637	12,841	15,739
Loss from operations	(18,892)	(26,637)	(12,841)	(15,739)
Other income (expense):				
Interest income, net	1,341	1,301	714	563
Other income (expense)	16	(8)	—	(43)
Total other income (expense)	1,357	1,293	714	520
Loss before provision for income taxes	(17,535)	(25,344)	(12,127)	(15,219)
Provision for income taxes	3	8	2	2
Net loss	\$ (17,538)	\$ (25,352)	\$ (12,129)	\$ (15,221)
Net loss per share — basic and diluted ⁽¹⁾	\$ (1.11)	\$ (1.59)	\$ (0.76)	\$ (0.95)
Weighted-average common shares outstanding — basic and diluted ⁽¹⁾	15,860,018	15,980,859	15,922,173	16,038,590
Pro forma net loss per share attributable to common stockholders — basic and diluted (unaudited) ⁽¹⁾		\$ (0.15)		\$ (0.09)
Pro forma weighted-average number of common shares — basic and diluted (unaudited) ⁽¹⁾		164,394,182		164,451,912

⁽¹⁾ See Note 11 to our audited financial statements and Note 10 to our unaudited condensed financial statements included elsewhere in this prospectus for an explanation of the method used to calculate net loss per share, basic and diluted, pro forma net loss per share, basic and diluted, and the weighted-average number of shares used in the computation of the per share amounts.

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	<u>As of December 31,</u>		<u>As of June 30,</u>
	<u>2018</u>	<u>2019</u>	<u>2020</u>
			<u>(unaudited)</u>
	(in thousands)		
Balance Sheet Data:			
Cash, cash equivalents and short-term marketable securities	\$ 61,907	\$ 101,486	\$ 86,136
Working capital ⁽¹⁾	59,912	97,570	81,704
Total assets	63,458	103,033	89,102
Total liabilities	2,370	4,574	5,177
Convertible preferred stock	107,228	168,933	168,933
Accumulated deficit	(50,088)	(75,440)	(90,661)
Total stockholder's deficit	(46,140)	(70,474)	(85,008)

(1) We define working capital as current assets less current liabilities. See our financial statements included elsewhere in this prospectus and related notes for further details regarding our current assets and current liabilities.

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 prospectus. 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 "Risk Factors" and in other parts of this prospectus.

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 \$17.5 million and \$25.4 million for the years ended December 31, 2018 and December 31, 2019, respectively, and \$12.1 million and \$15.2 million for the six months ended June 30, 2019 and June 30, 2020, respectively. As of June 30, 2020, we had an accumulated deficit of \$90.7 million. We do not currently have any product candidates in clinical trials or approved for sale, and we continue to incur significant research and development and general administrative expenses related to our operations. 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. In addition, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company. We expect to continue to incur significant losses for the foreseeable future.

We have funded our operations primarily from the issuance and sale of convertible preferred stock. As of June 30, 2020, we had \$86.1 million in cash, cash equivalents and short-term marketable securities. We believe that our existing capital resources, including \$70.0 million of gross proceeds received from the sale of 28,020,172 shares of our Series D convertible preferred stock in July 2020, will be sufficient to fund our planned operations for at least 12 months following the date of this offering.

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, depreciation and maintenance of research equipment and an allocation of related facilities costs. 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, the cost of services provided by outside contractors and the allocable portions of facility costs and general support services, 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 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

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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 Securities and Exchange Commission, 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 operate 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 Six Months Ended June 30, 2019 and 2020

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

Statement of operations data:	Six months ended June 30,		Change
	2019	2020 (unaudited)	
Operating expenses:			
Research and development	\$ 10,165	\$ 11,760	\$ 1,595
General and administrative	2,676	3,979	1,303
Total operating expenses	12,841	15,739	2,898
Loss from operations	(12,841)	(15,739)	(2,898)
Other income (expense):			
Interest income, net	714	563	(151)
Other income (expense)	—	(43)	(43)
Total other income (expense)	714	520	(194)
Loss before provision for income taxes	(12,127)	(15,219)	(3,092)
Provision for income taxes	2	2	—
Net loss	<u><u>\$ (12,129)</u></u>	<u><u>\$ (15,221)</u></u>	<u><u>\$ (3,092)</u></u>

Research and Development Expenses

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

Statement of operations data:	Six months ended June 30,		Change
	2019	2020 (unaudited)	
Research	\$ 4,720	\$ 3,207	\$(1,513)
Pre-clinical development	2,600	4,593	1,993
Personnel related	2,718	3,640	922
Stock-based compensation	127	320	193
Total	<u><u>\$10,165</u></u>	<u><u>\$ 11,760</u></u>	<u><u>\$ 1,595</u></u>

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Research and development expenses were \$10.2 million for the six months ended June 30, 2019, compared to \$11.8 million for the six months ended June 30, 2020. The increase of \$1.6 million was primarily due to the following:

- There was a decrease of \$1.5 million in research expense which was driven by a decline in costs from certain of our contract manufacturing initiatives.
- There was a \$2.0 million increase in our preclinical studies which were primarily associated with increased effort in developing our lead compound PC14586 through IND enabling studies.
- There was a \$0.9 million increase in compensation and employee related expenses, primarily driven by increases in salaries and bonus expense associated with increased headcount for personnel dedicated to developing PC14586.
- There was a \$0.2 million increase in stock-based compensation expense associated with increased headcount for personnel dedicated to developing PC14586.

General and Administrative Expenses

General and administrative expenses were \$2.7 million for the six months ended June 30, 2019, compared to \$4.0 million for the six months ended June 30, 2020. The increase of \$1.3 million was primarily due to the following:

- There was an increase in salary and bonus expense of \$0.5 million and an increase in personnel related costs of \$0.2 million associated with increased headcount to develop our financial and administrative staff. These increases were partially offset by a decrease in travel and entertainment expense of \$0.1 million.
- There was a \$0.3 million increase in expense for legal services, which is primarily driven by increased legal costs associated with international patent filings in selected countries during the six months ended June 30, 2020.
- There was a \$0.2 million increase in administrative consulting, primarily associated with increased costs with augmenting our administrative staff.

Interest Income, Net

Interest income, net was \$0.7 million for the six months ended June 30, 2019, compared to \$0.6 million for the six months ended June 30, 2020. The decrease of \$0.1 million is driven by decreased income from cash investments in marketable securities and U.S treasuries during the six months ended June 30, 2020.

[Table of Contents](#)**Comparison of the Years Ended December 31, 2018 and 2019**

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

Statement of operations data:	Year ended December 31,		Change
	2018	2019	
Operating expenses:			
Research and development	\$ 13,853	\$ 20,759	\$ 6,906
General and administrative	5,039	5,878	839
Total operating expenses	18,892	26,637	7,745
Loss from operations	(18,892)	(26,637)	(7,745)
Other income (expense):			
Interest income, net	1,341	1,301	(40)
Other income (expense)	16	(8)	(24)
Total other income (expense)	1,357	1,293	(64)
Loss before provision for income taxes	(17,535)	(25,344)	(7,809)
Provision for income taxes	3	8	5
Net loss	<u>\$(17,538)</u>	<u>\$(25,352)</u>	<u>\$(7,814)</u>

Research and Development Expenses

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

Statement of operations data:	Year ended December 31,		Change
	2018	2019	
Research	\$ 7,516	\$ 9,364	\$ 1,848
Pre-clinical development	1,179	5,811	4,632
Personnel related	4,844	5,282	438
Stock-based compensation	314	302	(12)
Total	<u>\$13,853</u>	<u>\$20,759</u>	<u>\$6,906</u>

Research and development expenses were \$13.9 million for the year ended December 31, 2018, compared to \$20.8 million for the year ended December 31, 2019. The increase of \$6.9 million was primarily due to the following:

- There was a \$1.8 million increase in research expense, driven primarily by a \$1.3 million increase in outside laboratory analytics, \$0.8 million increase in technical consulting, partially offset by a decrease of \$0.4 million in scientific contract expense.
- There was a \$4.6 million increase in preclinical development, which was primarily associated with increased effort in developing our lead candidate, PC14586. The \$4.6 million increase in preclinical studies is primarily driven by the initiation of an investigational new drug, or IND, enabling study for the Y220C mutation, for which we incurred approximately \$2.0 million in expense for the year ended December 31, 2019.
- There was an \$0.4 million increase in expenses for salaries and bonuses, primarily driven by increased headcount for personnel dedicated to developing PC14586.

General and Administrative Expenses

General and administrative expenses were \$5.0 million for the year ended December 31, 2018, compared to \$5.9 million for the year ended December 31, 2019. The increase of \$0.9 million was primarily due to the following:

- There was a \$0.4 million increase in expense for employee compensation, driven primarily by increased salary and bonus expense of \$0.5 million, partially offset by a decrease in stock-based compensation expense of \$0.2 million.
- There was a \$0.3 million increase in expense for outside services, which is primarily driven by increased legal costs of \$0.2 million associated for patent expenses and reviews of contracts executed with third-party contract research and manufacturing organizations during the year ended December 31, 2019.
- There was a \$0.2 million increase associated with facility related expenses during the year ended December 31, 2019.

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. Interest income, net was \$1.3 million for the year ended December 31, 2018, compared to \$1.3 million for the year ended December 31, 2019. There was no change in interest income, net for the year ended December 31, 2019 and December 31, 2018, due to a decrease in interest income of \$0.3 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, which was offset by a decrease of \$0.3 million of interest expense for the year ended December 31, 2019 compared to the year ended December 31, 2018.

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 June 30, 2020, we had cash, cash equivalents and short-term marketable securities of \$86.1 million and an accumulated deficit of \$90.7 million. We have financed our operations primarily through issuances of our convertible preferred stock. In 2019, we sold an aggregate of 28,798,050 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 28,020,172 shares of our Series D convertible preferred stock to accredited investors, generating gross proceeds of \$70.0 million.

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

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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 \$90.7 million through June 30, 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 the net proceeds from this offering, together with our existing cash, cash equivalents and short-term marketable securities, which includes the gross proceeds of approximately \$70.0 million from the Series D financing, will be sufficient to fund our operations through . 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,		Six months ended June 30,	
	2018	2019	2019	2020 (unaudited)
Cash used in operating activities	\$(15,178)	\$(22,065)	\$(11,211)	\$ (15,034)
Cash provided by investing activities	21,693	3,231	22,774	19,931
Cash provided by (used in) financing activities	—	61,805	100	(124)
Net increase in cash, cash equivalents and restricted cash	<u>\$ 6,515</u>	<u>\$ 42,971</u>	<u>\$ 11,663</u>	<u>\$ 4,773</u>

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2019, was \$11.2 million, which consisted primarily of net loss of \$12.1 million decreased by non-cash charges of \$0.7 million and by a net change of \$0.3 million in our net operating assets. The non-cash charges primarily consisted of stock-based compensation of \$0.4 million and depreciation of \$0.2 million. The change in our net operating assets and liabilities was primarily due to an increase in accrued compensation and accrued liabilities and outstanding payables in 2019.

Net cash used in operating activities for the six months ended June 30, 2020, was \$15.0 million, which consisted primarily of net loss of \$15.2 million decreased by non-cash charges of \$1.1 million partially offset by a net change of \$0.9 million in our net operating assets. The non-cash charges primarily consisted of stock-based compensation of \$0.7 million and depreciation and amortization expense of \$0.3 million. The change in our net operating assets and liabilities was primarily due to a decrease in outstanding payables in 2020.

Net cash used in operating activities for the year ended December 31, 2018, was \$15.2 million, which consisted primarily of net loss of \$17.5 million decreased by non-cash charges of \$1.7 million and by a net change of \$0.6 million in our net operating assets. The non-cash charges primarily consisted of stock-based compensation of \$1.1 million, depreciation of \$0.3 million and amortization of premiums on marketable securities of \$0.3 million. The change in our net operating assets and liabilities was primarily due to an increase in accrued liabilities and outstanding payables in 2018.

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 \$22.7 million of cash during the six months ended June 30, 2019, which consisted primarily of maturities of marketable securities of \$33.6 million, partially offset by purchases of marketable securities of \$10.7 million and purchases of property and equipment of \$0.1 million.

Our investing activities provided \$19.9 million of cash during the six months ended June 30, 2020, which consisted primarily of maturities of marketable securities of \$34.6 million, partially offset by purchases of marketable securities of \$14.6 million and purchases of property and equipment of \$0.1 million.

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Our investing activities provided \$21.7 million of cash during the year ended December 31, 2018, which consisted primarily of maturities of marketable securities of \$70.8 million, partially offset by purchases of marketable securities of \$48.7 million and purchases of property and equipment of \$0.5 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 \$0.1 million of cash during the six months ended June 30, 2019, which consisted primarily of exercises of stock options of \$0.1 million.

Our financing activities used \$0.1 million of cash during the six months ended June 30, 2020, which consisted primarily of payments of deferred offering costs associated with incremental legal, professional and other third-party fees directly associated with the planned IPO.

We had no cash flows from financing activities for the year ended December 31, 2018.

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, 2019 (in thousands):

	<u>Less than 1 year</u>	<u>1 to 3 years</u>	<u>3 to 5 years</u>	<u>More than 5 years</u>	<u>Total</u>
Operating lease obligations:	\$ 479	\$ 730	\$ 4	\$ —	\$ 1,213
Total:	<u>\$ 479</u>	<u>\$ 730</u>	<u>\$ 4</u>	<u>\$ —</u>	<u>\$ 1,213</u>

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.

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.

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. Due to the nature of specific terms of our nonemployee share option arrangements, we determined the contractual term is the appropriate expected term to be used in estimating the fair value of the nonemployee share options.
- *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.

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- *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 this offering, the fair value of the shares of common stock underlying the stock-based awards has been determined by our board of directors with input from management. Because there has been no public market for our common stock, our board of directors has 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 June 30, 2020, the total unrecognized compensation expense related to unvested employee and non-employee options was \$3.6 million, which we expect to recognize over an estimated weighted-average period of 2.9 years. Based upon the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, the aggregate intrinsic value of options outstanding as of June 30, 2020 was \$ million, of which \$ million related to vested options and \$ million related to unvested options.

Common Stock Valuations

The fair value of the shares of common stock underlying our stock-based awards has historically been determined by our board of directors with input from management and contemporaneous third-party valuations. We believe that our board of directors has the relevant experience and expertise to determine the fair value of our common stock. 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;

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- 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.

For valuations after the completion of this offering, our board of directors will determine the fair value of each share of underlying common stock 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, 2019 included elsewhere in this prospectus.

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 this prospectus and 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 complete this 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 this 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 this prospectus and 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.

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 \$78.1 million and short-term marketable securities of \$8.1 million as of June 30, 2020, which consists of interest-bearing U.S. treasury securities, money market funds and corporate debt securities. 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.

BUSINESS

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.

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. We are initially pursuing a tumor-agnostic development strategy and plan to submit our investigational new drug application, or IND, for PC14586 and start a Phase 1/2 clinical trial in the second half of 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. 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 U.S. Food and Drug Administration, or 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.*, only functions in cells with the p53 Y220C mutation) and exhibited robust anti-tumor activity evidenced by potent tumor growth inhibition, or TGI, and complete 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 plan to submit an IND for PC14586 and start a Phase 1/2 clinical trial in the second half 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. We intend to advance PC14586 into a Phase 1/2 clinical trial in multiple solid tumors with the p53 Y220C mutation in the second half of 2020. 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. We also plan to explore pursuing certain expedited regulatory pathways, such as fast track or breakthrough therapy designation, as well as orphan drug designation.
- **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 plan to work 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 plan to 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. Since inception, our vision has been supported by leading investors, including InterWest Partners, OrbiMed Advisors, Topspin, Euclidean Capital, Nextech Invest, Viking Global Investors, Boxer Capital of Tavistock Group and Osage University Partners.

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 Senior Vice President of Regulatory Affairs and Quality Assurance, 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;
- 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 (Merck), 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 expect to advance our next program, targeting p53 R273H mutations, into lead optimization in the second half of 2020. 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 ¹	Lead Optimization ²	IND-Enabling Studies ³	Phase 1	Phase 2	Phase 3	Next Key Anticipated Milestone	
p53 Y220C	PC14586	Tumor Agnostic								Phase 1/2 Trial Initiation 2H 2020
p53 R273H	Undisclosed	Tumor Agnostic							Enter Lead Optimization 2H 2020	

- (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.

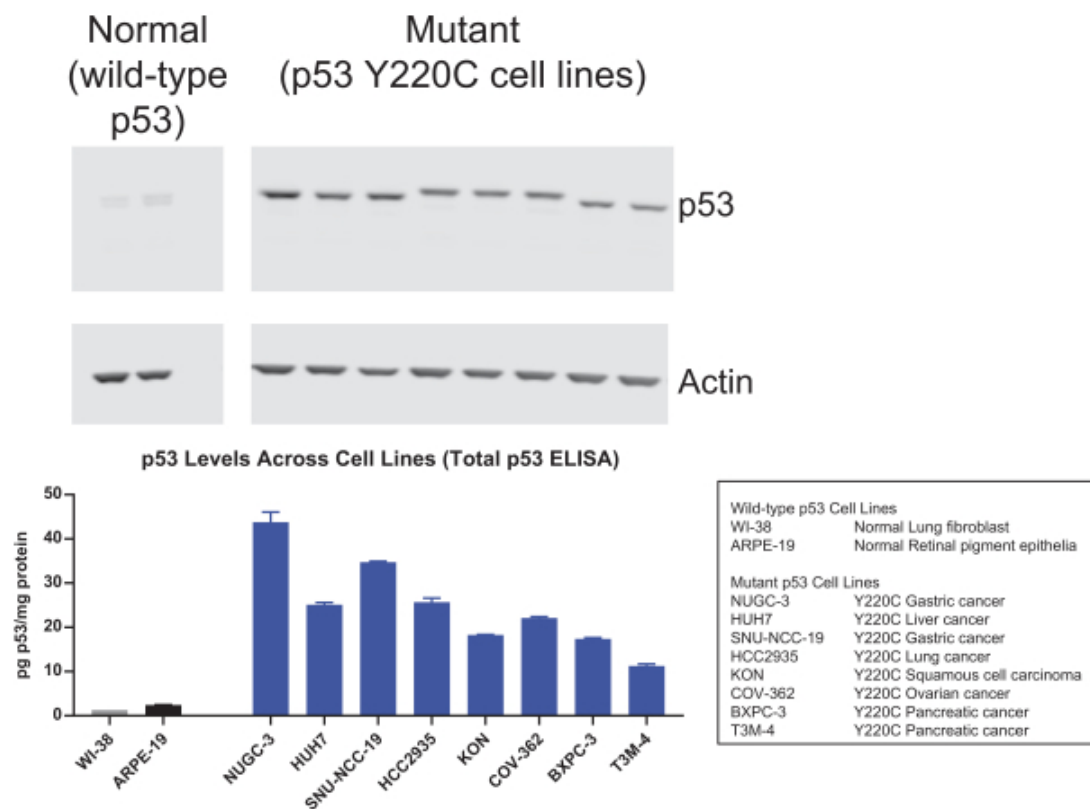
PC14586: A Selective Structural Corrector of p53 Y220C Mutations

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.

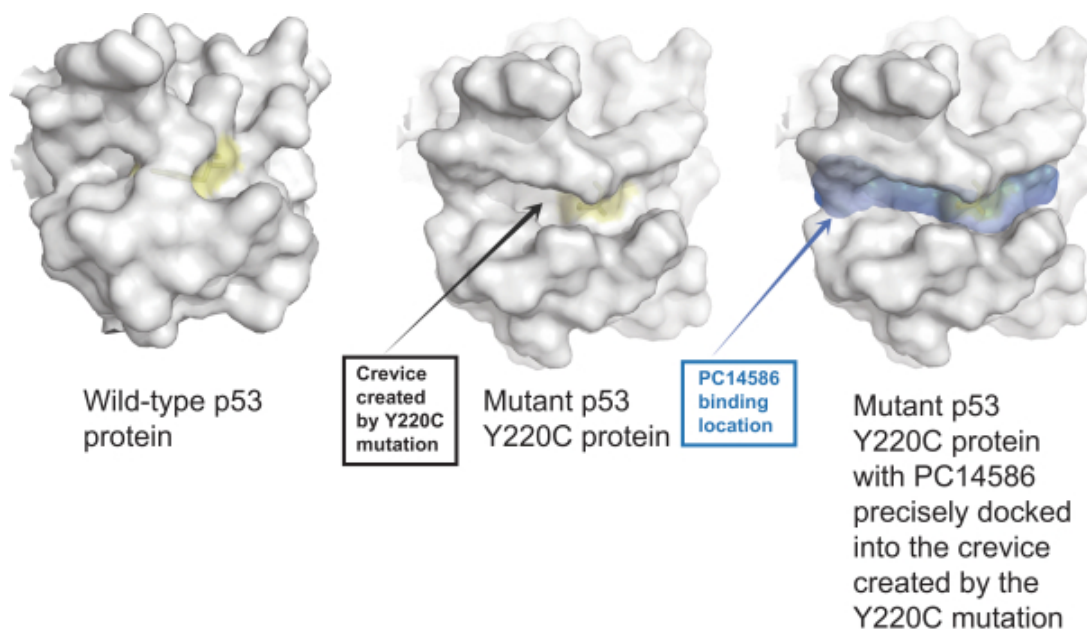
Y220C Mutant Cancer Cell Lines Contain Large Pools of Mutant p53 Y220C Target Protein Relative to Normal (Wild-type p53) Cell Lines



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.

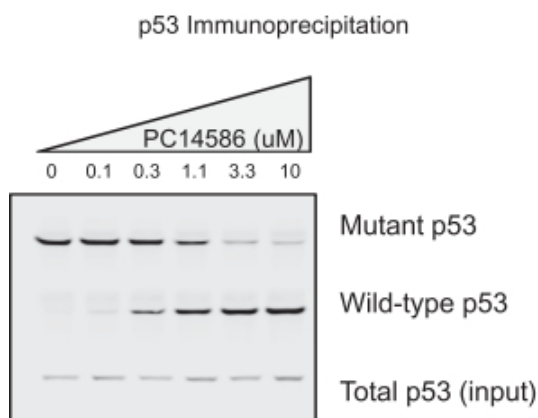
Mechanism of Action

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 precisely 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.

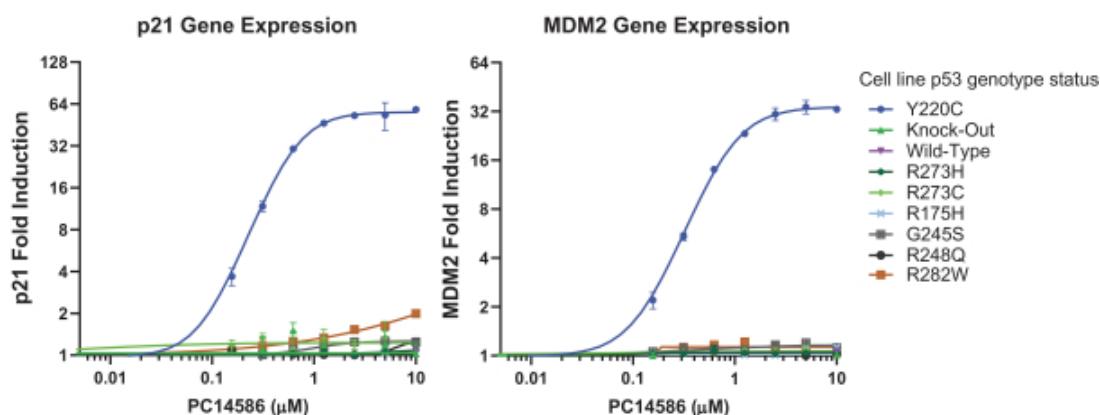
PC14586 Demonstrated Structural Conversion from Mutant p53 to Wild-type p53 *in vitro*



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 such as 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 seen 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.

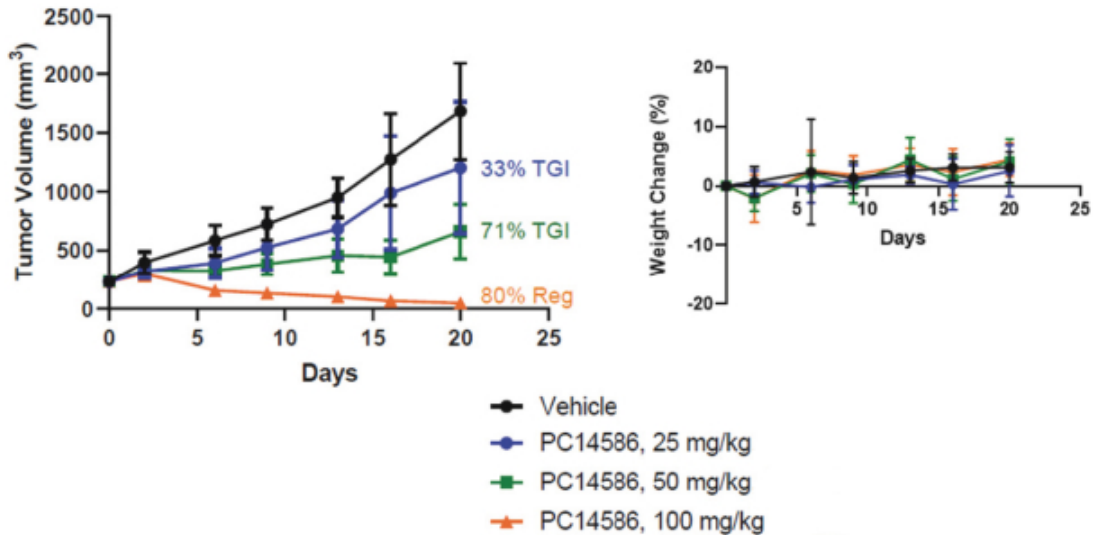
PC14586 Induced Transcription of p21 and MDM2 Only in Cell Lines with the p53 Y220C Mutation



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 20 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.

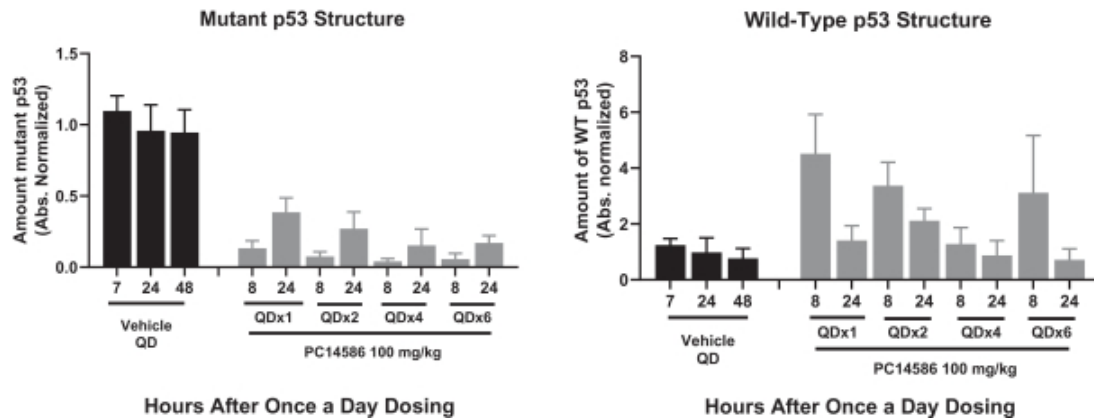
In the mutant p53 structure chart below, the amount of mutant p53 decreased at 8 hours after PC14586 administration on day 1 (QDx1), and the amount of mutant p53 rose by the 24 hour time point compared to the 8 hour time point in the QDx1 portion of the x-axis. When another dose of PC14586 was administered 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 *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

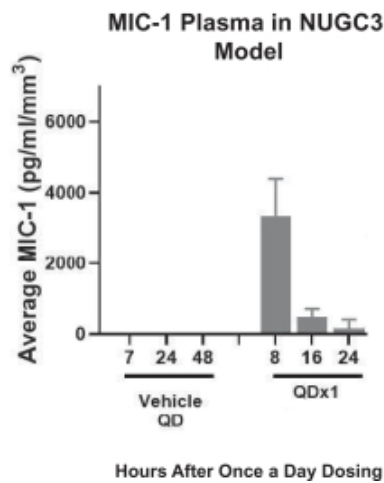
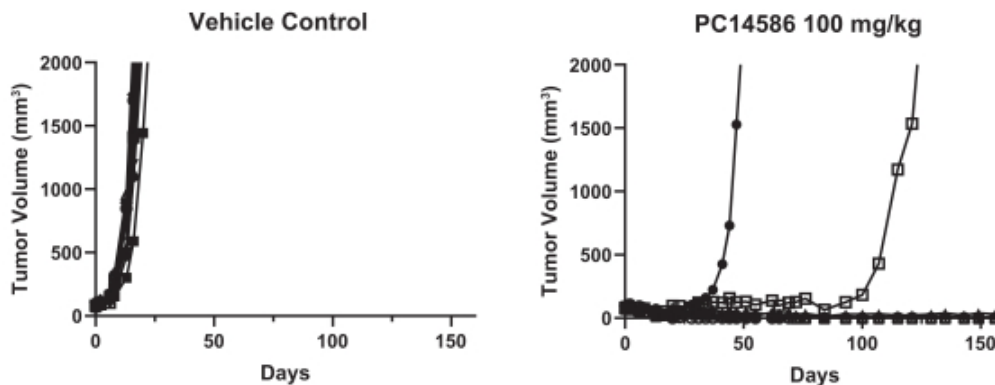


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We also created a human p53 knock-in, or HUPKI, mouse that expresses a p53 protein with the human p53 DNA binding domain and the p53 Y220C mutation. The HUPKI mouse presents spontaneously with sarcomas at six to eight months of age, which we can harvest 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 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

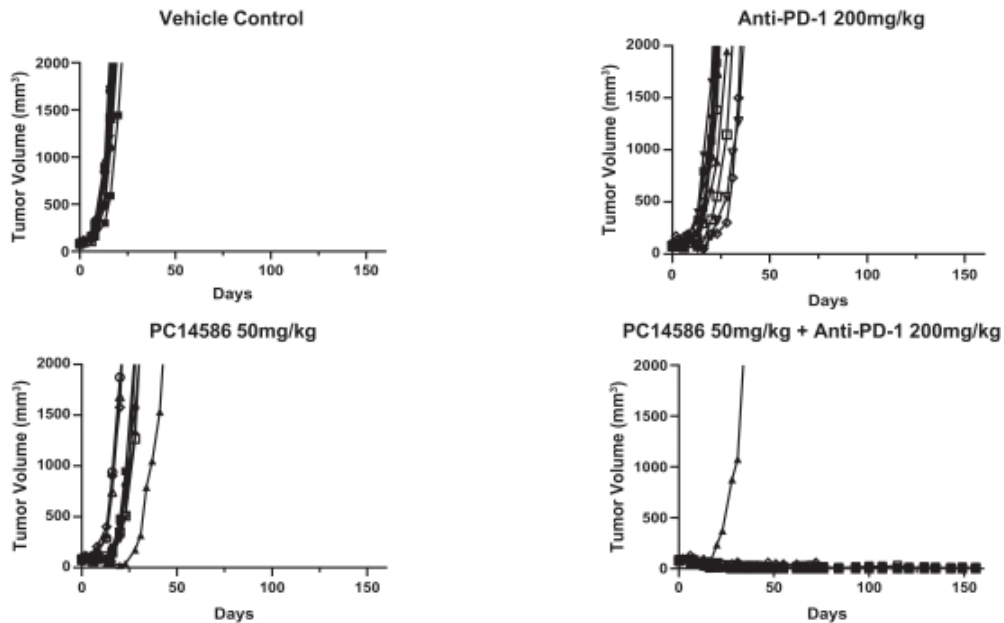
Note: Dosing ceased on day 70 in the PC14586 arm.

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 its impact on 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

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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 plan to submit our IND for PC14586 and start a Phase 1/2 clinical trial in the second half of 2020. 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

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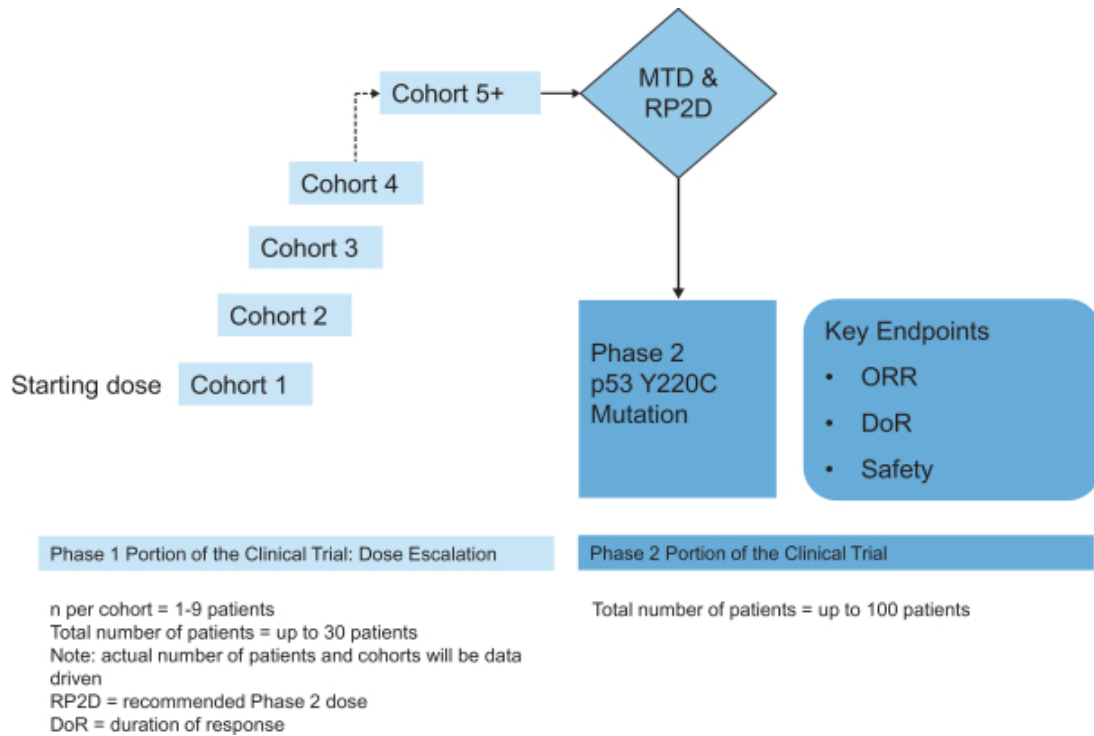
candidates, including Amgen (AMG 510), Mirati (MRTX849) and Black Diamond Therapeutics (BDTX-189), we believe our Phase 1/2 clinical trial has the potential to serve as a pivotal study. In our Phase 1/2 clinical trial, we plan to enroll patients with advanced solid tumors that harbor the p53 Y220C mutation, characterized by NGS of either a solid or blood-based (circulating serum tumor DNA) biopsy. The study employs an accelerated titration design, with the potential to expedite development of this product candidate by allowing dose escalation in single patients at each dose cohort until a ³ Grade 2 adverse event is observed. Subsequently in the Phase 1 portion of the trial, we plan to employ a modified toxicity probability interval, or mTPI, approach to identify the MTD.

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 Phase 1 portion involves dose escalation allowing single patient cohorts until ³ grade 2 drug-related adverse events are observed. The study utilizes a mTPI approach to enroll three or more patients per cohort until the MTD is reached and the Phase 2 dose is selected. 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 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.

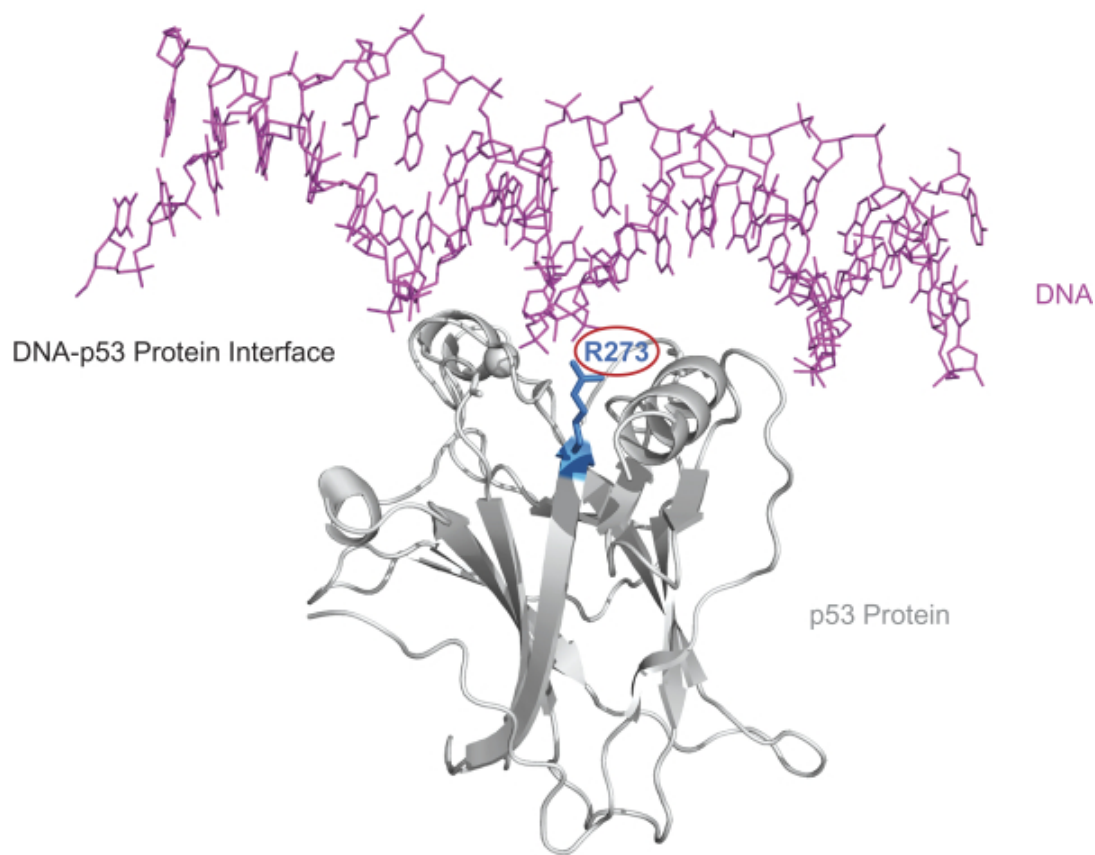
We may also seek fast track, orphan drug or breakthrough therapy designation from the FDA. In addition, we may engage in health authority interactions with agencies outside the United States such as in Europe and Japan, for example. We plan to collaborate with a partner to develop a companion diagnostic test.

R273H: Our Second Program

We expect to advance our next program, targeting the p53 R273H hotspot mutation, into lead optimization in the second half of 2020. 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

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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 does 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. We expect to advance this program into lead optimization in the second half of 2020.

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, 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, 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 June 1, 2020, we owned two issued US patents relating to methods of use and composition of matter of PMV compounds, including PC14586, and two pending US patent applications and 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. As of June 1, 2020, we owned one pending US patent application relating to methods of use and composition of matter of other PMV compounds.

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, in March 2020, as amended and updated from time to time, the FDA issued a guidance 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.

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;

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- 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

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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 addition, there may be other efforts to challenge, repeal or replace the ACA. 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. The CARES Act, which was signed into law on March 27, 2020, and designed to provide financial support and resources to individuals and businesses affected by COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020, through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the 2020 suspension.

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. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration's budget proposal for the fiscal year 2021 includes a \$135 billion 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 drugs. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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

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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 July 29, 2020, we had 38 full-time employees, including 16 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.

Facilities

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 that expires in July 2022. 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 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.

Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. As of the date of this prospectus, 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.

MANAGEMENT

Executive Officers, Directors and Key Employees

The following table sets forth the names, ages and positions of our executive officers, directors and key employees as of the date of this prospectus:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Executive Officers:		
David H. Mack, Ph.D.	58	President, Chief Executive Officer and Director
Winston Kung	45	Chief Operating Officer and Chief Financial Officer
Leila Alland, M.D.	58	Chief Medical Officer
Deepika Jalota, Pharm.D.	44	Senior Vice President, Head of Regulatory Affairs
Non-Employee Directors:		
Richard Heyman, Ph.D.	62	Director and Chairman of the Board of Directors
Arnold Levine, Ph.D.	81	Director
Arnold Oronsky, Ph.D.	80	Director
Thilo Schroeder, Ph.D.	39	Director
Peter Thompson, M.D.	61	Director
Key Employees:		
Thomas Davis, Ph.D.	57	Vice President, Biology
Melissa Dumble, Ph.D.	45	Vice President, Pharmacology and Translational Medicine
Binh Vu, Ph.D.	52	Vice President, Chemistry

(1) Member of the audit committee

(2) Member of the compensation committee

(3) Member of the corporate governance and nominating committee

Executive Officers

David H. Mack, Ph.D. has served as a member of our board of directors since June 2013 and as our Chief Executive Officer and President since July 2013. Previously, Dr. Mack was a general partner at Alta Partners, a venture capital firm focusing on investments in biotechnology and life sciences companies, from 2002 to 2012. Prior to working at Alta Partners, Dr. Mack served as Vice President of Genomics Research at Eos Biotechnology, which was acquired by Protein Design Labs in 2003. From 1994 to 1997, Dr. Mack served as the Head of Cancer Biology at Affymetrix, a biotechnology company that was acquired by Thermo Fisher (NYSE: TMO) in January 2016, where he oversaw the development and application of DNA array technology in the areas of oncology and inflammation. Dr. Mack is a member of the board of directors of Aduro BioTech (NASDAQ: ADRO), a biopharmaceutical company. Dr. Mack has co-authored more than 30 scientific articles and reviews, including papers published in *Cell*, *Science*, and *Nature*, and is an inventor on 26 issued US patents. Dr. Mack was an American Cancer Society Postdoctoral Fellow in microbiology and immunology at Stanford University School of Medicine. Dr. Mack received a B.A. in Molecular Biology from the University of California, Berkeley and a Ph.D. in Molecular Genetics and Cell Biology from the University of Chicago. We believe that Dr. Mack is qualified to serve on our board of directors because of the perspective and experience he provides as our Chief Executive Officer as well as his broad experience in the biotechnology and life sciences industries.

Winston Kung has served as our Chief Operating Officer and Chief Financial Officer since December 2017. From April 2013 to November 2017, Mr. Kung worked at Celgene Corporation, a global biopharmaceutical company, where he held multiple positions, including Vice President of

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Business Development and Global Alliances, and Chief Business Officer at Celgene Cellular Therapeutics (a wholly-owned subsidiary of Celgene Corporation). At Celgene, Mr. Kung led the formation of a strategic long-range plan for the company, along with overseeing multiple transactions and a team that managed the company's alliance portfolio of over 100 collaborations, equity investments and company integrations. Prior to working at Celgene, Mr. Kung worked at Citigroup from June 2010 to April 2013 in its Global Healthcare Investment Banking group and at Lehman Brothers (which was subsequently acquired by Barclays) from May 2007 to June 2010 in its Global Mergers and Acquisition Group. At Citigroup and Barclays, Mr. Kung worked on various transactions including public and private financings, merger and acquisitions, spin-outs and other financial advisory engagements. From August 2004 to May 2007, Mr. Kung worked at Amgen (NASDAQ: AMGN), a global biopharmaceutical company, as a co-founder of the Alliance Management group, and served as the deal lead on multiple acquisitions as part of the Corporate Development group. Mr. Kung also worked at Genentech, a biotechnology company (acquired by Roche), from November 1999 to September 2002 as part of the Business and Corporate Development group. Mr. Kung previously served on the board of directors of Alliqua BioMedial (NASDAQ: ALQA) and GNS Healthcare, a private, healthcare artificial intelligence company. Mr. Kung received a B.A. in Biology and International Relations from Brown University and a MBA from Harvard Business School.

Leila Alland, M.D. has served as our Chief Medical Officer since December 2019. From March 2018 to November 2019, Dr. Alland served as the Chief Medical Officer at Affimed, a clinical stage immune-oncology company. Dr. Alland served as the Chief Medical Officer at Tarveda Therapeutics, a biotechnology company, from January 2016 to March 2018. Previously, Dr. Alland served as the Vice President and Head of Oncology Early Clinical Development at AstraZeneca (NYSE: AZN) from October 2013 to December 2015. Dr. Alland has also held leadership positions at Bristol-Myers Squibb (NYSE: BMY) from April 2006 to September 2013, Novartis from November 2003 to March 2006 and Schering-Plough from June 2001 to November 2003, where she worked on a broad range of oncology products from early to late stage development and contributed to multiple successful drug approvals. From September 1994 to June 2000, Dr. Alland served as Assistant Professor of Pediatrics at Albert Einstein College of Medicine, where she was awarded the James S. McDonnell Foundation Scholar Award and pursued basic cancer research. Dr. Alland sits on the Scientific Advisory Council of Columbia University's Center for Radiological Research and serves as a reviewer for the Cancer Prevention and Research Institute of Texas. Dr. Alland serves as a member of the board of directors of Cytovia Therapeutics. Dr. Alland received a B.A. in Biology from the University of Pennsylvania and a M.D. from New York University School of Medicine. Dr. Alland completed her residency in Pediatrics at The Children's Hospital of Philadelphia and her fellowship in Pediatric Hematology/Oncology at The New York Hospital and Memorial Sloan-Kettering Cancer Center.

Deepika Jalota, Pharm.D. has served as our Senior Vice President and Head of Regulatory Affairs since June 2019. Previously, Dr. Jalota was employed by Bayer HealthCare Pharmaceuticals from July 2007 to May 2019 and held multiple leadership positions within Global Regulatory Affairs in oncology and other therapeutic areas. She was most recently Vice President, Global Regulatory Strategy, Oncology from July 2017 to June 2019 and was responsible for overseeing global regulatory strategy development for multiple early and late stage oncology assets. Dr. Jalota also served as Senior Director, Global Regulatory Strategy, Oncology from June 2016 to July 2017 and Director and Head of Global Regulatory Strategy, Dermatology and Ophthalmology from January 2014 to June 2016. Prior to joining Bayer HealthCare Pharmaceuticals, Dr. Jalota was employed by Sanofi-Aventis, Forest Laboratories and Procter and Gamble. Dr. Jalota received a B.S. in Pharmacy from Rutgers University, Ernest Mario School of Pharmacy and a Pharm.D. from the University of Florida, College of Pharmacy.

Non-Employee Directors

Richard Heyman, Ph.D. has served as a member of our board of directors and as our Chairman of our board of directors since June 2020. Dr. Heyman has served on the board of directors of ORIC Pharmaceuticals (NASDAQ: ORIC), a clinical-stage biopharmaceutical company, since March 2015 and was appointed the chairman of the board of directors in May 2018. Dr. Heyman also served as ORIC Pharmaceuticals's President and Chief Executive Officer, from November 2015 to May 2016, and as Acting President and Chief Executive Officer, from November 2017 to May 2018. Since June 2015, he has served as the Executive Chairman and Co-Founder of Metacrine, a private biotechnology company. Since 2019, Dr. Heyman has served as a venture partner for Arch Ventures, a venture capital firm. From August 2013 to April 2015, Dr. Heyman served as President and Chief Executive Officer of Seragon Pharmaceutical, which was acquired by Roche Genentech in 2014. Prior to that, he served as Co-Founder, President and Chief Executive Officer of Aragon Pharmaceuticals, a biotechnology company that was acquired by Johnson & Johnson (NYSE: JNJ), a medical device, pharmaceutical and consumer packaged goods company, in 2013. Dr. Heyman currently also serves on the board of directors of Gritstone Oncology (NASDAQ: GRTS), an oncology company. He is Vice Chair of the Board of Trustees at the Salk Institute and serves on the Board Foundation for the American Association for Cancer Research and on the executive committee at the University of California at San Diego Moores Cancer Center. Dr. Heyman received a B.S. in Chemistry from the University of Connecticut and a Ph.D. in Pharmacology from the University of Minnesota. We believe that Dr. Heyman is qualified to serve on our board of directors because of his perspective having served as both an executive and director of similar corporations, including public companies, his scientific background and his extensive career in the biotechnology industry.

Arnold Levine, Ph.D. has served as a member of our board of directors since June 2013. Since 2011, Dr. Levine has served as a Professor Emeritus at The Simons Center for Systems Biology at the Institute for Advanced Study in Princeton, New Jersey, an institute he helped establish. Dr. Levine trained as a Postdoctoral Fellow at California Institute of Technology in the laboratory of Robert Sinsheimer. Dr. Levine is a widely acclaimed leader in cancer research. Dr. Levine currently serves on the board of directors of Meira GTX (NASDAQ: MGTX), a clinical-stage gene therapy company, GeneCentric Therapeutics, a private biomarker producer, and Chugai Pharmabody Research, a subsidiary of Chugai Pharmaceutical focused on utilizing proprietary antibody engineering technologies. Dr. Levine previously was a member of the board of directors of Adaptive Biotechnologies (NASDAQ: ADPT), a commercial-stage biotechnology company. In 1979, Dr. Levine and others discovered the p53 tumor suppressor protein. Dr. Levine helped shape U.S. science priorities as chairman of an influential 1996 review panel on federal AIDS research funding. He also chaired the National Cancer Advisory Board, which advises the National Academy of Sciences and its Institute of Medicine on cancer policy. He was elected to the National Academy of Sciences in 1991 and to its Institute of Medicine in 1995. In April 2001, Levine received the first Albany Medical Center Prize in Medicine and Biomedical Research, the largest annual prize in science or medicine offered in the United States. In 1968, Dr. Levine joined Princeton University as an Assistant Professor, becoming a Professor of biochemistry in 1976. In 1979, he moved to the SUNY Stony Brook School of Medicine to Chair the Department of Microbiology. He returned to Princeton in 1984 and between 1984 and 1996, he presided over a major expansion of Princeton's life sciences programs as Chairman of the Department of Molecular Biology. From 1998 to 2002, Dr. Levine was President of the Rockefeller University. Dr. Levine received a B.A. from Harpur College, State University of New York and a Ph.D. in Microbiology from the University of Pennsylvania. We believe Dr. Levine is qualified to serve on our board of directors due to his extensive academic and professional experience in cancer research and molecular biology.

Arnold Oronsky, Ph.D. has served as a member of our board of directors since July 2013. Dr. Oronsky is a Managing Partner at InterWest Venture Management Company, a venture capital firm

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investing primarily in information technology and healthcare companies. Dr. Oronsky has worked at InterWest Partners since 1994. In addition, Dr. Oronsky also serves as a Senior Lecturer in the Department of Medicine at Johns Hopkins Medical School. Prior to joining InterWest Partners, Dr. Oronsky served as the Vice President for discovery research of the Lederle Laboratories division of American Cyanamid Company, where he directed the research for new drugs. Dr. Oronsky has published over 125 scientific articles and has served on the board of directors of Centrexion Therapeutics since 2013, Dynavax Technologies (NASDAQ: DVAX) since 1996, Epicent Rx since 2003, KalVista Pharmaceuticals (NASDAQ: KALV) since 2016, Prothex Pharmaceuticals since 2007 and Sera Prognostics since 2015. Dr. Oronsky previously served as a director of Applied Genetic Technologies (NASDAQ: AGTC) from 2003 to 2017 and Tesaro, a biopharmaceutical company acquired by GSK, from 2011 to 2018. Dr. Oronsky received a A.B. degree in History from New York University and a Ph.D. in Immunology from Columbia University. We believe Dr. Oronsky is qualified to serve on our board of directors because of his experience in the healthcare industry as well as his prior experience on the boards of U.S. private and public companies.

Thilo Schroeder, Ph.D. has served as a member of our board of directors since November 2019. Dr. Schroeder is a Partner at Nextech Invest Ltd. and has worked there since July 2012. Dr. Schroeder began his career at the pioneering cancer immunology company Micromet (acquired by Amgen) while studying at Ecole Supérieure de Biotechnologie de Strasbourg (ESBS) and conducting research at the University of Sydney. Dr. Schroeder currently serves as a member of the board of directors of Revolution Medicines (NASDAQ: RVMD), IDEAYA Biosciences (NASDAQ: IDYA), Circle Pharma, Silverback Therapeutics and MOMA Therapeutics. Dr. Schroeder was previously a member of the board of directors of ImaginAb, Blueprint Medicines (NASDAQ: BPMC) and Peloton Therapeutics (acquired by Merck). Dr. Schroeder studied biotechnology, protein biochemistry and process engineering at ESBS and received a Ph.D. in Biochemistry from the University of Zurich. We believe Dr. Schroeder is qualified to serve on our board of directors due to his professional experience as well as his prior experience serving on the boards of U.S. private and public companies.

Peter Thompson, M.D. has served as a member of our board of directors since November 2014. Dr. Thompson is a Private Equity Partner at OrbiMed Advisors LLC, an investment firm focused on the healthcare sector, where he previously served as a Venture Partner. Dr. Thompson currently serves on the board of directors of Alpine Immune Sciences (NASDAQ: ALPN), a clinical-stage immunotherapy company, Corvus Pharmaceuticals (NASDAQ: CRVS), a clinical-stage precision medicine company, and Prevail Therapeutics (NASDAQ: PRVL), a precision medicine company focusing on neurodegenerative disorders. Dr. Thompson also currently serves on the board of directors of several private companies. Dr. Thompson has previously served on the board of directors of Adaptimmune Therapeutics (NASDAQ: ADAP), a clinical-stage biopharmaceutical company, Principia Biopharma (NASDAQ: PRNB), a late-stage biopharmaceutical company, and Synthorx (NASDAQ: THOR), a clinical-stage biotechnology company. Dr. Thompson has cofounded numerous companies, including Edgewise Therapeutics, Silverback Therapeutics and Cleave Biosciences. Dr. Thompson also previously served in executive leadership roles at Trubion Pharmaceuticals, Chiron and Becton, Dickinson and Company. Dr. Thompson is an Affiliate Professor of Neurosurgery at the University of Washington. In addition, Dr. Thompson holds numerous patents and is a board-certified internist and oncologist. Dr. Thompson received a B.S. in Molecular Biology and Mathematics from Brown University and a M.D. from Brown University Medical School. We believe Dr. Thompson's experience in management and venture capital in the biopharmaceutical industry provides him with the qualifications and skills to serve as a member of our board of directors.

Key Employees

Thomas Davis, Ph.D. has served as our Vice President of Biology since March 2016. Prior to joining our company, Dr. Davis was Vice President of Preclinical Oncology and PTC Therapeutics,

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where he was responsible for building and developing the internal oncology portfolio. During his 13 year tenure at PTC Therapeutics, Dr. Davis's group developed three drug candidates, two of which (PTC299 and PTC596) have entered clinical trials. His industry experience began at Pharmacia Corporation, where he led a team tasked with expanding the selective COX2 inhibitor celecoxib (Celebrex, Pfizer) into the oncology arena. Dr. Davis has co-authored over 20 manuscripts and is an inventor on over 10 issued U.S. patents. Dr. Davis received a B.S. in Microbiology from Iowa State University and a Ph.D. in Microbiology and Immunology from the University of Kentucky. He also completed a Postdoctoral Fellowship at the University of Wisconsin, Madison.

Melissa Dumble, Ph.D. has served as our Vice President of Pharmacology and Translational Medicine since October 2017. Prior to joining our company, Dr. Dumble was a Research Leader at Bristol-Myers Squibb (BMS, Lawrenceville site) developing small molecules to regulate tumor intrinsic targets that may sensitize cancers to immuno-oncology agents. Before her tenure at BMS, she worked at PTC Therapeutics and Enzon Pharmaceuticals, leading drug discovery projects in oncology, infectious disease and genetic disorders from lead optimization to clinical trials. Dr. Dumble began her career at GSK Oncology, training as a pharmacologist and working on many of the marketed kinase inhibitors (e.g. Votrient™, Mekinist™, Tafenlar™). In addition, she led the team of scientists developing an oral Akt inhibitor to clinical trials. Dr. Dumble has co-authored over 20 manuscripts and is an inventor on 5 issued patents. Dr. Dumble received a B.S. in Biochemistry and Human Biology and a Ph.D. in Cell and Molecular Biology from the University of Western Australia. She also completed a Postdoctoral Fellowship at Baylor College of Medicine, Houston. Her studies were based on understanding the role of p53 in stem cell dynamics, cancer and aging.

Binh Vu, Ph.D. has served as our Vice President of Chemistry since June 2015 and served as our Director of Research from September 2013 to October 2014 and our Vice President of Pre-Clinical Discovery from November 2014 to May 2015. Prior to joining our company, Dr. Vu was a Research Leader at Roche where he spent 15 years working in small molecule oncology drug discovery. While at Roche, Dr. Vu was a key contributor to the discovery and development of Nutlins, small molecule MDM2 antagonists which target the p53 pathway. He has extensively published on p53 biology and drug discovery, and is an inventor on 14 issued U.S. patents. Dr. Vu received a B.S. in Chemistry from the University of California, Irvine and a Ph.D. in Chemistry from the University of California, Los Angeles. He also completed an NIH Postdoctoral Fellowship at the University of Texas at Austin.

Board Composition

Our board of directors currently consists of _____ members. After the completion of this offering, the number of directors will be fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws. The voting agreement and the provisions of our current certificate of incorporation that govern the election and designation of our directors will terminate in connection with this offering, after which no contractual obligations will concern the election of our directors. Each of our current directors will continue to serve as a director until the election and qualification of his or her successor, or until his or her earlier death, resignation or removal.

Classified Board of Directors

Our amended and restated certificate of incorporation, which will be effective immediately prior to the completion of this offering, will provide that our board of directors will be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of

stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our directors will be divided among the three classes as follows:

- The Class I directors will be _____, and their terms will expire at the annual meeting of stockholders to be held in 2021;
- The Class II directors will be _____, and their terms will expire at the annual meeting of stockholders to be held in 2022; and
- The Class III directors will be _____, and their terms will expire at the annual meeting of stockholders to be held in 2023.

At each annual meeting of stockholders, upon the expiration of the term of a class of directors, the successor to each such director in the class will be elected to serve from the time of election and qualification until the third annual meeting following his or her election and until his or her successor is duly elected and qualified, in accordance with our amended and restated certificate of incorporation and amended and restated bylaws. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of our directors. This classification of our board of directors may have the effect of delaying or preventing changes in control of our company.

Director Independence

We intend to apply to list our common stock on the Nasdaq Global Market. Under the rules of the Nasdaq Stock Market LLC, or Nasdaq, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of this offering. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and corporate governance and nominating committees be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Securities Exchange Act of 1934, as amended, or Exchange Act. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered to be independent for purposes of Rule 10A-3 and under the rules of Nasdaq, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (ii) be an affiliated person of the listed company or any of its subsidiaries.

To be considered independent for purposes of Rule 10C-1 and under the rules of Nasdaq, the board of directors of a listed company must affirmatively determine that each member of the compensation committee is independent, including a consideration of all factors specifically relevant to determining whether the director has a relationship to the company that is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (i) the source of compensation of such director, including any consulting, advisory or other compensatory fee paid by the company to such director and (ii) whether such director is affiliated with the company, a subsidiary of the company or an affiliate of a subsidiary of the company.

Our board of directors undertook a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or

her responsibilities. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that _____, representing _____ of our _____ directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is “independent” as that term is defined under the rules of Nasdaq. Dr. Mack is not an independent director because he is our President and Chief Executive Officer.

In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled “Certain Relationships and Related Party Transactions.” There are no family relationships among any of our directors or executive officers.

Board Leadership Structure

Our board of directors is currently chaired by Richard Heyman, Ph.D. As a general policy, our board of directors believes that separation of the positions of chair of our board of directors and Chief Executive Officer reinforces the independence of our board of directors from management, creates an environment that encourages objective oversight of management’s performance and enhances the effectiveness of our board of directors as a whole. As such, Dr. Mack serves as our Chief Executive Officer while Dr. Heyman serves as the chair of our board of directors, but is not an officer. We currently expect and intend the positions of chair of our board of directors and Chief Executive Officer to continue to be held by two individuals in the future.

Role of the Board in Risk Oversight

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks and operational risks. The audit committee is responsible for overseeing the management of risks relating to accounting matters and financial reporting. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The corporate governance and nominating committee is responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through discussions from committee members about such risks. Our board of directors believes its administration of its risk oversight function has not negatively affected the board of directors’ leadership structure.

Board Committees

Our board of directors has an audit committee, a compensation committee and a corporate governance and nominating committee, each of which has the composition and the responsibilities described below. Each committee intends to adopt a written charter that satisfies the applicable rules and regulations of the Securities Exchange Commission, or SEC, and the listing standards of Nasdaq, which we will post on our website at www.pmvpharma.com upon the completion of this offering. Information contained on, or that can be accessible through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

Audit Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our audit committee will be _____, and _____ will be the chair of our audit committee. Our board of directors has determined that all members are independent under the listing standards of Nasdaq and Rule 10A-3(b)(1) of the Exchange Act and that _____ is an audit committee financial expert, as that term is defined under the SEC rules implementing Section 407 of the Sarbanes-Oxley Act of 2002, as amended, and possesses financial sophistication, as defined under the rules of Nasdaq. Our board of directors has also determined that each member of our audit committee can read and understand fundamental financial statements, in accordance with applicable requirements. Our audit committee will oversee our corporate accounting and financial reporting process and assist our board of directors in monitoring our financial systems. Among other matters, our audit committee will also:

- select and hire the independent registered public accounting firm to audit our financial statements;
- help to ensure the independence and performance of the independent registered public accounting firm;
- approve audit and non-audit services and fees;
- review financial statements and discuss with management and the independent registered public accounting firm our annual audited and quarterly financial statements, the results of the independent audit and the quarterly reviews and the reports and certifications regarding internal controls over financial reporting and disclosure controls;
- prepare the audit committee report that the SEC requires to be included in our annual proxy statement;
- review reports and communications from the independent registered public accounting firm;
- review the adequacy and effectiveness of our internal controls and disclosure controls and procedures;
- review our policies on risk assessment and risk management;
- review and monitor conflicts of interest situations, and approve or prohibit any involvement in matters that may involve a conflict of interest or taking of a corporate opportunity;
- review related party transactions; and
- establish and oversee procedures for the receipt, retention and treatment of accounting related complaints and the confidential submission by our employees of concerns regarding questionable accounting or auditing matters.

Compensation Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our compensation committee will be _____, and _____ will be the chair of our compensation committee. Our board of directors has determined that all members are independent under the listing standards of Nasdaq and are “non-employee directors” as defined in Rule 16b-3 promulgated under the Exchange Act. Our compensation committee will oversee our compensation policies, plans and benefits programs. Among other matters, our compensation committee will also:

- oversee our overall compensation philosophy and compensation policies, plans and benefit programs;
- review and approve or recommend to the board of directors for approval compensation for our executive officers and directors;

- prepare the compensation committee report that the SEC will require to be included in our annual proxy statement; and
- administer our equity compensation plans.

Corporate Governance and Nominating Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our corporate governance and nominating committee will be _____, and _____ will be the chair of our corporate governance and nominating committee. Our board of directors has determined that all members of the corporate governance and nominating committee are independent under the listing standards of Nasdaq. Our corporate governance and nominating committee will oversee and assist our board of directors in reviewing and recommending nominees for election as directors. Among other matters, our corporate governance and nominating committee will:

- identify, evaluate and make recommendations to our board of directors regarding nominees for election to our board of directors and its committees;
- consider and make recommendations to our board of directors regarding the composition of our board of directors and its committees;
- review developments in corporate governance practices;
- evaluate the adequacy of our corporate governance practices and reporting; and
- evaluate the performance of our board of directors and of individual directors.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is or has been an officer or employee of our company. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

_____ and _____ have or may be deemed to have an interest in certain transactions requiring disclosure under Item 404 of Regulation S-K under the Securities Act of 1933, as amended, or Securities Act. These transactions between us and members of our compensation committee and affiliates of such members are disclosed in "Certain Relationships and Related Party Transactions," and such disclosure is incorporated by reference herein.

Scientific Advisory Board

We have established a scientific advisory board composed of leading academic and industry scientists. We seek advice and input from these scientists on an *ad hoc* basis, individually or as a group, to provide scientific and clinical feedback and advice related to our research and development platform and programs. The members of our advisory board consist of experts across a range of key disciplines relevant to our programs. Except for Drs. Levine and Heyman, who are members of our board of directors, our advisors are not our employees or directors and have no decision-making authority over our activities. Our advisors may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. All of our advisors are affiliated with other entities and devote only a small portion of their time to us. Our advisors receive cash and equity compensation based upon consulting services rendered.

Code of Business Conduct and Ethics

Prior to the completion of this offering, we intend to adopt a written code of business conduct and ethics that will apply to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. Following this offering, the code of business conduct and ethics will be available on our website at www.pmypharma.com. We intend to disclose future amendments to such code, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions or our directors on our website identified above. Information contained on, or that can be accessible through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

Director Compensation

Prior to this offering, we did not have a formal policy with respect to compensation payable to our non-employee directors. We reimburse our directors for expenses associated with attending meetings of our board of directors and its committees. Following the completion of this offering, we expect to implement an annual cash and equity compensation program for our non-employee directors.

The following table presents the total compensation that each of our then non-employee directors received during the year ended December 31, 2019.

	Fees Earned or Paid in Cash (\$)	Option Awards (\$)	All Other Compensation (\$)	Total (\$)
Arnold Levine, Ph.D.	—	—	100,000 ⁽¹⁾	100,000
Arnold Oronsky, Ph.D.	—	—	—	—
Thilo Schroeder, Ph.D.	—	—	—	—
Peter Thompson, M.D.	—	—	—	—
Steve Winick, J.D. ⁽²⁾	—	—	—	—

(1) Dr. Levine received an annual compensation of \$100,000 pursuant to a consulting agreement. For additional information regarding our consulting agreement with Dr. Levine, see "Certain Relationships and Related Party Transactions—Consulting Agreement with Arnold Levine, Ph.D."

(2) Mr. Winick resigned from our board of directors effective _____, 2020.

Directors who are also our employees receive no additional compensation for their service as directors. Dr. Mack was an employee director during 2019. See the section titled "Executive Compensation" for additional information about Dr. Mack's compensation.

EXECUTIVE COMPENSATION

Our named executive officers for 2019, who consist of our principal executive officer and the next two most highly compensated executive officers, are:

- David H. Mack, Ph.D., our President and Chief Executive Officer;
- Winston Kung, our Chief Operating Officer and Chief Financial Officer; and
- Deepika Jalota, our Senior Vice President and Head of Regulatory Affairs.

Summary Compensation Table

The following table sets forth information regarding the compensation of our named executive officers for the year ended December 31, 2019.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)⁽¹⁾</u>	<u>Option Awards (\$)⁽²⁾</u>	<u>Nonequity Incentive Plan Compensation (\$)⁽³⁾</u>	<u>Total (\$)</u>
David H. Mack, Ph.D. <i>President and Chief Executive Officer</i>	2019	461,250	—	—	166,860	628,110
Winston Kung <i>Chief Operating Officer and Chief Financial Officer</i>	2019	410,000	—	—	152,440	562,440
Deepika Jalota, Pharm.D <i>Senior Vice President and Head of Regulatory Affairs</i>	2019	196,875	75,000	177,341 ⁽⁴⁾	116,375	565,591

- (1) The amounts reported represent one-time sign on bonuses paid following the named executive officer's commencement of employment.
- (2) The amounts reported represent the aggregate grant-date fair value of the options calculated in accordance with ASC 718. Such grant-date fair value does not take into account any estimated forfeitures related to performance or service vesting conditions. The assumptions used in calculating the grant-date fair value of the option reported in this column are set forth in the section captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates." These amounts do not reflect the actual economic value that may be realized by the named executive officer.
- (3) The 2019 amounts reported represent cash bonuses earned under our 2019 bonus plan based upon the achievement of company objectives for the year ended December 31, 2019, which were paid in 2019. Our bonus plans are more fully described below under the section titled "—Management Bonus Plan."
- (4) Represents an August 21, 2019, grant of 475,000 options to Dr. Jalota pursuant to our 2013 Equity Incentive Plan, as amended, or 2013 Plan, as described further in the table of outstanding equity awards below.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2019:

Name	Grant Date ⁽¹⁾	Option Awards			
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$) ⁽²⁾	Option Expiration Date
David H. Mack, Ph.D.	5/12/2015 ⁽³⁾	2,608,000	—	0.10	5/12/2025
	11/16/2016 ⁽⁴⁾	1,267,017	—	0.26	11/16/2026
	5/16/2017 ⁽⁵⁾	1,566,791	859,209	0.56	5/16/2027
Winston Kung	2/22/2018 ⁽⁶⁾	2,506,440	—	0.61	2/22/2028
Deepika Jalota, Pharm.D.	8/21/2019 ⁽⁷⁾	—	475,000	0.67	8/21/2029

- (1) Each of the outstanding options to purchase shares of our common stock was granted pursuant to our 2013 Plan.
- (2) This column represents the fair market value of a share of our common stock on the date of grant, as determined by our board of directors.
- (3) The option vests as to 1/4th of the shares of our common stock underlying it on May 12, 2016, and as to 1/60th in monthly installments after the initial vesting date, subject to the named executive officer's continued service through each vesting date.
- (4) The option vests as to 1/48th of the shares of our common stock underlying it in monthly installments after November 16, 2016, subject to the named executive officer's continued service through each vesting date.
- (5) The option vests as to 1/48th of the shares of our common stock underlying it in monthly installments after May 16, 2017, subject to the named executive officer's continued service through each vesting date.
- (6) The option includes two tranches. The first tranche (covering 75% of the shares of our common stock underlying the option) vests as to 1/4th of the shares of our common stock underlying it on November 27, 2018, and as to an additional 1/48th of the shares of our common stock underlying it in monthly installments after the initial vesting date, subject to named executive officer's continued service through each vesting date. The second tranche (covering 25% of the total number of shares of our common stock underlying the option) vest as to 1/48th of the shares of our common stock underlying it in monthly installments, subject to named executive officer's continued service through each vesting date, following achievement of the performance vesting condition, which is the first to occur of (i) the first day of our initial public offering or (ii) an alliance transaction entered into by us with the approval of our board which is valued at \$100,000,000.
- (7) The option vests as to 1/4th of the shares of our common stock underlying it on June 10, 2020, and as to an additional 1/48th of the shares of our common stock underlying it in monthly installments after the initial vesting date, subject to the named executive officer's continued service through each vesting date.

Employment Arrangements with Our Named Executive Officers

David H. Mack, Ph.D.

We currently expect that, prior to the completion of this offering, we will enter into a continuing employment letter with Dr. Mack, our President and Chief Executive Officer. The confirmatory employment letter currently is expected to have no specific term and will provide for at-will employment. Dr. Mack's current annual base salary is \$, and Dr. Mack's annual target bonus is % of his annual base salary.

Winston Kung

We have entered into an employment offer letter agreement with Mr. Kung in connection with his employment with us. This offer letter provides for "at will" employment.

We currently expect that, prior to the completion of this offering, we will enter into a confirmatory employment letter with Mr. Kung, our Chief Operating Officer and Chief Financial Officer. The confirmatory employment letter currently is expected to have no specific term and will provide for at-will

employment. Mr. Kung's current annual base salary is \$ _____, and Mr. Kung's annual target bonus is _____ % of his annual base salary.

Deepika Jalota, Pharm.D.

We have entered into an employment offer letter agreement with Dr. Jalota in connection with his or her employment with us. This offer letter provides for "at will" employment.

We currently expect that, prior to the completion of this offering, we will enter into a confirmatory employment letter with Dr. Jalota, our Senior Vice President and Head of Regulatory Affairs. The confirmatory employment letter currently is expected to have no specific term and will provide for at-will employment. Dr. Jalota's current annual base salary is \$ _____, and Dr. Jalota's annual target bonus is _____ % of her annual base salary.

Management Bonus Plan

Each of our executive officers is eligible for an annual bonus under our management bonus plan and has an established target bonus amount as set forth in the section captioned "Executive Compensation—Employment Arrangements with Our Named Executive Officers." For 2019, our board determined each eligible executive officer's actual bonus based upon an assessment of achievement of corporate goals, which included specified study, pipeline and financial goals.

Potential Payments upon Termination or Change in Control

We currently have a Change in Control and Severance Policy, or Severance Policy, and have entered into participation agreements under the Severance Policy with certain employees, including Dr. Mack, Mr. Kung and Dr. Jalota.

The Severance Policy and related participation agreements provide that if we (or any of our subsidiaries) terminate a participant's employment during the period beginning three months prior to and ending 12 months after a "change in control" (as defined in the Severance Policy) (such period, the "change in control period") other than for "cause" (as defined in the Severance Policy), death or disability, and, in the case of Dr. Mack and Mr. Kung, the termination of employment by the participant for "good reason" (as defined in the Severance Policy), the participant will receive the following:

- 100% acceleration of unvested equity awards (in the case of performance-based equity awards, unless otherwise determined by us and set forth in the equity award agreement, all performance goals and other vesting criteria will be deemed achieved at 100% of target levels);
- a lump sum payment equal to the amount specified in the participant's participation agreement (18 months' base salary for Dr. Mack, 12 months' base salary for Mr. Kung and six months for Dr. Jalota);
- a lump sum payment equal to a pro-rata portion of the participant's target annual bonus for the year of termination; and
- payment or reimbursement of the participant's COBRA coverage or COBRA benefit, as applicable, for a time period specified in the participant's participation agreement (18 months for Dr. Mack, 12 months for Mr. Kung and six months for Dr. Jalota).

The Severance Policy and related participation agreements also provide that if we (or one of our subsidiaries) terminate a participant's employment outside the change in control period other than for cause, death or disability, the participant will receive the following:

- acceleration of vesting of time-based unvested equity awards equal to the amount specified in the participant's participation agreement (equal to the number of shares otherwise scheduled to

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vest during the 12 month period following the date of termination for Dr. Mack and the six month period following the date of termination for Mr. Kung and Dr. Jalota);

- a lump sum payment equal to amount specified in the participant's participation agreement (12 months' base salary for Dr. Mack and six months' base salary for Mr. Kung and Dr. Jalota); and
- payment or reimbursement of the participant's COBRA coverage or COBRA benefit, as applicable, for a time period specified in the participant's participation agreement (12 months for Dr. Mack and six months for Mr. Kung and Dr. Jalota).

In addition, the Severance Policy provides that if any payments or benefits received by a participant under the Severance Policy or otherwise would constitute "parachute payments" within the meaning of Section 280G of the U.S. Internal Revenue Code of 1986, as amended, or Code, and be subject to excise taxes imposed by Section 4999 of the Code, such amount will either be delivered in full or reduced so as not to be subject to excise taxation, whichever amount is higher, taking into account applicable taxes. The Severance Policy does not require us to provide any tax gross-ups.

To receive the severance described above, the participant must sign and not revoke our standard separation agreement and release of claims within the timeframe that is set forth in the Severance Policy.

Employee Benefit and Stock Plans

2020 Equity Incentive Plan (2020 Plan)

Prior to the effectiveness of this offering, we expect that our board of directors will adopt, and our stockholders will approve, our 2020 Equity Incentive Plan, or 2020 Plan. The 2020 Plan will be effective on the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part. Our 2020 Plan will provide for the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees and any of our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units, and performance shares to our employees, directors, and consultants and our subsidiary corporations' employees and consultants.

Authorized Shares. A total of _____ shares of our common stock are reserved for issuance pursuant to our 2020 Plan. In addition, the shares reserved for issuance under our 2020 Plan will also include (i) those shares reserved but unissued under our 2013 Plan as of the date of stockholder approval of the 2020 Plan and (ii) shares of our common stock subject to awards granted under our 2013 Plan that, after the date of stockholder approval of the 2020 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2020 Plan pursuant to (i) and (ii) is _____ shares). The number of shares available for issuance under our 2020 Plan will also include an annual increase on the first day of each fiscal year beginning with our 2021 fiscal year, equal to the lesser of:

- _____ shares;
- _____ % of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or
- such other amount as our board of directors may determine.

If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, or, with respect to restricted stock, restricted stock

units, performance units or performance shares, is forfeited to or repurchased by us due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under the 2020 Plan (unless the 2020 Plan has terminated). With respect to stock appreciation rights, only the net shares actually issued will cease to be available under the 2020 Plan and all remaining shares under stock appreciation rights will remain available for future grant or sale under the 2020 Plan (unless the 2020 Plan has terminated). Shares that have actually been issued under the 2020 Plan will not be returned to the 2020 Plan except if shares issued pursuant to awards of restricted stock, restricted stock units, performance shares, or performance units are repurchased by or forfeited to us, such shares will become available for future grant under the 2020 Plan. Shares used to pay the exercise price of an award or satisfy the tax withholding obligations related to an award will become available for future grant or sale under the 2020 Plan. To the extent an award is paid out in cash rather than shares, such cash payment will not result in a reduction in the number of shares available for issuance under the 2020 Plan.

Plan Administration. Our board of directors or one or more committees appointed by our board of directors will administer our 2020 Plan. The compensation committee of our board of directors will initially administer our 2020 Plan. In addition, if we determine it is desirable to qualify transactions under our 2020 Plan as exempt under Rule 16b-3 of the Securities Exchange Act of 1934, as amended, or Exchange Act, such transactions will be structured to satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of our 2020 Plan, the administrator has the power to administer our 2020 Plan and make all determinations deemed necessary or advisable for administering the 2020 Plan, including but not limited to, the power to determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2020 Plan, determine the terms and conditions of awards (including, but not limited to, the exercise price, the time or times at which awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of our 2020 Plan and awards granted under it, prescribe, amend and rescind rules relating to our 2020 Plan, including creating sub-plans, modify or amend each award, including but not limited to the discretionary authority to extend the post-termination exercisability period of awards (except no option or stock appreciation right will be extended past its original maximum term), and allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also has the authority to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered or cancelled in exchange for awards of the same type, which may have a higher or lower exercise price and/or different terms, awards of a different type, and/or cash or by which the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations and other actions are final and binding on all participants.

Stock Options. Stock options may be granted under our 2020 Plan. The exercise price of options granted under our 2020 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an option may not exceed ten years. With respect to any participant who owns more than 10% of the voting power of all classes of our (or any parent or subsidiary of ours) outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director, or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. In the absence of a specified time in an award agreement, if termination

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is due to death or disability, the option will remain exercisable for twelve months following the termination of service. In all other cases, in the absence of a specified time in an award agreement, the option will remain exercisable for three months following the termination of service. An option, however, may not be exercised later than the expiration of its term. Subject to the provisions of our 2020 Plan, the administrator determines the other terms of options.

Stock Appreciation Rights. Stock appreciation rights may be granted under our 2020 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding ten years. After the termination of service of an employee, director or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her stock appreciation rights agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the stock appreciation rights will remain exercisable for twelve months following the termination of service. In all other cases, in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for three months following the termination of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2020 Plan, the administrator determines the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock. Restricted stock may be granted under our 2020 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director, or consultant and, subject to the provisions of our 2020 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever vesting conditions it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us), except the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Restricted stock units may be granted under our 2020 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2020 Plan, the administrator determines the terms and conditions of restricted stock units, including the vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned restricted stock units in the form of cash, in shares or in some combination thereof. In addition, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Performance Units and Performance Shares. Performance units and performance shares may be granted under our 2020 Plan. Performance units and performance shares are awards that will result in a payment to a participant only if performance objectives established by the administrator are achieved or the awards otherwise vest. The administrator will establish performance objectives or other vesting criteria in its discretion, which, depending on the extent to which they are met, will determine the number or the value of performance units and performance shares to be paid out to participants. The administrator may set performance objectives based on the achievement of company-wide,

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divisional, business unit or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. After the grant of a performance unit or performance share, the administrator, in its sole discretion, may reduce or waive any performance objectives or other vesting provisions for such performance units or performance shares. Performance units will have an initial value established by the administrator on or prior to the grant date. Performance shares will have an initial value equal to the fair market value of our common stock on the grant date. The administrator, in its sole discretion, may pay out earned performance units or performance shares in cash, shares or in some combination thereof.

Outside Directors. All outside (non-employee) directors will be eligible to receive all types of awards (except for incentive stock options) under our 2020 Plan. To provide a maximum limit on the cash compensation and equity awards that can be made to our outside directors, our 2020 Plan provides that in any given fiscal year, an outside director will not be granted cash compensation and equity awards with an aggregate value greater than \$ (increased to \$ in the fiscal year of his or her initial service as an outside director), with the value of each equity award based on its grant date fair value as determined according to GAAP for purposes of this limit. Any cash compensation paid or awards granted to an individual for his or her services as an employee or consultant (other than as an outside director) will not count toward this limit.

Non-Transferability of Awards. Unless the administrator provides otherwise, our 2020 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime. If the administrator makes an award transferrable, such award will contain such additional terms and conditions as the administrator deems appropriate.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under our 2020 Plan, the administrator will adjust the number and class of shares that may be delivered under our 2020 Plan and/or the number, class and price of shares covered by each outstanding award and the numerical share limits set forth in our 2020 Plan.

Dissolution or Liquidation. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and, to the extent not exercised, all awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Change in Control. Our 2020 Plan provides that in the event of a merger or change in control, as defined under our 2020 Plan, each outstanding award will be treated as the administrator determines, without a participant's consent. The administrator is not required to treat all awards, all awards held by a participant or all awards of the same type similarly.

If a successor corporation does not assume or substitute for any outstanding award, then the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, all restrictions on restricted stock and restricted stock units will lapse, and for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met. If an option or stock appreciation right is not assumed or substituted in the event of a change in control, the administrator will notify the participant in writing or electronically that such option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

For awards granted to an outside director, in the event of a change in control, the outside director will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, all restrictions on restricted stock and restricted stock units will lapse and, for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met.

Clawback. Awards will be subject to any clawback policy of ours, and the administrator also may specify in an award agreement that the participant's rights, payments and/or benefits with respect to an award will be subject to reduction, cancellation, forfeiture and/or recoupment upon the occurrence of certain specified events. Our board of directors may require a participant to forfeit, return or reimburse us all or a portion of the award and/or shares issued under the award, any amounts paid under the award, and any payments or proceeds paid or provided upon disposition of the shares issued under the award in order to comply with such clawback policy or applicable laws.

Amendment; Termination. The administrator has the authority to amend, alter, suspend or terminate our 2020 Plan, provided such action does not materially impair the rights of any participant. Our 2020 Plan automatically will terminate in 2030, unless we terminate it sooner.

2013 Equity Incentive Plan, as amended

Our 2013 Equity Incentive Plan, as amended, or 2013 Plan, was originally adopted by our board of directors and approved by our stockholders in July 2013. Our 2013 Plan was most recently amended in November 2019 and approved by stockholders in November 2019.

Our 2013 Plan allows us to provide incentive stock options, within the meaning of Section 422 of the Code, nonstatutory stock options, stock appreciation rights, restricted stock awards and restricted stock units (each, an "award" and the recipient of such award, a "participant") to eligible employees, directors, and consultants of ours and any parent or subsidiary of ours. It is expected that as of one business day prior to the effectiveness of the registration statement of which this prospectus forms a part, our 2013 Plan will be terminated and we will not grant any additional awards under our 2013 Plan thereafter. However, our 2013 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under our 2013 Plan.

As of June 30, 2020, the following awards were outstanding under our 2013 Plan: stock options covering _____ shares of our common stock.

Plan Administration. Our 2013 Plan is administered by our board of directors or one or more committees appointed by our board of directors. Different committees may administer our 2013 Plan with respect to different service providers. The administrator has all authority and discretion necessary or appropriate to administer our 2013 Plan and to control its operation, including the authority to construe and interpret the terms of our 2013 Plan and the awards granted under our 2013 Plan. The administrator's decisions are final and binding on all participants and any other persons holding awards.

The administrator's powers include the power to institute an exchange program under which (i) outstanding awards are surrendered or cancelled in exchange for awards of the same type (which may have higher or lower exercise prices and different terms), awards of a different type or cash, (ii) participants would have the opportunity to transfer any outstanding awards to a financial institution or other person or entity selected by the administrator or (iii) the exercise price of an outstanding award is increased or reduced. The administrator's powers also include the power to prescribe, amend and

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rescind rules and regulations relating to our 2013 Plan, to modify or amend each award and to make all other determinations deemed necessary or advisable for administering our 2013 Plan.

Eligibility. Employees, directors and consultants of ours or our parent or subsidiary companies are eligible to receive awards, provided such consultants render bona fide services not in connection with the offer and sale of securities in a capital-raising transaction and do not directly promote or maintain a market for our securities. Only our employees or employees of our parent or subsidiary companies are eligible to receive incentive stock options.

Stock Options. Stock options have been granted under our 2013 Plan. Subject to the provisions of our 2013 Plan, the administrator determines the term of an option, the number of shares subject to an option and the time period in which an option may be exercised.

The term of an option is stated in the applicable award agreement, but the term of an option may not exceed ten years from the grant date. The administrator determines the exercise price of options, which generally may not be less than 100% of the fair market value of our common stock on the grant date, unless expressly determined in writing by the administrator on the option's grant date. However, an incentive stock option granted to an individual who directly or by attribution owns more than 10% of the total combined voting power of all of our classes of stock or of any our parent or subsidiary may have a term of no longer than 5 years from the grant date and will have an exercise price of at least 110% of the fair market value of our common stock on the grant date. In addition, to the extent that the aggregate fair market value of the shares with respect to which incentive stock options are exercisable for the first time by an employee during any calendar year (under all our plans and any parent or subsidiary) exceeds \$100,000, such options will be treated as nonstatutory stock options. Certain of the company's outstanding options under our 2013 Plan have an early exercise provisions pursuant to which the participant may exercise the option prior to the shares being fully vested.

The administrator determines how a participant may pay the exercise price of an option, and the permissible methods are generally set forth in the applicable award agreement. If a participant's status as a "service provider" (as defined in our 2013 Plan) terminates, that participant may exercise the vested portion of his or her option for the period of time stated in the applicable award agreement. Vested options generally will remain exercisable for three months or such longer period of time as set forth in the applicable award agreement if a participant's status as a service provider terminates for a reason other than death or disability. If a participant's status as a service provider terminates due to death or disability, vested options generally will remain exercisable for twelve months from the date of termination (or such other longer period as set forth in the applicable award agreement). In no event will an option remain exercisable beyond its original term. If a participant does not exercise his or her option within the time specified in the award agreement, the option will terminate. Except as described above, the administrator has the discretion to determine the post-termination exercisability periods for an option.

Non-transferability of Awards. Unless determined otherwise by the administrator, awards may not be sold, pledged, assigned, hypothecated or otherwise transferred in any manner other than by will or by the laws of descent and distribution. In addition, during an applicable participant's lifetime, only that participant may exercise their award. If the administrator makes an award transferable, such award may only be transferred (i) by will, (ii) by the laws of descent and distribution of cash, or (iii) as permitted by Rule 701 of the Securities Act of 1933, as amended, or Securities Act.

Certain Adjustments. If there is a dividend or other distribution (whether in the form of cash, shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, exchange of shares or our other securities or other change in our corporate structure affecting the shares, the administrator

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will make proportionate adjustments to the number and type of shares that may be delivered under our 2013 Plan or the number, type and price of shares covered by each outstanding award. The administrator's determination regarding such adjustments will be final, binding and conclusive.

Dissolution or Liquidation. In the event of our proposed dissolution or liquidation, the administrator will notify each participant as soon as practicable prior to the effective date of such proposed transaction. To the extent it has not been previously exercised, an award will terminate immediately prior to the consummation of such proposed action.

Merger and Change of Control. In the event of our merger with or into another corporation or entity or a "change in control" (as defined in our 2013 Plan), each outstanding award will be treated as the administrator determines, including, without limitation, that (i) awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof) with appropriate adjustments as to the number and kind of shares and prices; (ii) upon written notice to a participant, the participant's awards will terminate upon or immediately prior to the consummation of such merger or change in control; (iii) outstanding awards will vest and become exercisable, realizable or payable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon consummation of such merger or change in control, and, to the extent the administrator determines, terminate upon or immediately prior to the effectiveness of such merger or change in control; (iv) (A) the termination of an award in exchange for an amount of cash or property, if any, equal to the amount that would have been attained upon the exercise of such award or realization of the participant's rights as of the date of the occurrence of the transaction (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction the administrator determines in good faith that no amount would have been attained upon the exercise of such award or realization of the participant's rights, then such award may be terminated by us without payment) or (B) the replacement of such award with other rights or property selected by the administrator in its sole discretion or (v) any combination of the foregoing. The administrator will not be obligated to treat all awards, all awards a participant holds or all awards of the same type, similarly.

In the event that the successor corporation does not assume or substitute for an award (or portion thereof), the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, including shares as to which such awards would not otherwise be vested or exercisable, all restrictions on restricted stock and restricted stock units will lapse, and, with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at one hundred percent (100%) of target levels and all other terms and conditions met. In addition, if an option or stock appreciation right is not assumed or substituted in the event of a merger or change in control, the administrator will notify the participant in writing or electronically that the option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion, and the option or stock appreciation right will terminate upon the expiration of such period.

Amendment and Termination. Our board of directors may, at any time, terminate or amend our 2013 Plan in any respect, including, without limitation, amendment of any form of award agreement or instrument to be executed pursuant to our 2013 Plan. To the extent necessary and desirable to comply with applicable laws, we will obtain stockholder approval of any amendment to our 2013 Plan. No amendment or alteration of our 2013 Plan will impair the rights of a participant, unless mutually agreed otherwise between the participant and the administrator in writing. As noted above, it is expected that as of one business day prior to the effectiveness of the registration statement of which this prospectus forms a part, our 2013 Plan will be terminated and we will not grant any additional awards under our 2013 Plan thereafter.

401(k) Plan

We maintain a 401(k) retirement savings plan for the benefit of our employees, including our named executive officers, who satisfy certain eligibility requirements. Under the 401(k) plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. We do not provide for any matching contributions under the 401(k) plan.

Limitation of Liability and Indemnification Matters

Our amended and restated certificate of incorporation and amended and restated bylaws, each to be effective immediately after the completion of this offering, will provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by Delaware law. Delaware law prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or to our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which the director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated certificate of incorporation does not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, we have entered, and intend to continue to enter, into an indemnification agreement with each member of our board of directors and each of our officers prior to the completion of the offering. These agreements provide for the indemnification of our directors and officers for certain expenses and liabilities incurred in connection with any action, suit, proceeding or alternative dispute resolution mechanism or hearing, inquiry or investigation that may lead to the foregoing, to which they are a party, or are threatened to be made a party, by reason of the fact that they are or were a director, officer, employee, agent or fiduciary of our company, or any of our subsidiaries, by reason of any action or inaction by them while serving as an officer, director, agent or fiduciary, or by reason of the fact that they were serving at our request as a director, officer, employee, agent or fiduciary of another entity. In the case of an action or proceeding by or in the right of our company or any of our subsidiaries, no indemnification will be provided for any claim where a court determines that the indemnified party is prohibited from receiving indemnification. We believe that these charter and bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative

litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. Moreover, a stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation arrangements, including employment, termination of employment and change in control arrangements, with our directors and executive officers, including those discussed in the sections titled “Management” and “Executive Compensation,” and the registration rights described in the section titled “Description of Capital Stock—Registration Rights,” the following is a description of each transaction since January 1, 2017 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amount involved exceeded or will exceed \$120,000; and
- any of our directors, executive officers or holders of more than 5% of our outstanding capital stock, or any affiliate or immediate family member of, or person sharing a household with, any of these individuals or entities, had or will have a direct or indirect material interest.

Sales of Securities

Series D Preferred Stock Financing

In July 2020, we issued and sold an aggregate of 28,020,172 shares of our Series D convertible preferred stock, or Series D Preferred Stock, at a purchase price of \$2.4982 per share for an aggregate purchase price of approximately \$70.0 million. These shares of Series D Preferred Stock will convert into an aggregate of 28,020,172 shares of common stock immediately prior to the completion of this offering. The table below sets forth the number of shares of Series D Preferred Stock sold to our directors, executive officers and holders of more than 5% of our capital stock:

<u>Investor</u>	<u>Affiliated Director(s) or Officer(s)</u>	<u>Shares of Series D Preferred Stock</u>	<u>Total Purchase Price</u>
Nextech V Oncology S.C.S., SICAV-SIF	Thilo Schroeder, Ph.D.	4,002,882	\$ 10,000,000
Viking Global Opportunities Illiquid Investments Sub-master LP	—	4,002,882	\$ 10,000,000
Entities affiliated with OrbiMed Private Investments V LP	Peter Thompson, M.D.	4,002,881	\$ 10,000,000

Series C Preferred Stock Financing

In November 2019, we issued and sold an aggregate of 28,798,050 shares of our Series C convertible preferred stock, or Series C Preferred Stock, at a purchase price of \$2.1485 per share for an aggregate purchase price of approximately \$61.9 million. These shares of Series C Preferred Stock will convert into an aggregate of 28,798,050 shares of common stock immediately prior to the completion of this offering. The table below sets forth the number of shares of Series C Preferred Stock sold to our directors, executive officers and holders of more than 5% of our capital stock:

<u>Investor</u>	<u>Affiliated Director(s) or Officer(s)</u>	<u>Shares of Series C Preferred Stock</u>	<u>Total Purchase Price</u>
Nextech V Oncology S.C.S., SICAV-SIF	Thilo Schroeder, Ph.D.	9,308,820	\$ 19,999,999
Viking Global Opportunities Illiquid Investments Sub-master LP	—	6,981,615	\$ 14,999,999
Entities affiliated with Euclidean Capital LLC	—	4,654,409	\$ 9,999,997
OrbiMed Private Investments V LP	Peter Thompson, M.D.	2,728,331	\$ 5,861,819
InterWest Partners X, L.P.	Arnold Oronsky, Ph.D.	1,396,323	\$ 2,999,999

Series B Preferred Stock Financing

In February 2017, we issued and sold an aggregate of 40,396,799 shares of our Series B convertible preferred stock, or Series B Preferred Stock, at a purchase price of \$1.8251 per share for an aggregate purchase price of approximately \$73.7 million. These shares of Series B Preferred Stock will convert into an aggregate of 40,396,799 shares of common stock immediately prior to the completion of this offering. The table below sets forth the number of shares of Series B Preferred Stock sold to our directors, executive officers and holders of more than 5% of our capital stock:

<u>Investor</u>	<u>Affiliated Director(s) or Officer(s)</u>	<u>Shares of Series B Preferred Stock</u>	<u>Total Purchase Price</u>
Entities affiliated with Euclidean Capital LLC	—	21,916,604	\$ 39,999,993
OrbiMed Private Investments V LP	Peter Thompson, M.D.	5,669,940	\$ 10,348,207
InterWest Partners X, L.P.	Arnold Oronsky, Ph.D.	5,479,151	\$ 9,999,998
TopSpin Biotech Fund II, L.P.	Steve Winick ⁽¹⁾	5,479,151	\$ 9,999,998

(1) Mr. Winick resigned from our board of directors effective , 2020.

Investors' Rights Agreement

We are party to an amended and restated investors' rights agreement with certain holders of our capital stock, including entities affiliated with Euclidean Capital LLC, InterWest Partners X, L.P., Nextech V Oncology S.C.S., SICAV-SIF, OrbiMed Private Investments V LP, Viking Global Opportunities Illiquid Investments Sub-master LP and TopSpin Biotech Fund II, L.P. Under our investors' rights agreement, certain holders of our capital stock have the right to demand that we file a registration statement or request that their shares of our capital stock be covered by a registration statement that we are otherwise filing. See the section titled "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Voting Agreement

We are party to an amended and restated voting agreement, as amended, with certain holders of our capital stock, including entities affiliated with Euclidean Capital LLC, InterWest Partners X, L.P., Nextech V Oncology S.C.S., SICAV-SIF, OrbiMed Private Investments V LP, Viking Global Opportunities Illiquid Investments Sub-master LP and TopSpin Biotech Fund II, L.P. Upon the consummation of this offering, the obligations of the parties to the voting agreement to vote their shares so as to elect these nominees, as well as the other rights and obligations under this agreement, will terminate and none of our stockholders will have any special rights regarding the nomination, election or designation of members of our board of directors. Our existing certificate of incorporation contains provisions regarding election of members of the board of directors that correspond to the voting agreement; however, such provisions will be removed in the amended and restated certificate of incorporation that will be effective immediately prior to the completion of this offering.

Right of First Refusal

Pursuant to certain of our equity compensation plans and certain agreements with our stockholders, including an amended and restated right of first refusal and co-sale agreement, we or our assignees have a right to purchase shares of our capital stock which stockholders propose to sell to other parties. Certain holders of our capital stock, including entities affiliated with Euclidean Capital LLC, InterWest Partners X, L.P., Nextech V Oncology S.C.S., SICAV-SIF, OrbiMed Private

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Investments V LP, Viking Global Opportunities Illiquid Investments Sub-master LP and TopSpin Biotech Fund II, L.P., are party to the right of first refusal and co-sale agreement with a secondary right to purchase shares of our capital stock when certain stockholders propose to sell to other parties. These rights will terminate upon completion of this offering.

Consulting Agreement with Arnold Levine, Ph.D.

We are party to a consulting agreement with Arnold Levine, Ph.D., a co-founder of our company and one of our non-employee directors, pursuant to which Dr. Levine provides us with consulting and advisory services in exchange for an annual compensation of \$100,000.

Consulting Agreement with Richard Heyman, Ph.D.

We are party to a consulting agreement with Richard Heyman, Ph.D., one of our non-employee directors, pursuant to which Dr. Heyman provides us with consulting and advisory services in exchange for an annual cash compensation of \$12,500.

Director and Chairman Option Grants

On June 23, 2020, our board of directors approved two stock option grants for 238,680 and 795,600 shares of our common stock, each awarded at \$0.80, to newly-appointed director and Chairman of the board of directors Richard Heyman, Ph.D.

Indemnification Agreements

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and bylaws. The indemnification agreements and our amended restated certificate of incorporation and amended and restated bylaws that will be in effect upon the completion of this offering require us to indemnify our directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law. See the section titled “Executive Compensation—Limitation of Liability and Indemnification” for additional information.

Related Party Transaction Policy

Prior to the completion of this offering, we intend to adopt a formal written policy providing that we are not permitted to enter into any transaction that exceeds \$120,000 and in which any related person has a direct or indirect material interest without the consent of our audit committee. Our audit committee will have the primary responsibility for reviewing and approving or disapproving “related party transactions,” which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed \$120,000 and in which a related person has or will have a direct or indirect material interest. The charter of our audit committee will provide that our audit committee shall review and approve in advance any related party transaction. In approving or rejecting any such transaction, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to our audit committee, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person’s interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of July 31, 2020 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Securities Exchange Act of 1934, as amended, or Exchange Act.

We have based our calculation of the percentage of beneficial ownership prior to this offering on 164,451,912 shares of our common stock outstanding as of July 31, 2020, which includes 148,413,322 shares of our common stock resulting from the conversion of all 148,413,322 outstanding shares of our convertible preferred stock into our common stock, which will occur immediately prior to the completion of this offering, as if this conversion had occurred as of July 31, 2020. We have based our calculation of the percentage of beneficial ownership after this offering on _____ shares of our common stock outstanding immediately after the completion of this offering, assuming no exercise by the underwriters of their option to purchase additional shares. We have deemed shares of our common stock subject to stock options that are currently exercisable or exercisable within 60 days of July 31, 2020, to be outstanding and to be beneficially owned by the person holding the stock option for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

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Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o PMV Pharmaceuticals, Inc., 8 Clarke Drive, Suite 3, Cranbury, New Jersey 08512.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before the Offering	After the Offering
5% or Greater Stockholders:			
InterWest Partners X, L.P.(1)	33,772,242		
Entities affiliated with OrbiMed Advisors(2)	33,595,580		
Entities affiliated with Euclidean Capital LLC(3)	22,005,055		
Nextech V Oncology S.C.S., SICAV-SIF(4)	13,311,702		
Viking Global Opportunities Illiquid Investments Sub-master LP(5)	10,984,497		
Named Executive Officers:			
David H. Mack, Ph.D.(6)	7,541,308		
Winston Kung(7)	2,564,002		
Deepika Jalota, Pharm.D.(8)	159,687		
Non-Employee Directors:			
Richard Heyman, Ph.D.(9)	316,943		
Arnold Levine, Ph.D.(10)	2,250,000		
Arnold Oronsky, Ph.D.(1)	33,772,242		
Peter Thompson, M.D.(2)	33,593,580		
Thilo Schroeder, Ph.D.(4)	13,311,702		
All executive officers and directors as a group (9 persons)(11)	93,509,464		

* Represents beneficial ownership of less than one percent (1%) of the outstanding shares of our common stock.

- (1) Consists of (i) 8,529,997 shares of common stock issuable upon conversion of Series Seed convertible preferred stock, (ii) 18,366,771 shares of common stock issuable upon conversion of Series A convertible preferred stock, (iii) 5,479,151 shares of common stock issuable upon conversion of Series B convertible preferred stock and (iv) 1,396,323 shares of common stock issuable upon conversion of Series C convertible preferred stock all held by InterWest Partners X, L.P., or IW10. InterWest Management Partners X, LLC, or IMP10, is the general partner of IW10. Gilbert H. Kliman and Arnold L. Oronsky are the managing directors of IMP10, and Keval Desai and Khaled A. Nasr are venture members of IMP10. Each managing director and venture member of IMP10, including Arnold L. Oronsky, shares voting and investment power with respect to the securities held by IW10. IW10 is affiliated with InterWest Venture Management Company and Arnold L. Oronsky, a member of our board of directors. The address for the InterWest entities is 467 First Street, Suite 201, Los Altos, CA 94022.
- (2) Consists of (i) 31,592,140 shares held by OrbiMed Private Investments V, LP, or OPI V, (ii) 600,432 shares held by OrbiMed Genesis Master Fund, L.P., or Genesis Master Fund and (iii) 1,401,008 shares held by The Biotech Growth Trust PLC, or Biotech Growth Trust. Dr. Peter Thompson is an employee of OrbiMed Advisors LLC, or OrbiMed Advisors, and a member of our board of directors. OrbiMed Capital GP V LLC, or OrbiMed GP V, is the general partner of OPI V and OrbiMed Advisors is the managing member of OrbiMed GP V. OrbiMed Genesis GP LLC, or Genesis GP, is the general partner of Genesis Master Fund and OrbiMed Advisors is the managing member of Genesis GP. By virtue of such relationships, OrbiMed GP V, Genesis GP and OrbiMed Advisors may be deemed to have voting and investment power over the securities held by OPI V, Genesis Master Fund and Biotech Growth Trust and as a result, may be deemed to have beneficial ownership over such securities. OrbiMed Advisors exercises voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by OPI V and Genesis Master Fund. The business address of OPI V, Genesis Master Fund and Biotech Growth Trust is c/o OrbiMed Advisors LLC, 601 Lexington Avenue, 54th Floor, New York, NY 10022.
- (3) Consists of (i) 3,652,767 shares held of record by Greenland A LLC, (ii) 3,956,248 shares held of record by Greenland FP LLC, (iii) 698,161 shares held of record by Greenland NFP LLC, and (iv) 13,697,879 shares held of record by Greenland NFP B Ltd., such record holders together, the Greenland Entities. Euclidean Capital LLC, the Manager or Vice President (as the case may be) of the Greenland Entities, may be deemed to have shared voting control and investment discretion over the shares held by the Greenland Entities. The address for Euclidean and the Greenland Entities is c/o Euclidean Capital LLC, 160 Fifth Ave, 9th Fl, New York, NY 10010.
- (4) Consists of 13,311,702 shares held by Nextech V Oncology S.C.S., SICAV-SIF. Dr. Thilo Schroeder is a Partner at Nextech Invest AG and in the Investment Committee of Nextech Invest AG, with significant influence over Nextech V Oncology S.C.S., SICAV-SIF in terms of investment decisions, selling strategy of shares and voting power and as a result, may be deemed to have beneficial ownership over such securities. Nextech V GP S.à r.l. is the general partner of Nextech V Oncology S.C.S., SICAV-SIF. Dalia Bleyer, James Pledger and Thomas Lips are Managers of Nextech V GP S.à r.l.

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and each of Nextech V GP S.à r.l. and Messrs. Dalia Bleyer, James Pledger and Thomas Lips may be deemed to share voting and investment power with respect to the shares reported herein and disclaim beneficial ownership over such shares, except to the extent of their respective pecuniary interest therein, if any. The address of the entities listed herein is 8 rue Lou Hemmer L-1748 Senningerberg, Luxembourg.

- (5) Consists of 10,984,497 shares held by Viking Global Opportunities Illiquid Investments Sub-Master LP, or Opportunities Fund, which has the authority to dispose of and vote the shares directly owned by it, which power may be exercised by its general partner, Viking Global Opportunities Portfolio GP LLC, or Opportunities GP, and by Viking Global Investors LP, or VGI, which provides managerial services to Opportunities Fund. O. Andreas Halvorsen, David C. Ott and Rose Shabet, as Executive Committee members of Viking Global Partners LLC (the general partner of VGI) and Opportunities GP, have shared authority to direct the voting and disposition of investments beneficially owned by VGI and Opportunities GP. The business address of the Opportunities Fund is c/o Viking Global Investors LP, 55 Railroad Avenue, Greenwich, Connecticut 06830.
- (6) Consists of (i) 1,200,000 shares of common stock held by The Mack-Mulligan Revocable Trust, of which Dr. David Mack is a co-trustee, (ii) 300,000 shares of common stock held by Mack/Mulligan 2020 Irrevocable Descendants' Trust, of which Dr. Mack is a co-trustee and (iii) 6,041,308 shares of common stock issuable pursuant to options held directly by Dr. Mack, exercisable within 60 days of July 31, 2020.
- (7) Consists of 2,564,002 shares of common stock issuable pursuant to options held directly by Winston Kung, exercisable within 60 days of July 31, 2020.
- (8) Consists of 159,687 shares of common stock issuable pursuant to options held directly by Dr. Deepika Jalota, exercisable within 60 days of July 31, 2020.
- (9) Consists of 316,943 shares of common stock issuable pursuant to options held directly by Dr. Richard Heyman, exercisable within 60 days of July 31, 2020.
- (10) Consists of 2,250,000 shares of common stock held directly by Dr. Arnold Levine.
- (11) Consists of (i) 84,427,524 shares beneficially owned by our current executive officers and directors as of July 31, 2020 and (ii) 9,081,940 shares subject to options, exercisable within 60 days of July 31, 2020, of which 7,796,813 are vested as of such date.

DESCRIPTION OF CAPITAL STOCK

The following descriptions of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws that will be in effect immediately prior to the completion of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur upon the completion of this offering.

General

Upon the completion of this offering and the filing of our amended and restated certificate of incorporation in connection with this offering, our authorized capital stock will consist of _____ shares of common stock, par value \$0.00001 per share, and _____ shares of preferred stock, par value \$0.00001 per share.

Common Stock

Outstanding Shares

Based on 16,038,590 shares of common stock outstanding as of June 30, 2020, and after giving effect to the conversion of all of our outstanding convertible preferred stock into an aggregate of 148,413,322 shares of common stock, including the shares issuable upon the conversion of our Series D convertible preferred stock issued and sold in July 2020, which will occur immediately prior to the completion of this offering and the issuance of _____ shares of common stock in this offering, there will be _____ shares of common stock outstanding upon the completion of this offering. Upon the closing of our Series D convertible preferred stock financing in July 2020, we had 37 stockholders of record.

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 will 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 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.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering, upon payment and delivery in accordance with the underwriting agreement, will be fully paid and nonassessable.

Preferred Stock

Upon the completion of this offering, our board of directors will have the authority, without further action by the stockholders, to issue up to _____ 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. Upon completion of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Common Stock Options

As of June 30, 2020, we had outstanding options to purchase an aggregate of 20,653,300 shares of our common stock, with a weighted-average exercise price of \$0.50 per share, under our 2013 Equity Incentive Plan, or 2013 Plan. After June 30, 2020, we issued options to purchase an aggregate of _____ shares of our common stock, with a weighted-average exercise price of \$ _____ per share, under our 2013 Plan.

Warrant

As of June 30, 2020, we had an outstanding warrant to purchase an aggregate of 56,866 shares of our Series Seed convertible preferred stock at \$0.3517 per share. The warrant will be converted into a warrant to purchase an aggregate of 56,866 shares of our common stock, with an exercise price of \$0.3517 per share, upon the completion of this offering.

Registration Rights

After the completion of this offering, under our amended and restated investors' rights agreement, holders of up to 148,470,188 shares of common stock or their transferees, have the right to require us to register the offer and sale of their shares, or to include their shares in any registration statement we file, in each case as described below.

Demand Registration Rights

After the completion of this offering, holders of up to 148,470,188 shares of our common stock will be entitled to certain demand registration rights. At any time beginning after 180 days following the completion of this offering, or the subsequent date on which all market stand-off agreements applicable to this offering have terminated, the holders of at least 30% of the shares having registration rights then outstanding can request that we file a registration statement to register the offer and sale of their shares. We are only obligated to effect up to two such registrations. Each such request for registration must cover securities the anticipated aggregate gross proceeds of which, after deducting underwriting discounts and expenses, is at least \$5 million. These demand registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. If we determine that it would be materially detrimental to us and our stockholders to effect such a demand registration, we have the right to defer such registration, not more than twice in any twelve-month period, for a period of up to 90 days.

Form S-3 Registration Rights

After the completion of this offering, holders of up to 148,470,188 shares of our common stock will be entitled to certain Form S-3 registration rights. At any time when we are eligible to file a registration statement on Form S-3, the holders of the shares having these rights then outstanding can request that we register the offer and sale of their shares of our common stock on a registration statement on Form S-3 so long as the request covers securities the anticipated aggregate public offering price of which is at least \$5 million. These stockholders may make an unlimited number of requests for registration on a registration statement on Form S-3. However, we will not be required to effect a registration on Form S-3 if we have effected two such registrations within the twelve-month period preceding the date of the request. These Form S-3 registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. Additionally, if we determine that it would be seriously detrimental to us and our stockholders to effect such a demand registration, we have the right to defer such registration, not more than twice in any twelve-month period, for a period of up to 90 days.

Piggyback Registration Rights

After the completion of this offering, holders of up to 148,413,322 shares of our common stock will be entitled to certain “piggyback” registration rights. If we propose to register the offer and sale of shares of our common stock under the Securities Act of 1933, as amended, or Securities Act, all holders of these shares then outstanding can request that we include their shares in such registration, subject to certain marketing and other limitations, including the right of the underwriters to limit the number of shares included in any such registration statement under certain circumstances. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to (i) a registration related to any employee benefit plan, (ii) a registration relating to the offer and sale of debt securities, (iii) a registration relating to a corporate reorganization or other transaction covered by Rule 145 promulgated under the Securities Act, (iv) a registration on any registration form that does not permit secondary sales or (v) a registration pursuant to the demand or Form S-3 registration rights described in the preceding two paragraphs above, the holders of these shares are entitled to notice of the registration and have the right, subject to certain limitations, to include their shares in the registration.

Expenses of Registration

We will pay all expenses relating to any demand registrations, Form S-3 registrations and piggyback registrations, subject to specified limitations.

Termination

The registration rights terminate upon the earliest of (i) the date that is five years after the completion of this offering, (ii) immediately prior to the completion of certain liquidation events and (iii) as to a given holder of registration rights, the date after the completion of this offering when such holder of registration rights can sell all of such holder's registrable securities during any 90-day period pursuant to Rule 144 promulgated under the Securities Act.

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 that will be included in 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.

Preferred Stock

Our amended and restated certificate of incorporation will contain provisions that permit our board of directors to issue, without any further vote or action by the stockholders, shares of preferred stock in one or more series and, with respect to each such series, to fix the number of shares constituting the series and the designation of the series, the voting rights (if any) of the shares of the series and the powers, preferences or relative, participation, optional and other special rights, if any, and any qualifications, limitations or restrictions, of the shares of such series.

Classified Board

Our amended and restated certificate of incorporation will provide that 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. The term of the initial Class I directors shall terminate on the date of the 2021 annual meeting of stockholders, the term of the initial Class II directors shall terminate on the date of the 2022 annual meeting of stockholders, and the term of the initial Class III directors shall terminate on the date of the 2023 annual meeting of stockholders. At each annual meeting of stockholders beginning in 2021, 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 will provide that stockholders may only remove a director for cause by a vote of no less than a majority of the shares present in person or by proxy at a meeting of stockholders and entitled to vote.

Director Vacancies

Our amended and restated certificate of incorporation will authorize only our board of directors to fill vacant directorships.

No Cumulative Voting

Our amended and restated certificate of incorporation will provide 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 will provide that, except as otherwise required by law, 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 bylaws will 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 the amended and restated bylaws will not give the board of directors the power to approve or disapprove stockholder nominations of candidates to be elected at an annual meeting, the 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 will 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 common stock. Our amended and restated bylaws may be adopted, amended, altered or repealed by stockholders only upon approval of at least two-thirds of the voting power of all the then outstanding shares of the common stock. Additionally, our amended and restated certificate of incorporation will provide 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.

Exclusive Jurisdiction

Our amended and restated bylaws will provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum

for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim arising pursuant to the DGCL, any action regarding our amended and restated certificate of incorporation or amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. 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. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these provisions. Although we believe these provisions benefit us by providing increased consistency in the application of law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Please also see the section titled “Risk Factors—Our amended and restated bylaws that will become effective upon the closing of this offering 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.”

Business Combinations with Interested Stockholders

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.

Limitation on Liability and Indemnification

Our amended and restated certificate of incorporation and our amended and restated bylaws will provide that we must indemnify our directors and officers to the fullest extent authorized by the DGCL. We are expressly authorized to, and do, carry directors’ and officers’ insurance providing coverage for our directors, officers and certain employees for some liabilities. We believe that these indemnification provisions and insurance are useful to attract and retain qualified directors and executive directors.

The limitation on liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. In addition, your investment may be adversely affected to the extent we pay the costs of settlement and damage awards against

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directors and officers pursuant to these indemnification provisions. See the section titled “Executive Compensation—Limitation of Liability and Indemnification” for additional information.

Listing

We intend to apply to list our common stock on the Nasdaq Global Market under the symbol “PMVP.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is . The transfer agent and registrar’s address is .

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and although we expect that our common stock will be approved for listing on the Nasdaq Global Market, we cannot assure investors that there will be an active public market for our common stock following this offering. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. Future sales of substantial amounts of common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, however, could adversely affect the market price of our common stock and also could adversely affect our future ability to raise capital through the sale of our common stock or other equity-related securities of ours at times and prices we believe appropriate.

Upon completion of this offering, based on our shares of common stock outstanding as of June 30, 2020 and after giving effect to the conversion of all of the 148,413,322 shares of our convertible preferred stock outstanding at June 30, 2020 and the conversion of all of our Series D convertible preferred stock issued and sold in July 2020 into 28,020,172 shares of common stock, _____ shares of our common stock will be outstanding, or _____ shares of common stock if the underwriters exercise their option to purchase additional shares in full. All of the shares of common stock expected to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or Securities Act, unless held by our “affiliates,” as that term is defined in Rule 144 under the Securities Act. The remaining outstanding shares of our common stock will be deemed “restricted securities” as that term is defined under Rule 144. Restricted securities may be sold in the public market only if their offer and sale is registered under the Securities Act or if the offer and sale of those securities qualify for an exemption from registration, including exemptions provided by Rules 144 and 701 under the Securities Act, which are summarized below.

As a result of the lock-up agreements and market stand-off provisions described below and the provisions of Rules 144 or 701 and assuming no exercise of the underwriters’ option to purchase additional shares, the shares of our common stock that will be deemed “restricted securities” will be available for sale in the public market following the completion of this offering as follows:

- _____ shares will be eligible for sale on the date of this prospectus; and
- _____ shares will be eligible for sale upon expiration of the lock-up agreements and market stand-off provisions described below, beginning more than 180 days after the date of this prospectus.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

Lock-Up Agreements and Market Stand-off Agreements

Our officers, directors and the holders of substantially all of our capital stock and options have entered into market stand-off agreements with us and have entered into or will enter into lock-up agreements with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior consent of Goldman Sachs & Co. LLC, BofA Securities, Inc., Cowen and Company, LLC and Evercore Group L.L.C. See the section titled “Underwriting” for additional information.

Rule 144

Rule 144, as currently in effect, generally provides that, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, or Exchange Act, for at least 90 days, a stockholder who is not deemed to have been one of our affiliates at any time during the preceding three months and who has beneficially owned the shares of our capital stock proposed to be sold for at least six months is entitled to sell such shares in reliance upon Rule 144 without complying with the volume limitation, manner of sale or notice conditions of Rule 144. If such stockholder has beneficially owned the shares of our capital stock proposed to be sold for at least one year, then such person is entitled to sell such shares in reliance upon Rule 144 without complying with any of the conditions of Rule 144.

Rule 144 also provides that a stockholder who is deemed to have been one of our affiliates at any time during the preceding 90 days and who has beneficially owned the shares of our common stock proposed to be sold for at least six months is entitled to sell such shares in reliance upon Rule 144 within any three-month period beginning 90 days after the date of this prospectus a number of shares that does not exceed the greater of the following:

- 1% of the number of shares of our capital stock then outstanding, which will equal shares of common stock immediately after the completion of this offering, assuming no exercise by the underwriters of their option to purchase additional shares; or
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales of our capital stock made in reliance upon Rule 144 by a stockholder who is deemed to have been one of our affiliates at any time during the preceding 90 days are also subject to the current public information, manner of sale and notice conditions of Rule 144.

Rule 701

Rule 701 generally provides that, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a stockholder who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract and who is not deemed to have been one of our affiliates at any time during the preceding three months may sell such shares (to the extent such shares are not subject to a lock-up agreement) in reliance upon Rule 144 without complying with the current public information or holding period conditions of Rule 144. Rule 701 also provides that a stockholder who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract and who is deemed to have been one of our affiliates during the preceding 90 days may sell such shares under Rule 144 without complying with the holding period condition of Rule 144 (subject to the lock-up agreement referred to above, if applicable). However, all stockholders who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701 (subject to the lock-up agreements and market stand-off agreements referred to above, if applicable).

Form S-8 Registration Statement

After the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to equity awards outstanding or reserved for issuance under our equity compensation plans. The shares of our common stock covered by such registration statement will be eligible for sale in the public market without

restriction under the Securities Act immediately upon the effectiveness of such registration statement, subject to vesting restrictions, the conditions of Rule 144 applicable to affiliates, and any applicable market stand-off agreements and lock-up agreements. See the section titled “Executive Compensation—Employee Benefit and Stock Plans” for a description of our equity compensation plans.

Registration Rights

After the completion of this offering, holders of up to 148,470,188 shares of our common stock will be entitled to certain rights with respect to the registration of such shares under the Securities Act. The registration of these shares of our common stock under the Securities Act would result in these shares becoming eligible for sale in the public market without restriction under the Securities Act immediately upon the effectiveness of such registration, subject to the Rule 144 limitations applicable to affiliates. See the section titled “Description of Capital Stock—Registration Rights” for a description of these registration rights.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of the material U.S. federal income tax consequences of the ownership and disposition of our common stock acquired in this offering by a “non-U.S. holder” (as defined below), but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the U.S. Internal Revenue Code of 1986, as amended, or Code, Treasury Regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. We have not sought, and do not intend to seek, any ruling from the Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This summary assumes that the non-U.S. holder holds our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). This summary also does not address the tax considerations arising under the laws of any U.S. state or local or non-U.S. jurisdiction or under other U.S. federal tax laws, such as gift and estate tax laws. In addition, this discussion does not address tax considerations applicable to an investor’s particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions (except to the extent specifically set forth below), regulated investment companies, real estate investment trusts or other financial institutions;
- persons subject to the alternative minimum tax or the surtax on net investment income;
- tax-exempt organizations or governmental organizations;
- pension plans and tax-qualified retirement plans;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- brokers or dealers in securities or currencies;
- traders in securities or other persons that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);
- U.S. expatriates or certain former citizens or long-term residents of the United States;
- persons who hold our common stock as a position in a hedging transaction, “straddle,” “conversion transaction” or other risk reduction transaction or integrated investment;
- persons who hold or receive our common stock pursuant to the exercise of any option or otherwise as compensation;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an “applicable financial statement” as defined in Section 451(b) of the Code; or
- persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership, entity or arrangement classified as a partnership or flow-through entity for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership or other entity. A partner in a partnership or other such entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other such entity, as applicable.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal gift or estate tax rules or under the laws of any state, local, non-U.S. or other taxing jurisdiction or under any applicable tax treaty.

Non-U.S. Holder Defined

For purposes of this discussion, a “non-U.S. holder” is a beneficial owner of our common stock that, for U.S. federal income tax purposes, is not a partnership and is not:

- an individual who is a citizen or resident of the United States;
- a corporation or other entity taxable as a corporation created or organized in the United States or under the laws of the United States or any political subdivision thereof, or otherwise treated as such for U.S. federal income tax purposes;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (x) whose administration is subject to the primary supervision of a U.S. court and that has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (y) that has made a valid election under applicable Treasury Regulations to be treated as a U.S. person.

Distributions

As described in the section titled “Dividend Policy,” we have not declared or paid cash dividends on our capital stock since our inception, and we do not anticipate paying any cash dividends in the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, the excess will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under “—Gain on Disposition of Common Stock.”

Subject to the discussions below on effectively connected income, backup withholding and the Foreign Account Tax Compliance Act, Treasury Regulations issued thereunder and official IRS guidance, collectively FATCA, any dividend paid to you generally will be subject to U.S. federal withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty between the United States and your country of residence. In order to receive a reduced treaty rate, you must provide an IRS Form W-8BEN or W-8BEN-E or other appropriate version of IRS Form W-8, including any required attachments, certifying qualification for the reduced rate. A non-U.S. holder of shares of our common stock eligible for a reduced rate of U.S. federal withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the IRS. If the non-U.S. holder holds our common stock through a financial institution or other agent, the non-U.S. holder will

be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries. You should consult your tax advisors regarding your entitlement to benefits under an applicable tax treaty.

Dividends received by you that are treated as effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, such dividends are attributable to a permanent establishment or fixed base maintained by you in the United States) are generally exempt from the 30% U.S. federal withholding tax, subject to the discussions below on backup withholding and FATCA. In order to obtain this exemption, you must provide a properly executed IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to U.S. federal withholding tax, are taxed at the same rates applicable to U.S. persons, net of certain deductions and credits, subject to an applicable income tax treaty providing otherwise. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty between the United States and your country of residence. You should consult your tax advisor regarding any applicable tax treaties that may provide for different rules.

Gain on Disposition of Common Stock

Subject to the discussion below regarding backup withholding, you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with your conduct of a U.S. trade or business (and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by you in the United States);
- you are a non-resident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or
- our common stock constitutes a United States real property interest by reason of our status as a “United States real property holding corporation,” or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our U.S. and worldwide real property plus our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, your common stock will be treated as United States real property interests only if you actually (directly or indirectly) or constructively held more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay tax on the gain derived from the sale (net of certain deductions and credits) under regular U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be subject to tax at 30% (or such lower rate specified by an applicable income tax treaty) on the gain derived from

the sale, which gain may be offset by certain U.S. source capital losses, provided you have timely filed U.S. federal income tax returns with respect to such losses. You should consult your tax advisor regarding any applicable income tax or other treaties that may provide for different rules.

Backup Withholding and Information Reporting

Payments of dividends on or of proceeds from the disposition of our common stock made to you may be subject to information reporting and backup withholding at a current rate of 24% unless you establish an exemption, for example, by properly certifying your non-U.S. status on a properly completed IRS Form W-8BEN or W-8BEN-E or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that you are a U.S. person.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If backup withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Notwithstanding the foregoing, generally, we must report annually to the IRS the amount of distributions paid to you, your name and address and the amount of tax withheld, if any. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Foreign Account Tax Compliance Act (FATCA)

FATCA generally imposes a U.S. federal withholding tax of 30% on dividends on, and (subject to the proposed Treasury Regulations discussed below) the gross proceeds from a sale or other disposition of our common stock, paid to a “foreign financial institution” (as specially defined under these rules), unless otherwise provided by the Treasury Secretary or such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and (subject to the proposed Treasury Regulations discussed below) the gross proceeds from a sale or other disposition of our common stock paid to a “non-financial foreign entity” (as specially defined under these rules), unless otherwise provided by the Treasury Secretary or such entity provides the withholding agent with a certification identifying the substantial direct and indirect U.S. owners of the entity, certifies that it does not have any substantial U.S. owners, or otherwise establishes an exemption.

The withholding obligations under FATCA generally apply to dividends on our common stock. The withholding tax will apply regardless of whether the payment otherwise would be exempt from U.S. nonresident and backup withholding tax, including under the other exemptions described above. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of amounts so withheld. The Treasury Secretary has issued proposed regulations providing that the withholding provisions under FATCA do not apply with respect to payment of gross proceeds from a sale or other disposition of our common stock, which may be relied upon by a taxpayer (including an applicable withholding agent) until final regulations are issued.

An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Prospective investors should consult with their

tax advisors regarding the application of FATCA withholding to their investment in, and ownership and disposition of, our common stock.

The preceding discussion of U.S. federal income tax consequences is for general information only. It is not tax advice. Each prospective investor should consult his, her or its tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC, BofA Securities, Inc., Cowen and Company, LLC and Evercore Group L.L.C. are the representatives of the underwriters.

<u>Underwriters</u>	<u>Number of Shares</u>
Goldman Sachs & Co. LLC	
BofA Securities, Inc.	
Cowen and Company, LLC	
Evercore Group L.L.C.	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional _____ shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days from the date of this prospectus. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase _____ additional shares.

	<u>No Exercise</u>	<u>Full Exercise</u>
Per Share	\$	\$
Total	\$	\$

We estimate that our total out of pocket expenses for this offering, excluding the underwriting discounts and commissions, will be approximately \$ _____. We have also agreed to reimburse the underwriters certain of their expenses in an amount up to \$ _____.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended.

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$ _____ per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors, and holders of substantially all of our common stock and securities convertible into or exchangeable for our common stock have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of our common stock during the period from the date of this prospectus

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continuing through the date 180 days after the date of this prospectus, except with the prior written consent of the representatives. This agreement does not apply to any existing employee benefit plans. See the section titled “Shares Eligible for Future Sale” for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the shares. The initial public offering price has been negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We intend to apply to list our common stock on the Nasdaq Global Market under the symbol “PMVP.”

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on _____, in the over-the-counter market or otherwise.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of us (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

European Economic Area

In relation to each member state of the European Economic Area, or each, a Member State, no shares of our common stock have been offered or will be offered pursuant to the offering to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

- to any legal entity which is a qualified investor as defined in the Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares of our common stock shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares of common stock in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of common stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of common stock, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

This European Economic Area selling restriction is in addition to any other selling restrictions set out below.

United Kingdom

In the United Kingdom, this prospectus is only addressed to and directed at qualified investors who are (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000, as amended (Financial Promotion), Order 2005 (the Order) or (ii) high net worth entities and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). Any investment or investment activity to which this prospectus relates is available only to relevant persons and will only be engaged in with relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong), or Companies (Winding Up and Miscellaneous Provisions) Ordinance, or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or Securities and Futures Ordinance, or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

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Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for six months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore, or Regulation 32.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for six months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA or (6) as specified in Regulation 32.

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

LEGAL MATTERS

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, Palo Alto, California. Certain legal matters relating to the offering will be passed upon for the underwriters by Latham & Watkins LLP, Menlo Park, California. Certain members of, and investment partnerships comprised of members of, and persons associated with, Wilson Sonsini Goodrich & Rosati, Professional Corporation, own an interest representing less than one percent of the shares of our common stock.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2018 and 2019, and for the years then ended, as set forth in their report. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the Securities and Exchange Commission, or SEC, a registration statement on Form S-1 under the Securities Act of 1933, as amended, with respect to the shares of our common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document is not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC maintains an Internet website that contains the registration statement of which this prospectus forms a part, as well as the exhibits thereto. These documents, along with future reports, proxy statements and other information about us, are available at the SEC's website, www.sec.gov.

As a result of this offering, we will become subject to the information and reporting requirements of the Exchange Act of 1934, as amended, and, in accordance with this law, will file periodic reports, proxy statements and other information with the SEC. We also maintain a website at www.pmvpharma.com where these materials will be available. Upon the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on, or that can be accessible through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

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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, 2018 and 2019, the related statements of operations and comprehensive loss, changes in convertible preferred stock and stockholders' deficit and cash flows for the years then ended, 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, 2018 and 2019, and the results of its operations and its cash flows for the years then ended, 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 and in accordance with auditing standards generally accepted in the United States of America. 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. 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

June 26, 2020

PMV Pharmaceuticals, Inc.
Balance Sheets
(in thousands, except share and per share amounts)

	As of December 31, 2018	As of December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 30,307	\$ 73,278
Short-term marketable securities	31,600	28,208
Prepaid expenses and other current assets	332	607
Total current assets	62,239	102,093
Property and equipment, net	1,018	739
Other assets	201	201
Total assets	<u>\$ 63,458</u>	<u>\$ 103,033</u>
Liabilities, Convertible Preferred Stock, and Stockholders' Deficit		
Current liabilities		
Accounts payable	\$ 1,038	\$ 2,837
Accrued expenses	1,289	1,686
Total current liabilities	2,327	4,523
Other liabilities	43	51
Total liabilities	<u>2,370</u>	<u>4,574</u>
Commitments and contingencies (see Note 6)	—	—
Convertible preferred stock, accumulated liquidation value of \$107,512 and \$169,385 at December 31, 2018 and 2019, respectively (see Note 7)	107,228	168,933
Stockholders' deficit:		
Common stock, \$0.00001 par value, 130,000,000 and 175,068,944 shares authorized; 15,860,018 and 16,038,590 shares issued and outstanding at December 31, 2018 and 2019, respectively	—	—
Additional paid-in capital	3,961	4,969
Accumulated deficit	(50,088)	(75,440)
Accumulated other comprehensive loss	(13)	(3)
Total stockholders' deficit	(46,140)	(70,474)
Total liabilities, convertible preferred stock, and stockholders' deficit	<u>\$ 63,458</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, 2018	Year Ended December 31, 2019
Operating Expenses:		
Research and development	\$ 13,853	\$ 20,759
General and administrative	5,039	5,878
Total operating expenses	<u>18,892</u>	<u>26,637</u>
Loss from operations	(18,892)	(26,637)
Other income (expense):		
Interest income, net	1,341	1,301
Other income (expense)	16	(8)
Total other income (expense)	<u>1,357</u>	<u>1,293</u>
Loss before provision for income taxes	(17,535)	(25,344)
Provision for income taxes	3	8
Net loss	(17,538)	(25,352)
Unrealized gains on marketable securities, net of tax	52	10
Comprehensive loss	<u>\$ (17,486)</u>	<u>\$ (25,342)</u>
Net loss per share—basic and diluted	\$ (1.11)	\$ (1.59)
Weighted-average common shares outstanding	15,860,018	15,980,859
Pro forma net loss per share—basic and diluted (unaudited)		\$ (0.15)
Pro forma weighted-average common shares outstanding (unaudited)		164,394,182

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balances at December 31, 2017	91,595,100	\$ 107,228	15,860,018	\$ —	\$ 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	91,595,100	107,228	15,860,018	—	3,961	(13)	(50,088)	(46,140)
Issuance of Series C convertible preferred stock, net of issuance costs of \$168	28,798,050	61,705	—	—	—	—	—	—
Exercise of stock options	—	—	178,572	—	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	120,393,150	\$ 168,933	16,038,590	\$ —	\$ 4,969	\$ (3)	\$ (75,440)	\$ (70,474)

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

PMV Pharmaceuticals, Inc.
Statements of Cash Flows
(in thousands)

	Year Ended December 31, 2018	Year Ended December 31, 2019
Cash flows from operating activities:		
Net loss	\$ (17,538)	\$ (25,352)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	1,079	908
Depreciation	338	388
Amortization of premiums on marketable securities	319	62
Other	(13)	8
Prepaid expenses and other assets	(17)	(275)
Accounts payable	267	1,799
Accrued expenses	387	397
Net cash used in operating activities	<u>(15,178)</u>	<u>(22,065)</u>
Cash flows from investing activities:		
Acquisition of property and equipment	(452)	(109)
Purchase of marketable securities	(48,678)	(43,452)
Maturities of marketable securities	70,823	46,792
Net cash provided by investing activities	<u>21,693</u>	<u>3,231</u>
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock	—	61,873
Payment of equity issuance costs	—	(168)
Proceeds from exercise of stock options	—	100
Net cash provided by financing activities	<u>—</u>	<u>61,805</u>
Net increase in cash and cash equivalents	6,515	42,971
Cash and cash equivalents		
Cash and cash equivalents—beginning of period	23,792	30,307
Cash and cash equivalents—end of period	<u>\$ 30,307</u>	<u>\$ 73,278</u>
Supplemental disclosures of cash flow information		
Cash paid for income tax	\$ —	\$ 8

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

PMV Pharmaceuticals, Inc.
Notes to Financial Statements
December 31, 2018 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.

The Company has incurred net losses and negative cash flows from operations. During the year ended December 31, 2019, the Company incurred a net loss of \$25,352 and used \$22,065 of cash for operations. At December 31, 2019, the Company had accumulated deficit of \$75,440. Cash, cash equivalents and short-term marketable securities at December 31, 2019 were \$101,486. Management expects to incur substantial additional operating losses for the next several years and will 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 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

PMV Pharmaceuticals, Inc.
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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.

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.

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. 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' deficit. 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, 2018 and 2019, the Company recorded \$319 and \$62 of amortization, respectively.

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

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

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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.

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 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

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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.

Non-employee option awards are measured at the earlier of the commitment date for performance by the counterparty or the date when performance is complete, and compensation expense is recognized in the same manner as if we had paid cash for goods or services.

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 has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been 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, 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

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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.

Unaudited Pro Forma Financial Information

The unaudited pro forma net loss per share is computed using the weighted-average number of shares of common stock outstanding after giving pro forma effect to the conversion of all issued and outstanding shares of convertible preferred stock during the year ended December 31, 2019 into shares of common stock as if such conversion had occurred at January 1, 2019, or the date of original issuance, if later.

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 2018 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

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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.

The Company expects to qualify as an emerging growth company (“EGC”) upon issuance of its initial public offering. 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 retain its status as an EGC through December 31, 2022, and therefore expects to adopt ASU 2016-02 for the annual period ended December 31, 2022, with the provisions of the new standard reflected in quarterly periods thereafter. The Company is currently evaluating the impact of this accounting standard update on its financial statements.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments*, related to the classification of certain cash receipts and cash payments on the Statement of Cash Flows. The Company adopted the accounting standard effective January 1, 2019. There was no material impact on the financial statements.

In July 2017, the FASB issued ASU 2017-11, *I. Accounting for Certain Financial Instrument with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of the ASU simplifies the accounting for certain equity-linked financial instruments and embedded features with down round features that reduce the exercise price when the pricing of a future round of financing is lower (down round protection). Current accounting guidance provides that instruments with down round protection be classified as derivative liabilities with changes in fair value recorded through earnings. The updated guidance provides that instruments with down round protection are no longer precluded from being classified as equity. This guidance is effective for fiscal years beginning after December 15, 2018 and early adoption is permitted. This guidance must be applied retrospectively. The Company adopted this guidance on January 1, 2019 and the adoption did not have a material impact on its financial statements.

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 will adopt this guidance on January 1, 2020. The Company is currently evaluating the impact of adopting this standard 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

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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 is currently evaluating the impact of adopting this standard 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 a checking account held at one financial institution. 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 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, 2018 and 2019:

	As of December 31, 2019				
	Carrying Amount	Fair Value	Quoted Priced in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets					
Money market funds	1,680	1,680	1,680	—	—
Corporate debt 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>
	As of December 31, 2018				
	Carrying Amount	Fair Value	Quoted Priced in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets					
Money market funds	82	82	82	—	—
US government	3,977	3,977	3,977	—	—
Corporate debt securities	56,734	56,721	—	56,721	—
Total assets	<u>\$60,793</u>	<u>\$ 60,780</u>	<u>\$ 4,059</u>	<u>\$ 56,721</u>	<u>\$ —</u>

Cash Equivalents—Cash equivalents of \$29.2 million as of December 31, 2018 consisted of money market funds of \$0.1 million, and corporate debt securities of \$29.1 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 debt 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 \$31.6 million and \$28.2 million as of December 31, 2018 and 2019, respectively, 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.

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4. Property and Equipment, Net

	Years Ended	
	December 31, 2018	December 31, 2019
Machinery & equipment	\$ 1,789	\$ 1,898
Computers	8	8
Furniture & fixtures	9	9
Leasehold improvements	67	67
Total property and equipment	1,873	1,982
Less: Accumulated depreciation	(855)	(1,243)
Property and equipment, net	<u>\$ 1,018</u>	<u>\$ 739</u>

Depreciation expense for the years ended December 31, 2018 and 2019 was \$338 and \$388, respectively.

5. Accrued Expense

Accrued expense consists of the following:

	Years Ended	
	December 31, 2018	December 31, 2019
Accrued bonuses	\$ 893	\$ 1,281
Accrued vacation	279	367
Other accrued liabilities	117	38
Total	<u>\$ 1,289</u>	<u>\$ 1,686</u>

6. Commitments and Contingencies

In April 2017, the Company amended an existing operating lease for 18,446 square feet of office and laboratory space in Cranbury, New Jersey, that expires in June 2022. In August 2018, the Company signed an operating lease for 6,297 square feet of additional office and laboratory space in Cranbury, New Jersey, which expires in July 2022. In September 2018, the Company signed an operating lease for 3,292 square feet of additional office and laboratory space in Bedford, Massachusetts, which expires in August 2023.

The minimum lease payments under these leases are as follows:

Years Ended December 31,	
2020	\$ 479
2021	479
2022	251
2023	4
Thereafter	—
Total future minimum lease payments	<u>\$1,213</u>

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Rent expense recorded during the years ended December 31, 2018 and 2019 was \$479 and \$580, respectively.

At December 31, 2019, 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

The Company is authorized to issue up to 120,483,538 shares of convertible preferred stock with a par value of \$0.00001 per share. 8,729,029 shares have been designated as Series Seed convertible preferred stock (Series Seed Preferred), 42,526,138 shares have been designated as Series A convertible preferred stock (Series A Preferred), 40,396,799 shares have been designated as Series B convertible preferred stock (Series B Preferred) and 28,831,572 shares have been designated as Series C convertible preferred stock (Series C Preferred). At December 31, 2019, the Company had an aggregate of 120,393,150 shares of Series Seed Preferred, Series A Preferred, Series B Preferred and Series C Preferred (collectively, "Preferred Stock") issued and outstanding.

As of December 31, 2019, 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	8,729,029	8,672,163	\$ 3,008	\$ 3,050	8,672,163
Series A Preferred	42,526,138	42,526,138	30,593	30,734	42,526,138
Series B Preferred	40,396,799	40,396,799	73,627	73,728	40,396,799
Series C Preferred	28,831,572	28,798,050	61,705	61,873	28,798,050
	120,483,538	120,393,150	\$ 168,933	\$ 169,385	120,393,150

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

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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 \$0.3517 for Series Seed Preferred, \$0.7078 for Series A Preferred, \$1.8251 for Series B Preferred and \$2.1485 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 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 \$2.1485 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 \$0.3517, \$0.7078, \$1.8251 and \$2.1485, respectively.

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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.

Protective Provisions:

The holders of preferred stock have certain protective provisions.

As long as at least twenty percent (20%) of the shares of Preferred Stock originally issued remain outstanding (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations, reorganizations, reclassifications or the like), the Company shall not, either directly or by amendment, merger, consolidation, reclassification or otherwise, amend, alter or repeal any provision of the Company's Certificate of Incorporation or Bylaws in a manner that would adversely alter the rights, preferences, and privileges of Preferred Stock, or take certain other actions that would alter the rights, preferences, and privileges of Preferred Stock or effect liquidation, dissolution or winding up of the Company.

As long as at least twenty percent (20%) of the shares of Series A Preferred Stock originally issued remain outstanding (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations, reorganizations, reclassifications or the like), the Company shall not, either directly or by amendment, merger, consolidation, reclassification or otherwise, amend, alter or repeal any provision of the Company's Certificate of Incorporation or Bylaws in a manner that would adversely alter the rights, preferences, and privileges of the Series A Preferred without first obtaining approval of a majority of the outstanding shares of Series A Preferred.

As long as at least twenty percent (20%) of the shares of Series B Preferred Stock originally issued remain outstanding (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations, reorganizations, reclassifications or the like), the Company shall not, either directly or by amendment, merger, consolidation, reclassification or otherwise, amend, alter or repeal any provision of the Company's Certificate of Incorporation or Bylaws in a manner that would adversely alter the rights, preferences, and privileges of the Series B Preferred without first obtaining approval of a majority of the outstanding shares of Series B Preferred.

As long as at least twenty percent (20%) of the shares of Series C Preferred Stock originally issued remain outstanding (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations, reorganizations, reclassifications or the like), the Company shall not, either directly or by amendment, merger, consolidation, reclassification or otherwise, amend, alter or repeal any provision of the Company's Certificate of Incorporation or Bylaws in a manner that would adversely alter the rights, preferences, and privileges of the Series C Preferred or effect liquidation, dissolution or winding up of the Company, unless each share of Series C Preferred receives at least the original issue price of \$2.1485 in any such transaction, without first obtaining approval of a majority of the outstanding shares of Series C Preferred.

8. Common Stock

The Company is authorized to issue up to 175,068,944 shares of common stock with a par value of \$0.00001 per share. At December 31, 2018 and 2019, there were 15,860,018 and 16,038,590 shares issued and outstanding, respectively.

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Common stockholders are entitled to dividends if and when declared by the Board of Directors subject to the rights of the preferred stockholders. As of December 31, 2019, no dividends on common stock had been declared by the Company.

At December 31, 2018 and 2019, the Company had reserved shares of common stock for issuance as follows:

	December 31, 2018	December 31, 2019
Convertible preferred stock outstanding	91,595,100	120,393,150
Options issued and outstanding	14,140,032	14,573,100
Warrant issued and outstanding	56,866	56,866
Shares available for future stock option grants	3,669,997	8,058,357
Total	109,461,995	143,081,473

9. Stock Plan

In 2014, the Company adopted the 2013 Stock Plan (the "Plan"). As of December 31, 2019, there were 23,363,923 shares of common stock authorized and 8,058,357 shares available for issuance under the Plan. Under the Plan, the Company may issue shares of common stock and options to purchase common stock to employees and consultants. Options granted under the Plan may be Incentive Stock Options or Non-statutory Stock Options, as determined by the Administrator at the time of grant. Stock Purchase Rights may also be granted under the Plan. The term shall be no more than ten years from the date of grant thereof. In the case of an Incentive Stock Option granted to an optionee who, at the time the option is granted, owns stock representing more than 10% of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the term of the option shall be five years from the date of grant or such shorter term as may be provided in the option Agreement.

In the case of an Incentive Stock Option, (i) granted to an employee who, at the time of grant of such option, owns stock representing more than 10% of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the exercise price shall be no less than 110% of the Fair Market Value per Share on the date of grant; (ii) granted to any other employee, the per share exercise price shall be no less than 100% of the Fair Market Value per Share on the date of grant. In the case of a Non-statutory Stock Option; (i) granted to a Service Provider who, at the time of grant of such option, owns stock representing more than 10% of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the exercise price shall be no less than 110% of the Fair Market Value per Share on the date of grant; (ii) granted to any other service provider, the per share exercise price shall be no less than 100% of the Fair Market Value per Share on the date of grant. Notwithstanding the foregoing, options may be granted with a per share exercise price other than as required above pursuant to a merger or other corporate transaction.

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The options may include provisions permitting exercise of the option prior to full vesting. Any unvested shares so purchased shall be subject to repurchase by the Company at the original exercise price of the option.

	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)
Balances, December 31, 2017	6,448,937	11,361,092	\$ 0.26	8.56	\$ 3,270
Shares reserved for issuance	—	—			
Options granted	(4,215,465)	4,215,465	\$ 0.61		
Options forfeited / cancelled	1,436,525	(1,436,525)	\$ 0.61		
Options exercised	—	—	\$ —		
Balances, December 31, 2018	3,669,997	14,140,032	\$ 0.38	7.88	\$ 4,118
Shares reserved for issuance	5,000,000	—			
Options granted	(1,315,000)	1,315,000	\$ 0.67		
Options forfeited / cancelled	703,360	(703,360)	\$ 0.57		
Options exercised	—	(178,572)	\$ 0.56		
Balances, December 31, 2019	<u>8,058,357</u>	<u>14,573,100</u>	<u>\$ 0.39</u>	7.08	\$ 5,048
At December 31, 2019					
Vested		<u>9,884,600</u>	\$ 0.32	6.59	\$ 4,197
Exercisable		<u>11,509,852</u>	\$ 0.34	6.72	\$ 4,648

The aggregate intrinsic value of options vested and exercisable as of December 31, 2019 is calculated based on the difference between the exercise price and the current fair value of our common stock. The intrinsic value of options exercised in 2019 was \$20. There were no stock option exercises in 2018.

At December 31, 2019, the total compensation cost related to nonvested service-based awards not yet recognized is \$1,481. The weighted-average period over which the nonvested awards is expected to be recognized is 1.9 years.

Stock-Based Compensation for Employees

Employee options generally vest over four years. Stock-based compensation expense recognized during the years ended December 31, 2018 and 2019 for stock-based awards granted to employees based on the grant date fair value estimated in accordance with the provisions of ASC 718 was \$847 and \$854, respectively. The unrecognized compensation cost as of December 31, 2019 is expected to be recognized over a weighted-average amortization period of 2.0 years.

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

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requisite service period of the awards. The fair value of employee stock options was estimated using the following assumptions:

	Years Ended December 31,	
	2018	2019
Weighted average grant date fair value of common stock	\$0.61	\$0.67
Risk-free interest rate	2.68% – 2.83%	1.49% – 2.51%
Expected life (in years)	5.99	5.27 – 6.37
Dividend yield	0%	0%
Expected volatility	63.74% – 81.20%	72.07% – 72.69%

Expected Term: The Company uses the simplified method to calculate expected term described in the Securities and Exchange Commission's Staff Accounting Bulletin No. 107, which takes into account vesting term and expiration date of the options.

Volatility: Volatility is based on an average of the historical volatilities of comparable publicly traded companies for the expected term.

Risk Free Interest Rate: The risk-free rate is based on the U.S. Treasury yields in effect at the time of grant for periods corresponding with the expected term of the option.

Dividend Yield: The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and therefore, used an expected dividend yield of zero in the valuation model.

During the year ended December 31, 2018, the Company granted 626,610 stock options at a grant-date fair value of \$0.49 per share to an executive that vests only upon the attainment of certain liquidity events. The Company does not believe that it is probable that the performance condition will be satisfied and did not record any stock compensation expense in the years ended December 31, 2018 and 2019 for this option grant. The unrecognized compensation cost associated with this award was \$305, a portion of which will be cumulatively caught-up upon achievement of the liquidity event.

Stock-Based Compensation for Non-Employees

Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services. There were no stock options granted to non-employees during the years ended December 31, 2018 and 2019.

Non-employee options generally vest over two to three years. Stock-based compensation expense is remeasured every reporting period as the options vest in accordance with the provisions of ASC 505-50. Stock compensation expense recognized during the years ended December 31, 2018 and 2019 for stock-based awards granted to non-employees was \$232 and \$54, respectively.

No income tax benefits have been recognized relating to stock-based compensation expenses and no tax benefits have been realized from exercised stock options.

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Total Stock-Based Compensation

Total stock-based compensation expense recorded under ASC 718 and ASC 505-50 related to options granted to employees and nonemployees was allocated to research and development and general and administrative expense as follows:

	Years Ended	
	December 31, 2018	December 31, 2019
Research and development	\$ 314	\$ 302
General and administrative	765	606
Total stock-based compensation	\$ 1,079	\$ 908

10. Income Taxes

The provision for income taxes consisted of current state taxes of \$3 and \$8 for the years ended December 31, 2018 and 2019, respectively. The effective tax rate for the Company for the year ended December 31, 2018 and for the year ended December 31, 2019 was zero percent. A reconciliation of income tax computed at the statutory federal income tax rate to the provision (benefit) for income taxes included in the accompanying statements of operations for the Company is as follows:

	Years Ended	
	December 31, 2018	December 31, 2019
Expected provision at statutory federal rate	21%	21%
State tax—net of federal benefit	8%	7%
Tax credits	1%	1%
Other	-1%	0%
Changes in valuation allowance	-29%	-29%
Effective income tax rate	<u>0%</u>	<u>0%</u>

For the years ended December 31, 2018 and 2019, 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.

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The tax effects of temporary differences and carryforwards that give rise to significant portions of the net deferred tax assets are presented below:

	Years Ended	
	December 31, 2018	December 31, 2019
Deferred tax assets:		
Net operating loss carryforwards	\$ 12,098	\$ 18,707
Stock compensation	315	473
Research and development credits	1,115	1,497
Accruals and reserves	353	490
Total deferred tax assets	13,881	21,167
Valuation allowance	(13,812)	(21,106)
Deferred tax assets recognized	69	61
Deferred tax liabilities:		
Fixed assets and depreciation	(69)	(61)
Total deferred tax liabilities	(69)	(61)
Net deferred tax assets	\$ —	\$ —

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.

At December 31, 2018 and 2019, the Company had net operating loss carryforwards of \$43,045 and \$66,352, respectively. At December 31, 2018, the Company had state net operating loss carryforwards for New Jersey, California and Massachusetts of approximately \$38,822, \$4,912 and \$363, 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 \$1,658 and \$2,169, respectively, at December 31, 2018 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. 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, 2018 and 2019, the Company had not accrued any interest or penalties related to uncertain tax positions.

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If the ending balance of \$415 and \$543 of unrecognized tax benefits as of December 31, 2018 and 2019, respectively, were recognized, none of the recognition would affect the income tax rate. The following table summarizes the activity related to the Company's unrecognized tax benefits:

	Years Ended	
	December 31, 2018	December 31, 2019
Unrecognized tax benefits, beginning of year	\$ 252	\$ 415
Reductions based on prior year tax positions	—	(31)
Additions based on current year tax positions	163	159
Unrecognized tax benefits, end of year	<u>\$ 415</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 2019 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.

11. Net Loss per Share and Unaudited Pro Forma 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:

	Years Ended	
	December 31, 2018	December 31, 2019
Convertible preferred stock (as converted)	91,595,100	120,393,150
Warrants to purchase common stock	56,866	56,866
Common stock options issued and outstanding	14,140,032	14,573,100
Total	<u>105,791,998</u>	<u>135,023,116</u>

	Years Ended	
	December 31, 2018	December 31, 2019
Net loss	\$ (17,538)	\$ (25,352)
Weighted-average number of shares—basic and diluted	15,860,018	15,980,859
Net loss per share—basic and diluted	\$ (1.11)	\$ (1.59)

Unaudited Pro Forma Financial Information

The unaudited pro forma net loss per share is computed using the weighted-average number of shares of common stock outstanding after giving pro forma effect to the conversion of all issued and

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outstanding shares of convertible preferred stock during the year ended December 31, 2019 into shares of common stock as if such conversion had occurred at January 1, 2019, inclusive of 28,020,172 shares of Series D preferred stock issued in July 2020.

	Year Ended December 31, 2019
Net loss	\$ (25,352)
Weighted-average number of shares—basic and diluted	15,980,859
Adjust: Assumed weighted-average effect of conversion of convertible preferred stock (unaudited)	148,413,322
Pro Forma weighted-average number of shares—basic and diluted	164,394,182
Pro Forma net loss per share—basic and diluted	\$ (0.15)

12. Related Parties

The Company has a consulting agreement with a member of the Board of Directors. Consulting fees paid in the year ended December 31, 2018 and 2019 were \$100. There were no amounts owed under the consulting agreement at December 31, 2018 or 2019.

13. Subsequent Events

Subsequent events have been evaluated through June 26, 2020, which is the date the financial statements were issued.

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Condensed Balance Sheets
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	December 31, 2019	June 30, 2020 (unaudited)	Pro forma June 30, 2020 (unaudited)
Assets			
Current assets			
Cash and cash equivalents	\$ 73,278	\$ 78,051	\$ 148,021
Short-term marketable securities	28,208	8,085	8,085
Prepaid expenses and other current assets	607	651	651
Total current assets	102,093	86,787	156,757
Property and equipment, net	739	609	609
Deferred offering costs	—	1,505	1,475
Other assets	201	201	201
Total assets	<u>\$ 103,033</u>	<u>\$ 89,102</u>	<u>\$ 159,042</u>
Liabilities, Convertible Preferred Stock, and Stockholders' (Deficit) Equity			
Current liabilities			
Accounts payable	\$ 2,837	\$ 2,146	\$ 2,146
Accrued expenses	1,686	2,937	2,907
Total current liabilities	4,523	5,083	5,053
Other liabilities	51	94	94
Total liabilities	<u>4,574</u>	<u>5,177</u>	<u>5,147</u>
Convertible preferred stock, accumulated liquidation value of \$169,385, \$169,385, and \$0 at December 31, 2019, June 30, 2020 (unaudited), and pro forma June 30, 2020 (unaudited), respectively (see Note 6)	168,933	168,933	—
Stockholders' (deficit) equity			
Common stock, \$0.00001 par value, 175,068,944, 175,068,944, and 175,068,944 shares authorized; 16,038,590, 16,038,590, and 164,451,912 shares issued and outstanding at December 31, 2019, June 30, 2020 (unaudited), and pro forma June 30, 2020 (unaudited), respectively	—	—	2
Additional paid-in capital	4,969	5,648	244,549
Accumulated deficit	(75,440)	(90,661)	(90,661)
Accumulated other comprehensive loss	(3)	5	5
Total stockholders' (deficit) equity	(70,474)	(85,008)	153,895
Total liabilities, convertible preferred stock, and stockholders' (deficit) equity	<u>\$ 103,033</u>	<u>\$ 89,102</u>	<u>\$ 159,042</u>

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

PMV Pharmaceuticals, Inc.
Condensed Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Six Months Ended June 30, 2019 (unaudited)	Six Months Ended June 30, 2020 (unaudited)
Operating Expenses:		
Research and development	\$ 10,165	\$ 11,760
General and administrative	2,676	3,979
Total operating expenses	<u>12,841</u>	<u>15,739</u>
Loss from operations	(12,841)	(15,739)
Other income (expense):		
Interest income, net	714	563
Other income (expense)	—	(43)
Total other income (expense)	<u>714</u>	<u>520</u>
Loss before provision for income taxes	(12,127)	(15,219)
Provision for income taxes	<u>2</u>	<u>2</u>
Net loss	(12,129)	(15,221)
Unrealized gains on marketable securities, net of tax	16	8
Comprehensive loss	<u>\$ (12,113)</u>	<u>\$ (15,213)</u>
Net loss per share — basic and diluted	\$ (0.76)	\$ (0.95)
Weighted-average common shares outstanding	15,922,173	16,038,590
Pro forma net loss per share - basic and diluted		\$ (0.09)
Pro forma weighted-average common shares outstanding		164,451,912

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	91,595,100	\$ 107,228	15,860,018	\$ —	\$ 3,961	\$ (13)	\$ (50,088)	\$ (46,140)
Exercise of stock options (unaudited)	—	—	178,572	—	100	—	—	100
Stock-based compensation expense (unaudited)	—	—	—	—	430	—	—	430
Net loss (unaudited)	—	—	—	—	—	—	(12,129)	(12,129)
Unrealized gain on available for sale investments (unaudited)	—	—	—	—	—	16	—	16
Balance at June 30, 2019	91,595,100	\$ 107,228	16,038,590	\$ —	\$ 4,491	\$ 3	\$ (62,217)	\$ (57,723)
Balance at December 31, 2019	120,393,150	168,933	16,038,590	—	4,969	(3)	(75,440)	(70,474)
Stock-based compensation expense (unaudited)	—	—	—	—	679	—	—	679
Net loss (unaudited)	—	—	—	—	—	—	(15,221)	(15,221)
Unrealized gain on available for sale investments (unaudited)	—	—	—	—	—	8	—	8
Balance at June 30, 2020	120,393,150	\$ 168,933	16,038,590	\$ —	\$ 5,648	\$ 5	\$ (90,661)	\$ (85,008)
Issuance of Series D Convertible Preferred Stock (unaudited)	28,020,172	69,970	—	—	—	—	—	—
Conversion of convertible preferred stock into common stock (unaudited)	(148,413,322)	(238,903)	148,413,322	2	238,901	—	—	238,903
Pro forma balance at June 30, 2020	—	\$ —	164,451,912	\$ 2	\$ 244,549	\$ 5	\$ (90,661)	\$ 153,895

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

PMV Pharmaceuticals, Inc.
Condensed Statements of Cash Flows
(unaudited)
(in thousands)

	Six Months Ended June 30, 2019 (unaudited)	Six Months Ended June 30, 2020 (unaudited)
Cash flows from operating activities:		
Net loss	\$ (12,129)	\$ (15,221)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	430	679
Depreciation	186	182
Amortization of premiums on marketable securities	35	147
Other	—	43
Prepaid expenses and other assets	(95)	(44)
Accounts payable	137	(1,205)
Accrued expenses	225	385
Net cash used in operating activities	<u>(11,211)</u>	<u>(15,034)</u>
Cash flows from investing activities:		
Acquisition of property and equipment	(101)	(51)
Purchase of marketable securities	(10,735)	(14,618)
Maturities of marketable securities	33,610	34,600
Net cash provided by investing activities	<u>22,774</u>	<u>19,931</u>
Cash flows from financing activities:		
Payment of deferred offering costs	—	(124)
Proceeds from exercise of stock options	100	—
Net cash provided by (used in) financing activities	<u>100</u>	<u>(124)</u>
Net increase in cash, cash equivalents and restricted cash	11,663	4,773
Cash and cash equivalents		
Cash, cash equivalents and restricted cash - beginning of period	30,307	73,278
Cash, cash equivalents and restricted cash - end of period	<u>\$ 41,970</u>	<u>\$ 78,051</u>
Supplemental disclosures of cash flow information		
Cash paid for income tax	\$ 2	\$ 2
Supplemental disclosures of noncash financing activities		
Unpaid offering costs	\$ —	\$ 1,382

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

PMV Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
(unaudited)
(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.

The Company has incurred net losses and negative cash flows from operations. During the six months ended June 30, 2020, the Company incurred a net loss of \$15,221 and used \$15,034 of cash for operations. At June 30, 2020, the Company had accumulated deficit of \$90,661. Cash, cash equivalents and short-term marketable securities at June 30, 2020 were \$86,136. Management expects to incur substantial additional operating losses for the next several years and will 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

The Company's significant accounting policies are disclosed in the audited financial statements for the year ended December 31, 2019, included elsewhere in this prospectus. Since the date of those financial statements, there have been no changes to its significant accounting policies except as noted below.

Basis of Presentation

The unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company's management, the accompanying unaudited interim consolidated financial statements contain all adjustments that are necessary to present fairly the Company's financial position as of June 30, 2020, the results of its operations and other comprehensive loss for the six months ended June 30, 2020 and 2019, convertible preferred stock and stockholders' deficit for the six months ended June 30, 2020 and 2019 and cash flows for the six months ended June 30, 2020 and 2019. Such adjustments are of a normal and recurring nature. The results for the six months ended June 30, 2020 are not necessarily indicative of the results for the year ending December 31, 2020, or for any future period. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2019, and the notes thereto, which are included elsewhere in this prospectus.

Notes to Condensed Financial Statements
(unaudited)

(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. 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' deficit. Premiums and discounts on marketable debt securities are amortized into earnings over the life of the security. For the six-months ended June 30, 2019 and 2020, the Company recorded \$35 and \$147 of amortization, respectively.

Comprehensive Income/Loss

The Company recorded \$16 and \$8 in other comprehensive income related to unrealized gains on marketable securities, net of tax for the six-months ended June 30, 2019 and 2020, respectively. The Company presents comprehensive income in a single statement within its financial statements.

Unaudited Pro Forma Financial Information

The unaudited pro forma net loss per share is computed using the weighted-average number of shares of common stock outstanding after giving pro forma effect to the conversion of all issued and outstanding shares of convertible preferred stock during the year ended December 31, 2019 into shares of common stock as if such conversion had occurred at January 1, 2020, inclusive of 28,020,172 shares of common stock issuable upon the conversion of the Company's Series D convertible preferred stock ("Series D Preferred Stock") issued in July 2020.

Upon the closing of the Company's qualified initial public offering (see Note 6), all of the outstanding shares of convertible preferred stock will automatically convert into shares of common stock. The unaudited pro forma condensed balance sheet and the unaudited pro forma condensed statements of convertible preferred stock and stockholders' (deficit) equity give pro forma effect to the issuance and sale in July 2020 of an aggregate of 28,020,172 shares of the Company's Series D Preferred Stock for gross proceeds of \$70.0 million and the conversion of all issued and outstanding shares of convertible preferred stock as of June 30, 2020 into shares of common stock, inclusive of 28,020,172 shares of common stock issuable upon the conversion of the Company's Series D Preferred Stock issued in July 2020. The shares of common stock expected to be issued and the proceeds expected to be received in the initial public offering ("IPO") are excluded from such pro forma financial information.

Deferred Offering Costs

The Company capitalizes incremental legal, professional, accounting, and other third-party fees that are directly associated with the planned IPO as other non-current assets until the IPO is consummated. After consummation of the IPO, these costs will be recorded in stockholders' deficit as a reduction of additional paid-in-capital generated from the offering. If the Company terminates its plan for an IPO, any costs deferred will be expensed immediately. As of June 30, 2020, deferred offering costs were \$1,475.

**Notes to Condensed Financial Statements
(unaudited)**

(in thousands, except share and per share amounts)

Recently Issued and Adopted Accounting Pronouncements

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 on January 1, 2020. The adoption of this standard did not have a material impact on the Company's financial statements.

Recently Issued Accounting Standards Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes – Simplifying the Accounting for Income Taxes*. The new guidance simplifies the accounting for income taxes by removing several exceptions in the current standard and adding guidance to reduce complexity in certain areas, such as requiring that an entity reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. The new standard is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022 for all non-public entities, with early adoption permitted. The Company is currently assessing the impact that adopting this standard will have 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 includes a checking account held at one financial institution. 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, any future 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 product candidates will receive the necessary clearances. If the Company is denied clearance, clearance is delayed or it is 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

Notes to Condensed Financial Statements
(unaudited)

(in thousands, except share and per share amounts)

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.

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, 2019 and June 30, 2020:

	As of June 30, 2020 (unaudited)				
	Carrying Amount	Fair Value	Quoted priced in active markets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Assets					
Money market funds	48,657	48,657	48,657	—	—
Corporate debt securities	32,081	32,086	—	32,086	—
Total assets	<u>\$80,738</u>	<u>\$ 80,743</u>	<u>\$ 48,657</u>	<u>\$ 32,086</u>	<u>\$ —</u>
	As of December 31, 2019				
	Carrying Amount	Fair Value	Quoted Priced in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets					
Money market funds	1,680	1,680	1,680	—	—
Corporate debt 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>

Cash Equivalents — 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. Cash equivalents of \$72.7 million as of June 30, 2020 consisted of money market funds of \$48.7 million and corporate debt securities of \$24.0 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 and \$8.1 million as of December 31, 2019 and June 30, 2020, respectively, 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.

Notes to Condensed Financial Statements
(unaudited)
(in thousands, except share and per share amounts)

4. Property and Equipment, Net

	December 31, 2019	June 30, 2020 (unaudited)
Machinery & equipment	\$ 1,898	\$ 1,950
Computers	8	8
Furniture & fixtures	9	9
Leasehold improvements	67	67
Total property and equipment	1,982	2,034
Less: Accumulated depreciation	(1,243)	(1,425)
Property and equipment, net	<u>\$ 739</u>	<u>\$ 609</u>

Depreciation expense for the six months ended June 30, 2019 and 2020 was \$186 and \$182, respectively.

5. Accrued Expenses

Accrued expenses consists of the following:

	Year ended December 31, 2019	Six months ended June 30, 2020 (unaudited)
Accrued bonuses	\$ 1,281	\$ 924
Accrued vacation	367	554
Accrued legal and professional services	—	868
Accrued research and development costs	—	476
Other accrued liabilities	38	115
Total	<u>\$ 1,686</u>	<u>\$ 2,937</u>

6. Convertible Preferred Stock

The Company is authorized to issue up to 120,483,538 shares of convertible preferred stock with a par value of \$0.00001 per share. 8,729,029 shares have been designated as Series Seed convertible preferred stock (Series Seed Preferred), 42,526,138 shares have been designated as Series A convertible preferred stock (Series A Preferred), 40,396,799 shares have been designated as Series B convertible preferred stock (Series B Preferred) and 28,831,572 shares have been designated as Series C convertible preferred stock (Series C Preferred). As of June 30, 2020, the Company had an aggregate of 120,393,150 shares of Series Seed Preferred, Series A Preferred, Series B Preferred and Series C Preferred, (collectively, "Preferred Stock") issued and outstanding.

Notes to Condensed Financial Statements
(unaudited)

(in thousands, except share and per share amounts)

As of December 31, 2019 and June 30, 2020, the Preferred Stock consisted of the following (in thousands, except for share data):

	<u>Preferred Stock Authorized</u>	<u>Preferred Stock Issued and Outstanding</u>	<u>Carrying Value</u>	<u>Liquidation Preference</u>	<u>Common Stock Issuable Upon Conversion</u>
Series Seed Preferred	8,729,029	8,672,163	\$ 3,008	\$ 3,050	8,672,163
Series A Preferred	42,526,138	42,526,138	30,593	30,734	42,526,138
Series B Preferred	40,396,799	40,396,799	73,627	73,728	40,396,799
Series C Preferred	28,831,572	28,798,050	61,705	61,873	28,798,050
	<u>120,483,538</u>	<u>120,393,150</u>	<u>\$ 168,933</u>	<u>\$ 169,385</u>	<u>120,393,150</u>

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 June 30, 2020.

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 \$0.3517 for Series Seed Preferred, \$0.7078 for Series A Preferred, \$1.8251 for Series B Preferred and \$2.1485 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.

Notes to Condensed Financial Statements
(unaudited)

(in thousands, except share and per share amounts)

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 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 \$2.1485 per share (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations, reorganizations, reclassifications or the like). At June 30, 2020, the conversion price for each share of Series Seed Preferred, Series A Preferred, Series B Preferred and Series C Preferred is \$0.3517, \$0.7078, \$1.8251 and \$2.1485, 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.

Protective Provisions:

The holders of preferred stock have certain protective provisions.

As long as at least twenty percent (20%) of the shares of Preferred Stock originally issued remain outstanding (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations, reorganizations, reclassifications or the like), the Company shall not, either directly or by amendment, merger, consolidation, reclassification or otherwise, amend, alter or repeal any provision of the Company's Certificate of Incorporation or Bylaws in a manner that would adversely alter the rights, preferences, and privileges of Preferred Stock, or take certain other actions that would alter the rights, preferences, and privileges of Preferred Stock or effect liquidation, dissolution or winding up of the Company.

As long as at least twenty percent (20%) of the shares of Series A Preferred Stock originally issued remain outstanding (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations, reorganizations, reclassifications or the like), the Company shall not, either directly or by amendment, merger, consolidation, reclassification or otherwise, amend, alter or repeal any provision of the Company's Certificate of Incorporation or Bylaws in a manner that would adversely alter the rights, preferences, and privileges of the Series A Preferred without first obtaining approval of a majority of the outstanding shares of Series A Preferred.

Notes to Condensed Financial Statements
(unaudited)

(in thousands, except share and per share amounts)

As long as at least twenty percent (20%) of the shares of Series B Preferred Stock originally issued remain outstanding (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations, reorganizations, reclassifications or the like), the Company shall not, either directly or by amendment, merger, consolidation, reclassification or otherwise, amend, alter or repeal any provision of the Company's Certificate of Incorporation or Bylaws in a manner that would adversely alter the rights, preferences, and privileges of the Series B Preferred without first obtaining approval of a majority of the outstanding shares of Series B Preferred.

As long as at least twenty percent (20%) of the shares of Series C Preferred Stock originally issued remain outstanding (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations, reorganizations, reclassifications or the like), the Company shall not, either directly or by amendment, merger, consolidation, reclassification or otherwise, amend, alter or repeal any provision of the Company's Certificate of Incorporation or Bylaws in a manner that would adversely alter the rights, preferences, and privileges of the Series C Preferred or effect liquidation, dissolution or winding up of the Company, unless each share of Series C Preferred receives at least the original issue price of \$2.1485 in any such transaction, without first obtaining approval of a majority of the outstanding shares of Series C Preferred.

7. Common Stock

The Company is authorized to issue up to 175,068,944 shares of common stock with a par value of \$0.00001 per share. At December 31, 2019 and June 30, 2020, there were 16,038,590 and 16,038,590 shares issued and outstanding, respectively.

Common stockholders are entitled to dividends if and when declared by the Board of Directors subject to the rights of the preferred stockholders. As of June 30, 2020, no dividends on common stock had been declared by the Company.

At December 31, 2019 and June 30, 2020, the Company had reserved shares of common stock for issuance as follows:

	December 31, 2019	June 30, 2020 (unaudited)
Convertible preferred stock outstanding	120,393,150	120,393,150
Options issued and outstanding	14,573,100	20,653,300
Warrants issued and outstanding	56,866	56,866
Shares available for future stock option grants	8,058,357	1,978,157
Total	143,081,473	143,081,473

8. Stock Plan

In 2014, the Company adopted the 2013 Stock Plan (the "Plan"). As of June 30, 2020, there were 23,363,923 shares of common stock authorized and 1,978,157 shares available for issuance under the Plan. Under the Plan, the Company may issue shares of common stock and options to purchase common stock to employees and consultants. Options granted under the Plan may be Incentive Stock Options or Non-statutory Stock Options, as determined by the Administrator at the time of grant. Stock Purchase Rights may also be granted under the Plan. The term shall be no more than ten years from the date of grant thereof. In the case of an Incentive Stock Option granted to an optionee who, at the

Notes to Condensed Financial Statements
(unaudited)

(in thousands, except share and per share amounts)

time the option is granted, owns stock representing more than 10% of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the term of the option shall be five years from the date of grant or such shorter term as may be provided in the option Agreement.

In the case of an Incentive Stock Option, (i) granted to an employee who, at the time of grant of such option, owns stock representing more than 10% of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the exercise price shall be no less than 110% of the Fair Market Value per Share on the date of grant; (ii) granted to any other employee, the per share exercise price shall be no less than 100% of the Fair Market Value per Share on the date of grant. In the case of a Non-statutory Stock Option; (i) granted to a Service Provider who, at the time of grant of such option, owns stock representing more than 10% of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the exercise price shall be no less than 110% of the Fair Market Value per Share on the date of grant; (ii) granted to any other service provider, the per share exercise price shall be no less than 100% of the Fair Market Value per Share on the date of grant. Notwithstanding the foregoing, options may be granted with a per share exercise price other than as required above pursuant to a merger or other corporate transaction.

The options may include provisions permitting exercise of the option prior to full vesting. Any unvested shares so purchased shall be subject to repurchase by the Company at the original exercise price of the option.

	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)
Balances, December 31, 2018	3,669,997	14,140,032	\$ 0.38	7.88	\$ 4,118
Shares reserved for issuance	5,000,000	—			
Options granted	(1,315,000)	1,315,000	\$ 0.67		
Options forfeited / cancelled	703,360	(703,360)	\$ 0.56		
Options exercised	—	(178,572)	\$ 0.57		
Balances, December 31, 2019	8,058,357	14,573,100	\$ 0.39	7.08	\$ 5,048
Shares reserved for issuance (unaudited)	—	—			
Options granted	(6,273,700)	6,273,700	\$ 0.76		
Options forfeited / cancelled (unaudited)	193,500	(193,500)	\$ 0.26		
Options exercised (unaudited)	—	—			
Balances, June 30, 2020 (unaudited)	<u>1,978,157</u>	<u>20,653,300</u>	<u>\$ 0.50</u>	7.52	\$ 6,099
At December 31, 2019					
Vested		<u>9,884,600</u>	\$ 0.32	6.59	\$ 4,197
Exercisable		<u>11,509,852</u>	\$ 0.34	6.72	\$ 4,648
At June 30, 2020					
Vested (unaudited)		<u>11,268,495</u>	\$ 0.34	6.27	\$ 5,130
Exercisable (unaudited)		<u>12,240,192</u>	\$ 0.36	6.36	\$ 5,400

Notes to Condensed Financial Statements
(unaudited)

(in thousands, except share and per share amounts)

The aggregate intrinsic value of options vested and expected to vest and exercisable as of June 30, 2020 is calculated based on the difference between the exercise price and the current fair value of our common stock. The intrinsic value of options exercised in 2019 was \$20. There were no stock option exercises in 2020.

At June 30, 2020, the total compensation cost related to nonvested awards not yet recognized is \$3,694. The weighted-average period over which the nonvested awards is expected to be recognized is 2.9 years.

Stock-Based Compensation

Stock options granted generally vest over two to four years. The unrecognized compensation cost as of June 30, 2020 is expected to be recognized over a weighted-average amortization period of 2.9 years. No income tax benefits have been recognized relating to stock-based compensation expenses and no tax benefits have been realized from exercised stock options.

The Company estimated the fair value of the options using the Black-Scholes options valuation model. The fair value of the options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value was estimated using the following assumptions:

	Six Months Ended June 30,	
	2019 (unaudited)	2020 (unaudited)
Weight average grant-date fair value of common stock	\$0.67	\$0.76
Risk-free interest rate	2.31% – 2.51%	0.40% – 1.51%
Expected life (in years)	5.27 – 6.37	5.20 – 6.40
Dividend yield	0%	0%
Expected volatility	72.33% – 72.64%	70.70% – 73.85%

Expected Term: The Company uses the simplified method to calculate expected term described in the Securities and Exchange Commission's Staff Accounting Bulletin No. 107, which takes into account vesting term and expiration date of the options.

Volatility: Volatility is based on an average of the historical volatilities of comparable publicly traded companies for the expected term.

Risk Free Interest Rate: The risk-free rate is based on the U.S. Treasury yields in effect at the time of grant for periods corresponding with the expected term of the option.

Dividend Yield: The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and therefore, used an expected dividend yield of zero in the valuation model.

During the year ended December 31, 2018, the Company granted 626,610 stock options at a grant-date fair value of \$0.49 per share to an executive that vests only upon the attainment of certain liquidity events. The Company does not believe that it is probable that the performance condition will be satisfied and did not record any stock compensation expense in the years ended December 31, 2018 and 2019 nor in the six-month period ended June 30, 2020 for this option grant. The unrecognized compensation cost associated with this award was \$305, a portion of which will be cumulatively caught-up upon achievement of the liquidity event.

Notes to Condensed Financial Statements
(unaudited)

(in thousands, except share and per share amounts)

Stock-based compensation expense recorded under ASC 718 (and under ASC 718 and ASC 505 in 2019, prior to the adoption of ASU 2018-07) related to stock options granted was allocated to research and development and general and administrative expense as follows:

	For the Six Months Ended	
	June 30, 2019 (unaudited)	June 30, 2020 (unaudited)
Research and development	\$ 127	\$ 320
General and administrative	303	359
Total stock-based compensation	<u>\$ 430</u>	<u>\$ 679</u>

9. Income Taxes

During the six months ended June 30, 2019 and 2020, the Company recorded a full valuation allowance on federal and state deferred tax assets since management does not forecast the Company to be in a taxable position in the near future.

10. Net Loss per Share and Unaudited Pro Forma 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:

	For the Six Months Ended	
	June 30, 2019 (unaudited)	June 30, 2020 (unaudited)
Convertible preferred stock (as converted)	91,595,100	120,393,150
Warrants to purchase common stock	56,866	56,866
Common stock options issued and outstanding	14,208,100	20,653,300
Total	<u>105,860,066</u>	<u>141,103,316</u>

Neither the Company's convertible preferred stock nor restricted stock subject to future vesting participates in losses.

	For the Six Months Ended	
	June 30, 2019 (unaudited)	June 30, 2020 (unaudited)
Net loss	\$ (12,129)	\$ (15,221)
Weighted-average number of shares—basic and diluted	15,922,173	16,038,590
Net loss per share—basic and diluted	<u>\$ (0.76)</u>	<u>\$ (0.95)</u>

Notes to Condensed Financial Statements
(unaudited)

(in thousands, except share and per share amounts)

The unaudited pro forma basic and diluted net loss per share of common stock has been prepared to give effect to the conversion of all outstanding shares of redeemable convertible preferred stock into shares of common stock as if such conversion had occurred at January 1, 2020, inclusive of 28,020,172 shares of common stock issuable upon the conversion of Series D Preferred Stock issued in July 2020.

	For the Six Months Ended June 30, 2020
Net loss	\$ (15,221)
Weighted-average number of shares—basic and diluted	16,038,590
Adjust: Assumed weighted-average effect of conversion of convertible preferred stock (unaudited)	148,413,322
Pro Forma weighted-average number of shares—basic and diluted	164,451,912
Pro Forma net loss per share—basic and diluted (unaudited)	\$ (0.09)

11. Related Parties

The Company has a consulting agreement with a member of the Board of Directors. Consulting fees paid in the six months ended June 30, 2019 and 2020 was \$50 and \$56, respectively. There were no amounts owed under the consulting agreement at December 31, 2019 or June 30, 2020.

12. Subsequent Events

Subsequent events have been evaluated through July 31, 2020, which is the date the financial statements were issued.

In July 2020, the Company issued 28,020,172 shares of Series D Preferred Stock at a price of \$2.4982 per share, resulting in gross proceeds of \$70,000. In July 2020, the Company amended its certificate of incorporation such that it is now authorized to issue 350,217,456 shares of capital stock, including 201,747,258 shares of common stock, 8,729,029 shares of Series Seed Preferred Stock, 42,526,138 shares of Series A Preferred Stock, 40,396,799 shares of Series B Preferred Stock, 28,798,050 shares of Series C Preferred Stock and 28,020,172 shares of Series D Preferred Stock.

Shares

PMV Pharmaceuticals, Inc.



Common Stock

PRELIMINARY PROSPECTUS

Goldman Sachs & Co. LLC

BofA Securities

Cowen

Evercore ISI

Through and including _____, 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II**INFORMATION NOT REQUIRED IN THE PROSPECTUS****ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION**

The following table sets forth the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimates except the SEC registration fee, the FINRA filing fee and the exchange listing fee.

	Amount to be Paid
SEC registration fee	\$ *
FINRA filing fee	*
Exchange listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees	*
Miscellaneous expenses	*
Total	\$ *

* To be provided by amendment.

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Section 145 of the General Corporation Law of the State of Delaware, or DGCL, empowers a corporation to indemnify its directors and officers and to purchase insurance with respect to liability arising out of their capacity or status as directors and officers, provided that the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to our best interests, and, with respect to any criminal action, had no reasonable cause to believe the person's actions were unlawful. The DGCL further provides that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under the corporation's bylaws, any agreement, a vote of stockholders or otherwise. The amended and restated certificate of incorporation of the registrant expected to be in effect immediately prior to the completion of this offering provides for the indemnification of the registrant's directors and officers to the fullest extent permitted under the DGCL. In addition, the amended and restated bylaws of the registrant to be in effect immediately prior to the completion of this offering require the registrant expected to fully indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (whether civil, criminal, administrative or investigative) by reason of the fact that such person is or was a director or officer of the registrant, or is or was a director or officer of the registrant serving at the registrant's request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, to the fullest extent permitted by applicable law.

Section 102(b)(7) of the DGCL permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) for payments of unlawful dividends or

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unlawful stock repurchases or redemptions or (iv) for any transaction from which the director derived an improper personal benefit. The registrant's amended and restated certificate of incorporation to be in effect immediately prior to the completion of this offering provides that the registrant's directors shall not be personally liable to it or its stockholders for monetary damages for breach of fiduciary duty as a director and that if the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of the registrant's directors shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Section 174 of the DGCL provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

As permitted by the DGCL, the registrant has entered, and intends to continue to enter, into separate indemnification agreements with each of the registrant's directors and certain of the registrant's officers that require the registrant, among other things, to indemnify them against certain liabilities that may arise by reason of their status as directors, officers or certain other employees.

The registrant expects to obtain and maintain insurance policies under which its directors and officers are insured, within the limits and subject to the limitations of those policies, against certain expenses in connection with the defense of, and certain liabilities that might be imposed as a result of, actions, suits or proceedings to which they are parties by reason of being or having been directors or officers. The coverage provided by these policies may apply whether or not the registrant would have the power to indemnify such person against such liability under the provisions of the DGCL.

These indemnification provisions and the indemnification agreements entered, and intended to be entered, into between the registrant and the registrant's officers and directors may be sufficiently broad to permit indemnification of the registrant's officers and directors for liabilities (including reimbursement of expenses incurred) arising under the Securities Act of 1933, as amended, or Securities Act.

The underwriting agreement between the registrant and the underwriters to be filed as Exhibit 1.1 to this registration statement provides for the indemnification by the underwriters of the registrant's directors and officers and certain controlling persons against specified liabilities, including liabilities under the Securities Act with respect to information provided by the underwriters specifically for inclusion in the registration statement.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

The following list sets forth information regarding all unregistered securities sold by us since January 1, 2017. No underwriters were involved in the sales and the certificates representing the securities issued and sold contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

- (a) In February 2017, we issued and sold an aggregate of 40,396,799 shares of our Series B convertible preferred stock at a purchase price of \$1.8251 per share for aggregate proceeds of \$73.7 million to a total of nine (9) accredited investors.
- (b) In November 2019, we issued and sold an aggregate of 28,798,050 shares of our Series C convertible preferred stock at a purchase price of \$2.1485 per share for aggregate proceeds of approximately \$61.9 million to ten (10) accredited investors.

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- (c) In July 2020, we issued and sold an aggregate of 28,020,172 shares of our Series D convertible preferred stock at a purchase price of \$2.4982 per share for aggregate proceeds of approximately \$70.0 million to seven (7) accredited investors.
- (d) From January 2017 through July 31, 2020, we granted to our employees, directors, consultants and other service providers stock options to purchase an aggregate of 16,264,740 shares of common stock upon the exercise of options under our 2013 Equity Incentive Plan, as amended, or 2013 Plan, at exercise prices per share ranging from \$0.56 to \$0.80, for an aggregate exercise price of approximately \$10.68 million.
- (e) From January 2017 through July 31, 2020, we issued and sold to certain of our employees, directors, consultants and other service providers an aggregate of 178,572 shares of common stock upon the exercise of options under our 2013 Plan at an exercise price per share of \$0.56, for an aggregate exercise price of approximately \$100,000.00.

The offers, sales and issuances of the securities described in Items 15(a), 15(b) and 15(c) were exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired 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 securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited person and had adequate access, through employment, business or other relationships, to information about the registrant.

The offers, sales and issuances of the securities described in Items 15(d) and 15(e) were exempt from registration under the Securities Act under either (i) Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or (ii) Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of such securities were the registrant's employees, consultants or directors and received the securities under our 2013 Plan. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

ITEM 16. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

(a) Exhibits.

See the Exhibit Index immediately preceding the signature page hereto for a list of exhibits filed as part of this registration statement on Form S-1, which Exhibit Index is incorporated herein by reference.

(b) Financial Statement Schedules.

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

ITEM 17. UNDERTAKINGS

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
1.1*	Form of Underwriting Agreement, including Form of Lock-up Agreement.
3.1*	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.
3.2*	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect immediately prior to the completion of this offering.
3.3*	Bylaws of the Registrant, as currently in effect.
3.4*	Form of Amended and Restated Bylaws of the Registrant, to be in effect immediately prior to the completion of this offering.
4.1*	Amended and Restated Investors' Rights Agreement, dated July 17, 2020, by and among the Registrant and certain of its stockholders.
4.2*	Specimen common stock certificate of the Registrant.
5.1*	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation.
10.1+*	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.
10.2+*	2013 Equity Incentive Plan, as amended, and forms of agreement thereunder.
10.3+*	2020 Equity Incentive Plan and forms of agreements thereunder, to be in effect prior to the completion of this offering.
10.4+*	Employment Offer Letter, dated _____, 2020, by and between the Registrant and David H. Mack, Ph.D.
10.5+*	Employment Offer Letter, dated _____, 2020, by and between the Registrant and Winston Kung.
10.6+*	Employment Offer Letter, dated _____, 2020, by and between the Registrant and Leila Alland, M.D.
10.7+*	Employment Offer Letter, dated _____, 2020, by and between the Registrant and Deepika Jalota, Pharm.D.
10.8+*	Change in Control and Severance Policy.
10.9+*	Change in Control and Severance Policy Participation Agreement, dated September 19, 2019, by and between the Registrant and David H. Mack, Ph.D.
10.10+*	Change in Control and Severance Policy Participation Agreement, dated September 19, 2019, by and between the Registrant and Winston Kung, Ph.D.
10.11+*	Change in Control and Severance Policy Participation Agreement, dated December 2, 2019, by and between the Registrant and Leila Alland, M.D.
10.12+*	Change in Control and Severance Policy Participation Agreement, dated December 2, 2019, by and between the Registrant and Deepika Jalota, Pharm.D.
10.13+*	Consulting Agreement, dated January 1, 2016, by and between the Registrant and Arnold Levine, Ph.D.
10.14+*	Consulting Agreement, dated July 14, 2017, by and between the Registrant and Richard Heyman, Ph.D.

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<u>Exhibit Number</u>	<u>Description</u>
10.15*	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.
23.1*	Consent of Independent Registered Public Accounting Firm.
23.2*	Consent of Wilson Sonsini Goodrich & Rosati, Professional Corporation (included in Exhibit 5.1).
24.1*	Power of Attorney (see page II-6 to this Form S-1).

* To be filed by amendment.

+ Indicated management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cranbury, New Jersey, on _____, 2020.

PMV PHARMACEUTICALS, INC.

By: _____
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 as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities (including his or her capacity as a director and/or officer of registrant) to sign any or all amendments (including post-effective amendments) to this registration statement and any and all additional registration statements pursuant to Rule 462(b) of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as they, he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agents or any of them, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ David H. Mack, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	, 2020
_____ Winston Kung	Chief Operating Officer and Chief Financial Officer (Principal Financial and Accounting Officer)	, 2020
_____ Richard Heyman, Ph.D.	Director and Chairman of the Board of Directors	, 2020
_____ Arnold Levine, Ph.D.	Director	, 2020
_____ Arnold Oronsky, Ph.D.	Director	, 2020
_____ Thilo Schroeder, Ph.D.	Director	, 2020
_____ Peter Thompson, M.D.	Director	, 2020