

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

**FORM 10-K**

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2019

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number 001-38697

**PhaseBio Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)  
  
1 Great Valley Parkway, Suite 30  
Malvern, Pennsylvania  
(Address of Principal Executive Offices)

03-0375697  
(I.R.S. Employer  
Identification No.)

19355  
(Zip Code)

(610) 981-6500

(Registrant's telephone number, including area code)  
Securities registered pursuant to Section 12(b) of the Act:

(Title of Class)	Trading Symbol	(Name of exchange on which registered)
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Common Stock, par value \$0.001 per share

PHAS

The Nasdaq Stock Market, LLC

Securities registered pursuant to section 12(g) of the Act: **None**

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

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2019 was approximately \$254.7 million based on the closing price on the NASDAQ Global Select Market reported for such date. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

**Class of Common Stock**

**Outstanding Shares as of March 26, 2020**

Common Stock, \$0.001 par value

28,780,640

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement, to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934, for its 2020 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

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## SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or this Annual Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. “Business,” Part I, Item 1A. “Risk Factors,” and Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” but are also contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue” and “ongoing,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- the timing, progress and results of clinical trials of PB2452, PB1046, PB6440 and any other potential product candidates, including statements regarding the timing of initiation and completion of preclinical studies or clinical trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing of any submission of filings for regulatory approval of PB2452, PB1046, PB6440 and any other product candidates and our ability to obtain and maintain regulatory approvals for PB2452, PB1046, PB6440 or any other product candidates for any indication;
- our expectations regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of our product candidates, if approved for commercial use;
- our manufacturing capabilities and strategy, including the scalability and commercial viability of our manufacturing methods and processes and our ability to maintain agreements with third parties;
- our expectations regarding the scope of any approved indication for PB2452, PB1046 and PB6440;
- our ability to successfully commercialize our product candidates;
- our ability to leverage our proprietary elastin-like polypeptide technology to identify and develop future product candidates
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our ability to establish or maintain collaborations or strategic relationships;
- our ability to identify, recruit and retain key personnel;
- our ability to protect and enforce our intellectual property position for our product candidates and our research and development programs, and the scope of such protection;
- our financial performance;
- our competitive position and the development of and projections relating to our competitors or our industry;
- the impact of laws and regulations; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

You should refer to “Item 1A. Risk Factors” in this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this Annual Report represent our views as of the date of this Annual Report. We anticipate that

subsequent events and developments may cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

You should read this report and the documents that we reference in this report, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

All brand names or trademarks appearing in this Annual Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report are referred to without the symbols ® and ™, but such references should not be construed as any indication that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. Unless the context requires otherwise, references in this report to “PhaseBio,” the “Company,” “we,” “us,” and “our” refer to PhaseBio Pharmaceuticals, Inc.

## PART I

### Item 1. Business.

#### Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases. Our lead product candidate, PB2452, is a novel reversal agent for the antiplatelet drug ticagrelor, which we are developing for the reversal of the antiplatelet effects of ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. Based on feedback from the United States Food and Drug Administration, or FDA, we intend to seek approval of PB2452 in the United States through an accelerated approval process. In September 2019, we completed a Phase 2a clinical trial of PB2452 where we observed immediate and complete reversal of ticagrelor's antiplatelet activity within five minutes following initiation of infusion and sustained reversal for over 20 hours. PB2452 has been generally well tolerated in our completed trials, with no drug-related serious adverse events, or SAEs. We are currently conducting a Phase 2b trial of PB2452 and recently commenced our pivotal Phase 3 clinical trial. We are developing PB2452 pursuant to a co-development agreement, or the SFJ Agreement, with SFJ Pharmaceuticals X, Ltd., an SFJ Pharmaceuticals Group company, or SFJ. Under the SFJ Agreement, SFJ has agreed to pay us up to \$120.0 million to support the clinical development of PB2452. Our second product candidate, PB1046, is a once-weekly fusion protein currently in a Phase 2b clinical trial for the treatment of pulmonary arterial hypertension, or PAH. PB1046 utilizes our proprietary half-life extending elastin-like polypeptide, or ELP, technology, which also serves as an engine for our preclinical pipeline. As we advance our clinical programs for PB2452 and PB1046 with site activations and patient enrollment, we remain in close contact with our clinical research organizations, clinical sites and suppliers to attempt to assess the impacts that COVID-19 may have on our clinical trials and current timelines and to consider whether we can implement appropriate mitigating measures to help lessen such impacts. At this time, however, we cannot fully forecast the scope of impacts that COVID-19 may have on our ability to initiate trial sites, enroll and assess patients, supply study drug and report trial results. We are also developing our preclinical product candidate, PB6440, for treatment-resistant hypertension. We retain worldwide commercial rights to all of our product candidates.

#### *PB2452*

PB2452 is a novel recombinant human monoclonal antibody antigen-binding fragment, or Fab fragment, designed to reverse the antiplatelet activity of ticagrelor. Ticagrelor is an antiplatelet therapy widely prescribed to reduce the rates of death, heart attack and stroke in patients with acute coronary syndrome, or ACS, or who have previously experienced a heart attack. The American College of Cardiology, American Heart Association and European Society of Cardiology guidelines recognize ticagrelor as the preferred antiplatelet therapy for ACS. In 2019, ticagrelor, currently marketed by AstraZeneca plc, or AstraZeneca, under the brand names Brilinta and Brilique, had worldwide sales of \$1.6 billion, an increase of 20% over 2018 sales. Ticagrelor binds to platelets to prevent them from forming blood clots, which could restrict blood flow to critical organs in these patients, causing heart attacks or strokes. Due to ticagrelor's antiplatelet activity, patients on ticagrelor have an elevated risk of spontaneous bleeding. In addition, patients on ticagrelor who need urgent surgery cannot wait the recommended five days for ticagrelor's effect to dissipate and are at increased risk of major bleeding during and after surgery. There are currently no other known reversal agents approved or in clinical development for ticagrelor or any other antiplatelet drugs. In the European Union, an extracorporeal whole blood purification adsorber device is available that may be useful for non-specific removal of ticagrelor during some cardiac procedures when used in conjunction with cardiopulmonary bypass. Upon approval, PB2452 would be the only therapeutic agent available for specific reversal of ticagrelor. We believe the availability of PB2452 as a specific reversal agent could expand ticagrelor's use by mitigating concerns regarding bleeding risk and uniquely position ticagrelor as the only oral antiplatelet drug with a reversal agent. In our Phase 1 and Phase 2a clinical trials, PB2452 achieved immediate and complete reversal of ticagrelor's antiplatelet activity, with potential customizable duration of reversal based on the dosing regimen, which we believe has the potential to bring life-saving therapeutic benefit to these patients by increasing the safety of ticagrelor.

In September 2019, we completed a Phase 2a clinical trial of PB2452 in older and elderly subjects dosed with ticagrelor and aspirin and in healthy younger subjects on supratherapeutic doses of ticagrelor. In this trial, we observed a statistically significant reversal of ticagrelor within five minutes of initiation of PB2452 infusion, which was sustained for over 20 hours. Platelet function was normalized by 15 minutes, 30 minutes for the supratherapeutic ticagrelor-dose cohort, following initiation of PB2452 infusion and remained normal for over 20 hours. PB2452 was generally well tolerated, with only minor adverse events, or AEs reported. These results are consistent with results observed in healthy younger subjects treated with ticagrelor in our Phase 1 trial. The older and elderly subjects in the Phase 2a trial resembled the patient population most likely to be treated with ticagrelor and to potentially benefit from PB2452, if approved.

The FDA granted Breakthrough Therapy designation for PB2452 in April 2019. The European Medicines Agency, or the EMA, granted PB2452 Priority Medicines, or PRIME, designation in February 2020. Based on feedback from the FDA, we intend to submit a Biologics License Application, or BLA, for potential accelerated approval based on an interim analysis of the first approximately 100 patients treated in our Phase 3 trial, with approximately 50 patients with uncontrolled major or life-threatening bleeding and approximately 50 patients requiring urgent surgery or an invasive procedure. We recently commenced our pivotal Phase 3 clinical trial. Based on an 18-month estimated enrollment timeline for the first 100 patients in the Phase 3 trial, we are targeting to submit our BLA for PB2452 in the second half of 2022. To support full approval for patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure, and consistent with the recommendation of the FDA, we plan to enroll a total of 200 patients in the Phase 3 trial. After we submit our BLA with data from the first 100 patients, we intend to complete the Phase 3 trial and establish a post-approval registry in accordance with FDA requirements. The Committee for Medicinal Products for Human Use, or CHMP, of the EMA has also generally agreed with our proposed clinical development plan for PB2452.

#### *PB1046*

PB1046 is being developed as a once-weekly, novel treatment for PAH, a progressive, life-threatening, orphan disease caused by vasoconstriction and structural deterioration of the pulmonary arteries, which can lead to heart failure and, eventually, death. PB1046 is a subcutaneously-injected, sustained-release analogue of the native human peptide vasoactive intestinal peptide, or VIP. VIP is a neurohormone that relaxes the muscles surrounding blood vessels, causing them to dilate, which results in improved blood flow. In contrast to the currently approved therapies for PAH, which only target vasodilation, we believe that VIP also suppresses the adverse remodeling of blood vessels and increases cardiac contractility and relaxation. We believe that PB1046 has the potential to be disease-modifying and complementary to current standard-of-care therapies for PAH.

We have completed two clinical trials of subcutaneously-injected PB1046 in subjects with cardiovascular diseases. In these trials, PB1046 was observed to be well tolerated, with no drug-related SAEs. In both trials, we observed that patients who received PB1046 experienced statistically significant reductions in blood pressure that were sustained for at least one week, with no reported episodes of symptomatic hypotension. We have also completed enrollment of an exploratory Phase 1b/2a clinical trial to evaluate the effects of PB1046 on pulmonary arterial pressure in PAH patients with a CardioMEMS device, an implanted hemodynamic monitor that continuously reports pulmonary arterial pressure and cardiac function. In preliminary results from this trial, we observed reductions in pulmonary arterial pressure and increases in cardiac output, which we believe are consistent with potential beneficial effects of PB1046. We have begun dosing patients in a randomized, double-blinded, controlled Phase 2b clinical trial in which we plan to enroll approximately 60 PAH patients to assess the safety, tolerability and efficacy of PB1046. This clinical trial will evaluate the effects of PB1046 on pulmonary arterial pressure and exercise tolerance, including the distance the patient can walk in six minutes, which is an important clinical endpoint that the FDA has previously used as the basis for approval of other PAH drugs. We have temporarily paused enrollment of new patients in this trial as a precaution to minimize potential exposure of this patient population at high risk of serious illness from COVID-19. However, we have also informed investigators that they may continue dosing PB1046 and performing assessments for current trial participants if they deem it appropriate and such activities are permitted by their respective institutions. Additionally, we continue to identify new trial sites for future initiation. Although we have been targeting to report results from this trial in the fourth quarter of 2020, we believe that the COVID-19 outbreak will temporarily prevent us from being able to initiate new trial sites and enroll new patients, likely delaying our ability to report the results of this trial into 2021.

PB1046 and certain other preclinical product candidates, are based on our proprietary ELP technology. Our ELP technology extends the circulating half-life of proteins and peptides and also provides a sustained-release mechanism, resulting in exposure of active molecules for periods of a week or longer from a single subcutaneous injection. We believe that our ELP technology enhances solubility, stability and bioavailability, provides extended drug exposure and creates product candidates that are straightforward to manufacture and administer. Our strategy is to apply our ELP technology to proteins and peptides with well-characterized therapeutic activities but suboptimal half-lives to improve their pharmacokinetics, enable their use as pharmaceutical products and allow for more convenient dosing regimens. To date, we have not observed any drug-related SAEs in any of the over 500 subjects in clinical trials of our ELP product candidates.

#### *PB6440*

PB6440 is a highly selective aldosterone synthase inhibitor being developed for treatment-resistant hypertension. In preclinical studies to date, PB6440 demonstrated dose-dependent aldosterone reduction without a significant increase in 11-deoxycorticosterone or deoxycortisol in both rodent and primate models. The oral bioavailability and pharmacokinetic profiles observed in these preclinical studies appear suitable for once-daily oral dosing in humans. To date, no evidence of toxicity has been observed in either *in vitro* toxicity studies or in animal models, including primates. We currently plan to initiate

nonclinical Investigational New Drug Application, or IND, -enabling studies for PB6440 in 2020, which are expected to be followed by an IND filing and a first-in-human trial in early 2021.

## Strategy

Our strategy is to identify, develop and commercialize novel therapies for cardiopulmonary diseases. The key elements of our strategy include:

- **Continue to advance PB2452 through clinical development and regulatory approval.** We intend to develop and commercialize PB2452 as a novel reversal agent for the antiplatelet drug ticagrelor. We recently completed a Phase 2a clinical trial of PB2452 in older and elderly subjects dosed with ticagrelor and aspirin and in healthy younger subjects on suprathreshold doses of ticagrelor. In October 2019, we initiated a multi-center Phase 2b clinical trial in healthy older and elderly subjects. In collaboration with SFJ, we recently commenced our pivotal Phase 3 clinical trial in patients on ticagrelor with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure, and we plan to perform an interim assessment of an initial subset of patients in this trial. We have received Breakthrough Therapy designation and plan to submit a BLA seeking accelerated approval of PB2452 prior to completion of the Phase 3 clinical trial, based on biomarker data from an initial subset of the Phase 3 patients. The EMA granted PB2452 PRIME designation, and the CHMP has generally agreed with our clinical development plan.
- **Continue to develop PB1046.** We intend to advance PB1046 through clinical trials as a once-weekly novel treatment for PAH that is vasodilatory, potentially disease-modifying and complementary to the current standard of care therapies. We are currently conducting a Phase 2b clinical trial of PB1046. We have temporarily paused enrollment of new patients as we assess the impact of COVID-19. Based on the results of this trial, we intend to advance this product candidate into Phase 3 clinical development for the treatment of PAH.
- **Broaden the potential therapeutic applications of PB1046.** Due to improvements in pharmacokinetics that we have observed with our ELP technology, we believe that the therapeutic potential of VIP can be applied to a variety of other orphan indications. Preclinical data suggest PB1046 may have clinical benefit in cardiomyopathy associated with Duchenne Muscular Dystrophy, or DMD, heart failure and other cardiomyopathies and in cystic fibrosis. As such, we intend to strategically broaden the therapeutic applications of PB1046 by exploring its development in additional indications.
- **Continue the preclinical development of PB6440 for treatment-resistant hypertension.** We are planning to initiate IND-enabling studies for PB6440 in 2020. We expect to file an IND for PB6440 with the FDA in order to initiate a first-in-human trial in early 2021.
- **Leverage our ELP technology platform to expand our development pipeline.** We believe that our ELP technology enhances solubility, stability and bioavailability, provides extended drug exposure and creates product candidates that are straightforward to manufacture and administer. As such, we plan to utilize our platform to identify product candidates for additional indications. We intend to apply our ELP technology to improve the pharmacokinetics of proteins and peptides with well-characterized therapeutic activities but suboptimal half-lives, in order to improve their pharmacokinetics, enable their use as pharmaceutical products and allow for more convenient dosing regimens.
- **Commercialize our product candidates.** We have entered into exclusive license agreements with AstraZeneca for PB2452 and Duke University, or Duke, for our ELP technology pursuant to which we retain worldwide commercial rights to our product candidates. In addition, we own all of the assets and intellectual property rights related to PB6440. If approved, we intend to commercialize PB2452 and PB6440 independently in the United States and with a collaboration partner internationally. We intend to explore collaborations or partnerships to commercialize PB1046, if approved. As we advance towards regulatory approvals for our product candidates, we intend to establish a focused marketing and sales infrastructure.

## Pipeline

Our preclinical and clinical-stage pipeline is set forth below:

Program	Indication/Therapeutic Area	Pre-Clinical	Phase 1	Phase 2	Phase 3	WW Commercial Rights	Milestones
PB2452	Reversal of Ticagrelor Antiplatelet Activity	Phase 3 ongoing <i>Breakthrough Therapy designation granted in April 2019</i>				PHASE Bio	Q1 2020: • Initiated Phase 3 trial based on plan to pursue accelerated regulatory pathway
PB1046	Pulmonary Arterial Hypertension (PAH)	Phase 2b ongoing (Enrollment paused due to COVID-19 risk to PAH patients)				PHASE Bio	2021: • Reporting of Phase 2b trial results
PB6440	Resistant Hypertension	IND-enabling activities				PHASE Bio	1H 2021: • Plan to initiate first-in-human clinical trial
<b>Partnering Opportunities</b>							
GLP2-ELP	Short Bowel Syndrome	Late research				PHASE Bio	
CNP-ELP	Achondroplasia	Late research				PHASE Bio	
Early Programs	PROPRIETARY LONG ACTING INJECTABLE RECOMBINANT BIOPOLYMERS (Elastin-like Polypeptides – ELPs)					PHASE Bio	

## PB2452: Antiplatelet Therapy Reversal Agent for Ticagrelor

Our lead product candidate, PB2452, is a novel ticagrelor reversal agent, which we are developing for the reversal of the antiplatelet effects of ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. In September 2019, we completed a Phase 2a clinical trial of PB2452 in older and elderly subjects and in healthy younger subjects on supratherapeutic doses of ticagrelor, in which we observed a statistically significant reversal of ticagrelor within five minutes of initiation of PB2452 infusion, which was sustained for over 20 hours. We are currently conducting a Phase 2b clinical trial of PB2452 and recently commenced our pivotal Phase 3 clinical trial.

### Background on Acute Coronary Syndrome

ACS describes a range of conditions associated with sudden reduced blood flow to the heart, including unstable angina and myocardial infarction, or heart attack. ACS is caused by the inappropriate formation of clots in the coronary arteries. These blood clots are made up primarily of platelets, small lens-shaped cells found in the blood that normally aggregate at sites of injury to help stop bleeding. According to the Centers for Disease Control and Prevention, approximately 805,000 Americans have a heart attack every year, and heart attacks are a leading cause of death in the developed world.

The primary treatment for ACS is the use of antiplatelet drugs to prevent the worsening of existing clots or to reduce the formation of additional clots. These clots can occur in the heart or in stents that are placed in the blocked coronary artery to keep the blood vessel open or elsewhere in the body. Without antiplatelet drugs, patients are at a significantly increased risk of recurrent heart attacks, stroke and death. The standard of care for ACS patients is dual antiplatelet therapy, or DAPT, which is a combination of aspirin and an inhibitor of a specific receptor found on platelets known as the P2Y<sub>12</sub> receptor. This combination is started after a patient experiences a heart attack or other manifestation of ACS and has been shown to significantly reduce platelet aggregation and clot formation and reduce the frequency of recurrent heart attacks, stroke and death.

While the antiplatelet drugs used in DAPT have proven effective at improving overall outcomes in ACS patients, their suppression of blood clotting increases patients' risk of bleeding. Bleeding events in patients on antiplatelet therapy, which can occur spontaneously or as a result of injury or surgery, are classified as minor or major. In the 18,000-patient clinical trial, Platelet Inhibition and Patient Outcomes, or PLATO, conducted by AstraZeneca, ticagrelor was shown to be superior to the antiplatelet drug clopidogrel, marketed under the brand name Plavix, in reducing recurrent heart attack, stroke and death in patients with ACS. However, in both treatment groups, 11% to 12% of patients in the trial suffered major bleeding events, and in 5.8% of patients, these major bleeding events were fatal or life-threatening. The causes of bleeding varied in the trial population. In approximately 3% of the patients on ticagrelor, the major bleeding events were spontaneous and not related to any medical procedure, whereas approximately 9% of patients on ticagrelor developed major bleeding that was related to procedures like coronary artery bypass surgery, or CABG. Although the trial protocol recommended that patients who needed CABG stop taking ticagrelor for one to three days prior to surgery, nearly half of all ticagrelor patients needed surgery urgently and could not wait the up to three days for ticagrelor's effect to dissipate so normal blood clotting could be restored. Overall, up to 80% of patients who underwent CABG surgery in the trial suffered a major or life-threatening bleeding event related to the surgery, and for those who needed urgent surgery and could not wait three days for the effects of ticagrelor to dissipate,



approximately 50% experienced a fatal or life-threatening bleeding event. While some of this risk was likely associated with patients' underlying conditions, the overall bleeding risk is significantly increased by antiplatelet drugs, and the current United States and European prescribing information for ticagrelor suggests suspension of ticagrelor treatment for five days prior to surgery.

Despite the increased bleeding risk, antiplatelet drugs, along with anticoagulant drugs that are used to prevent clots in veins, represent some of the most widely prescribed drugs in the United States due to their lifesaving effects. There are currently no other known reversal agents approved or in clinical development for ticagrelor or any other antiplatelet drugs. In the European Union, an extracorporeal whole blood purification adsorber device is available that may be useful for non-specific removal of ticagrelor during some cardiac procedures when used in conjunction with cardiopulmonary bypass. Upon approval, PB2452 would be the only therapeutic agent available for specific reversal of ticagrelor. In the absence of a specific reversal agent, physicians have limited treatment options, and sometimes administer platelet transfusions, which are unproven in this setting. The ability to quickly reverse the antiplatelet activity of ticagrelor and restore normal clotting would increase its safety, both in instances of major bleeding as well as in situations where surgical or other medical interventions associated with bleeding are urgently needed.

### ***Background on Antiplatelet Drugs***

The three oral antiplatelet P2Y<sub>12</sub> receptor antagonist drugs prescribed in DAPT are clopidogrel, marketed under the brand name Plavix; prasugrel, marketed under the brand name Effient; and ticagrelor, marketed under the brand names Brilinta and Brilique. Unlike clopidogrel and prasugrel that permanently bind to and inhibit the target receptors on platelets, ticagrelor binds to the P2Y<sub>12</sub> receptor in a transient manner, quickly cycling on and off the receptor. We believe this transient binding of ticagrelor presents a unique opportunity to develop a specific reversal agent for ticagrelor, whereas the permanent binding of the other drugs to the receptor precludes a reversal agent from being developed.

We consider ticagrelor to be the best-in-class P2Y<sub>12</sub> antiplatelet agent because it has demonstrated a superior benefit-risk profile compared to other products in the P2Y<sub>12</sub> class. In 2019, ticagrelor had worldwide sales of \$1.6 billion, an increase of 20% over 2018 sales. Ticagrelor has achieved this level of market share despite the availability of generic versions of clopidogrel and prasugrel. We believe ticagrelor growth is being driven in part by treatment guidelines from the American College of Cardiology, American Heart Association and the European Society of Cardiology that recognize ticagrelor as the preferred antiplatelet treatment for ACS. We believe that the availability of a reversal agent could further drive the use of ticagrelor by making it the only reversible oral P2Y<sub>12</sub> antiplatelet treatment, thereby conferring a possible safety benefit over the other agents. Furthermore, based on the growth of clopidogrel prescriptions after the introduction of a generic form of that drug, we believe ticagrelor prescriptions could grow significantly after its patents expire in 2024 and generic competition drives prices down to similar levels as other P2Y<sub>12</sub> antiplatelet therapies.

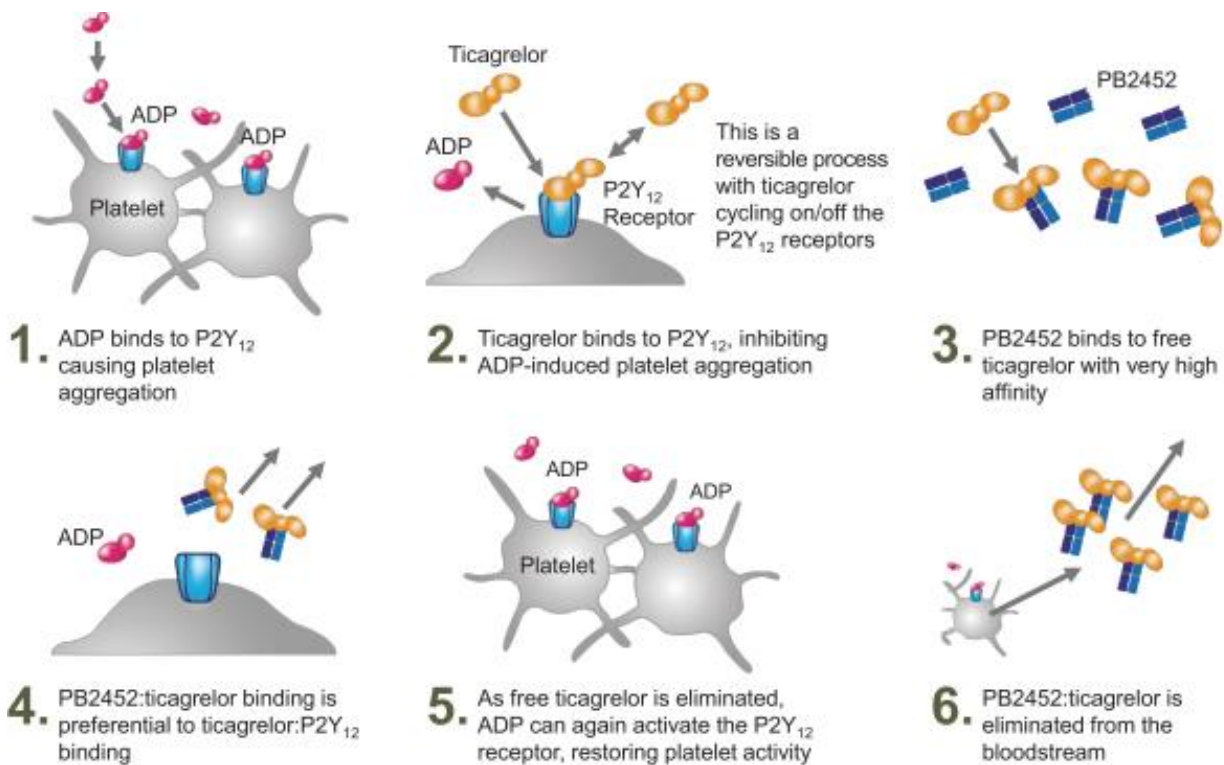
### ***Our Solution: PB2452***

PB2452 is a human Fab fragment that binds to ticagrelor with high affinity and specificity to reverse ticagrelor's antiplatelet activity. We believe that the availability of PB2452 may further differentiate ticagrelor from other P2Y<sub>12</sub> receptor antagonists by providing for better clinical management of the balance between the desired antiplatelet effect and prevention or control of bleeding. We exclusively licensed PB2452 from MedImmune Limited, or MedImmune, a wholly-owned subsidiary of AstraZeneca.

### ***PB2452 Background***

Ticagrelor works by binding to the P2Y<sub>12</sub> receptor on platelets, thereby preventing adenosine diphosphate, or ADP, from causing platelet aggregation. Ticagrelor binds transiently to the P2Y<sub>12</sub> receptor, quickly cycling on and off, and allowing PB2452 to bind to free ticagrelor, thereby preventing ticagrelor's inactivation of the receptor and removing ticagrelor from circulation. With ticagrelor removed, ADP can once again activate the P2Y<sub>12</sub> receptor and induce platelet aggregation. This activity is illustrated below.

### **Mechanism of action of ticagrelor and its reversal by PB2452**



PB2452 binds to ticagrelor with an affinity that is approximately 100 times stronger than ticagrelor's affinity for the P2Y<sub>12</sub> receptor. This high affinity enables PB2452 to bind to free ticagrelor, resulting in an immediate reversal of ticagrelor's effect and restoration of platelet activity.

### **Clinical Development of PB2452**

#### *Phase 3 Clinical Trial*

We recently commenced our pivotal Phase 3 clinical trial. We expect to enroll a total of 200 ticagrelor patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure in this global, multi-center, non-randomized, open-label trial and file for an accelerated approval based upon approximately 100 patients. The primary endpoints for this trial are the reversal of the antiplatelet effects of ticagrelor with intravenous infusion of PB2452 as measured by the VerifyNow® PRUtest® biomarker and achievement of clinical hemostasis in enrolled patients.

#### *Phase 2b Clinical Trial*

In October 2019, we announced that the first patient had been dosed in the Phase 2b trial of PB2452. The multi-center, randomized, double-blind, placebo-controlled trial is designed to evaluate the safety and efficacy of PB2452 in reversing the antiplatelet effects of ticagrelor as part of a dual antiplatelet regimen including low-dose aspirin. Approximately 200 older and elderly (ages 50-80) subjects are expected to be enrolled, resembling the patient population most likely to be treated with ticagrelor and potentially benefit from PB2452, if approved. Subjects will be randomized in a ratio of 3:1 and will receive either PB2452 or placebo, with approximately 150 subjects receiving PB2452. The primary endpoint of the trial is reversal of the antiplatelet effects of ticagrelor with intravenous infusion of PB2452 or placebo, as measured by the VerifyNow PRUtest biomarker. We expect that the results of this trial will further support our BLA safety database.

#### *Phase 2a Clinical Trial*

In September 2019, we completed a Phase 2a clinical trial of PB2452 in older and elderly subjects dosed with ticagrelor and aspirin and in healthy younger subjects on supratherapeutic doses of ticagrelor. We observed a statistically significant reversal of ticagrelor within five minutes of initiation of PB2452 infusion, which was sustained for over 20 hours. Platelet function was normalized by 15 minutes (30 minutes for the supratherapeutic ticagrelor-dose cohort) following initiation of PB2452 infusion and remained normal for over 20 hours. PB2452 was generally well tolerated, with only minor AEs reported. These results are consistent with results observed in healthy younger subjects treated with ticagrelor in our Phase 1 trial. The older and elderly subjects in the Phase 2a trial resemble the patient population most likely to be treated with ticagrelor and to potentially benefit from PB2452, if approved.

#### *Phase 1 Clinical Trial*

In September 2018, we completed a Phase 1 dose escalation clinical trial of PB2452, delivered as an intravenous infusion in healthy subjects pre-dosed with ticagrelor that was designed to identify the target dose, determine proof of concept and evaluate the safety and tolerability of PB2452. In the trial, we observed that PB2452 immediately and completely reversed the antiplatelet effects of ticagrelor. We conducted this trial pursuant to an IND application that we sponsored and that became effective in March 2018. In March 2019, the full results from this trial of PB2452 were published in the *New England Journal of Medicine*.

Our Phase 1 clinical trial enrolled 64 subjects across 10 sequential dose cohorts. Based on pharmacokinetic and pharmacodynamic data from the early dose cohorts in the trial, we adjusted the intravenous infusion of PB2452 to identify the optimal dose and dosing regimen for future trials and for the target patient populations. The initial three cohorts of subjects were dosed with 30-minute intravenous infusions of PB2452 alone in order to assess pharmacokinetics and safety. Subsequent cohorts were pre-dosed with the standard clinical regimen of ticagrelor for two days prior to administration of PB2452 to enable direct assessment of reversal of ticagrelor's inhibition of platelet aggregation using platelet function assays. There were no PB2452-related AEs or SAEs in any of the dose cohorts.

In cohorts 5 and 6, which were the first cohorts in which potentially pharmacodynamically active doses of PB2452 were administered, we saw immediate and complete reversal of ticagrelor's antiplatelet activity based upon restoration of platelet function. In 11 out of 12 subjects, platelet function was restored at the first measured time point at the end of the 30-minute infusion. The duration of reversal varied from approximately one to four hours depending upon the dose level and subject, with longer duration at higher doses. In cohort 7, we modified the dosing regimen to deliver a total dose of 18 g, with 3 g delivered in the first five minutes of infusion, followed by 15 g delivered at a constant rate over an additional seven hours and 55 minutes. In cohort 7, we observed that all subjects achieved complete and sustained restoration of platelet function within two hours after the start of infusion. The duration of reversal in cohort 7 lasted approximately 16 hours from the start of the infusion as measured by restoration of platelet activity.

In cohorts 8, 9 and 10, the dosing regimen of PB2452 was further refined to achieve both a more rapid onset of reversal and a longer duration of reversal compared to earlier cohorts. We administered a total dose of 18 g, with the initial 6 g delivered as a bolus in cohorts 8, 9 and 10. The remaining 12 g was administered after the initial bolus for an additional 12 to 16 hours in cohorts 8, 9 and 10. In each of these cohorts, we observed both immediate and complete reversal within the first five minutes following initiation of infusion and a sustained duration of reversal of over 20 hours. We intend to further evaluate the dose and dosing regimens observed in these cohorts in future clinical trials.

#### *Future Clinical Development Plans*

Based on feedback from the FDA, we intend to submit a BLA for potential accelerated approval based on an interim analysis of the first approximately 100 patients treated in our Phase 3 trial, with approximately 50 patients with uncontrolled major or life-threatening bleeding and approximately 50 patients requiring urgent surgery or an invasive procedure. Based on an 18-month estimated enrollment timeline for the first 100 patients in the Phase 3 trial, we are targeting to submit our BLA for PB2452 in the second half of 2022. To support full approval for patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure, and consistent with the recommendation of the FDA, we plan to enroll 200 total patients in the Phase 3 trial. After we submit our BLA with data from the first 100 patients, we intend to complete the Phase 3 trial and establish a post-approval registry in accordance with FDA requirements.

In April 2019, the FDA granted Breakthrough Therapy designation for PB2452. The EMA granted PB2452 PRIME designation, and the CHMP has generally agreed with our clinical development plan.

#### **PB1046 for the Treatment of Pulmonary Arterial Hypertension**

We are developing our second product candidate, PB1046, as a once-weekly novel treatment for PAH. PB1046 is based on our proprietary ELP half-life extension technology. We are currently conducting a Phase 2b clinical trial in PAH patients to assess the safety, tolerability and efficacy of PB1046. We have received two orphan drug designations for PB1046 from the FDA: one for the treatment of PAH and a second for cardiomyopathy associated with DMD. In February 2018, we received Small Business Innovation Research, or SBIR, grants from the National Institutes of Health in an aggregate amount of \$2.8 million to support the clinical development of PB1046 for the treatment of PAH for the period from February 17, 2018 to July 31, 2020. In connection with the SBIR grants, the United States government will receive a non-exclusive, royalty-free license to use any technology we develop under such grants. For the years ended December 31, 2019 and 2018, we had recognized \$1.8 million and \$0.7 million, respectively, of grant revenue under the SBIR grants.

### ***Background on PAH***

PAH is a progressive and life-threatening orphan disease with no known cure. Common symptoms, which worsen as the disease progresses, include shortness of breath, fatigue, angina, fainting, light headedness and abdominal distension. The disease is caused by abnormal constriction and adverse remodeling of the arteries and is characterized by high blood pressure in the pulmonary arteries, the blood vessels leading from the heart to the lungs. This pressure restricts blood circulation through the lungs resulting in poor oxygenation, abnormal strain on the heart's right ventricle and underfilling of the left ventricle. Over time, the remodeling worsens as inflammatory cells are recruited. This leads to tissue scarring and fibrosis, which results in severe restriction of blood flow, increasing the risk of developing life-threatening blood clots, heart failure and premature death.

The clinical severity of PAH is classified according to a system originally developed for heart failure by the New York Heart Association and then modified by the World Health Organization for patients with PAH, ranging from functional class I (no symptoms) through functional class IV (severe symptoms). Most standard-of-care therapy is initiated in patients who have progressed to class II or beyond.

According to the Pulmonary Hypertension Association, there are approximately 30,000 patients diagnosed with PAH in the United States. There are several approved therapies for PAH, and patients initially start treatment with a combination of two oral therapies. While advances in the treatment of PAH over the last two decades have markedly improved median survival from 2.8 years to approximately 9 years after diagnosis, PAH patients still face significant burdens from their disease and premature death. We estimate, based on publicly disclosed data, that the global PAH market was valued at \$6.0 billion in 2018 and is expected to reach \$10.0 billion by the end of 2025.

### ***Limitations of Current Therapies for PAH***

There is currently no cure for PAH. The three main classes of currently approved drugs for the treatment of PAH are all systemic vasodilators that directly modulate vasoconstrictive or vasodilatory pathways. These currently approved therapies for PAH focus on three distinct molecular pathways: the endothelin pathway, the nitric oxide pathway and the prostacyclin pathway. The classes of drugs that target these three pathways are:

- ***Endothelin Receptor Antagonists.*** Endothelin receptor antagonists work by blocking the action of endothelin-1, a potent vasoconstrictor, thereby increasing blood flow to the lungs. These drugs, which are delivered orally, include bosentan and macitentan, marketed by Actelion as Tracleer and Opsumit, and ambisentan, marketed by Gilead as Letairis.
- ***Nitric Oxide Pathway Modulators.*** Nitric oxide is a naturally occurring molecule that is widely recognized as important in a number of biological processes. Nitric oxide causes blood vessels to relax and widen, resulting in an increase in blood flow. Oral drugs such as sildenafil, marketed by Pfizer as Revatio, and tadalafil, marketed by United Therapeutics as Adcirca, are phosphodiesterase type 5 inhibitors that work by enhancing the activity of naturally occurring nitric oxide.
- ***Prostacyclin Analogues and IP Prostacyclin Receptor Agonists.*** Patients with PAH have been shown to have reduced levels of prostacyclin, a naturally occurring substance that relaxes the pulmonary blood vessels, prevents platelet aggregation and inhibits the proliferation of smooth muscle cells in the pulmonary vessels. Prostacyclin analogues and IP prostacyclin receptor agonists, such as iloprost, treprostinil and selexipag, marketed by Bayer and Actelion as Ventavis, United Therapeutics as Remodulin and Actelion as Upravi, respectively, mimic the effects of prostacyclin and are approved therapies for PAH.

These drugs have been shown to improve exercise capacity, quality of life, pulmonary arterial pressure and short-term survival in PAH patients and suggest enhanced long-term survival based on observational studies. However, none of the

current treatments is curative and long-term prognosis remains poor. These therapies have a singular approach to treating PAH by modulating the vasoconstrictive or vasodilatory pathways but have limited ability to address other disease processes such as inflammation, cell proliferation, fibrosis and vascular remodeling. Furthermore, these drugs can cause hypotension, which can cause fainting and dizziness and can be life-threatening. As the disease progresses, additional vasodilator therapies are typically added to existing therapies rather than replacing drugs that are no longer providing sufficient benefit.

### ***Our Solution: PB1046***

PB1046, a novel, subcutaneously-injected VIP analogue, is a recombinant fusion protein composed of VIP and our proprietary ELP technology. Based on the pharmacokinetic profile of PB1046 observed in our clinical trials, the fusion of VIP to ELP results in both a longer circulating half-life and a prolonged absorption profile, potentially enabling once-weekly dosing. We believe that, in addition to vasodilation, PB1046 may suppress the adverse remodeling of blood vessels and increase cardiac contractility and relaxation. PB1046 has been administered to more than 60 patients with hypertension or a history of cardiac disease in three Phase 1/2 clinical trials conducted in the United States with no drug-related SAEs to date.

### ***PB1046 Background***

VIP is a peptide hormone produced in many tissues throughout the body. Native VIP exerts its function in the body by binding to two distinct receptors: vasoactive intestinal peptide receptor 1, or VPAC1, and vasoactive intestinal peptide receptor 2, or VPAC2. As is the case for many other peptide hormones, the body uses VIP for distinct purposes in different locations. VPAC1 is found predominantly in the gastrointestinal tract, while VPAC2 is found predominantly in the myocardial wall and pulmonary arteries. VIP plays a key role in the relaxation of smooth muscles, which in turn leads to the dilation of blood vessels and to the lowering of arterial blood pressure. VIP also inhibits airway and pulmonary vascular smooth muscle cell proliferation and has broad anti-inflammatory properties, in addition to neutralizing a variety of pulmonary vasoconstrictors, including endothelin.

We designed PB1046 using our ELP technology to harness the positive therapeutic effects of native VIP while addressing the drawbacks that make native VIP inappropriate for use as a direct therapy. Native VIP is rapidly degraded, and, when injected into the body, is eliminated within minutes, limiting its therapeutic effect. High levels of native VIP also result in severe gastrointestinal problems due to VPAC1 activation. We have used our ELP technology to extend the half-life of VIP in PB1046 to approximately 60 hours. In addition, we designed PB1046 to be active predominantly on VPAC2 rather than VPAC1 in order to preferentially affect the lung and cardiac tissue and reduce the potential for gastrointestinal side effects associated with VPAC1 activation.

### ***Clinical Development of PB1046***

We have completed two clinical trials of subcutaneously-injected PB1046. In these trials, PB1046 was observed to be well tolerated, with no drug-related SAEs. In both trials, we observed that patients receiving PB1046 experienced reductions in blood pressure that were sustained for at least one week, with no reported episodes of symptomatic hypotension.

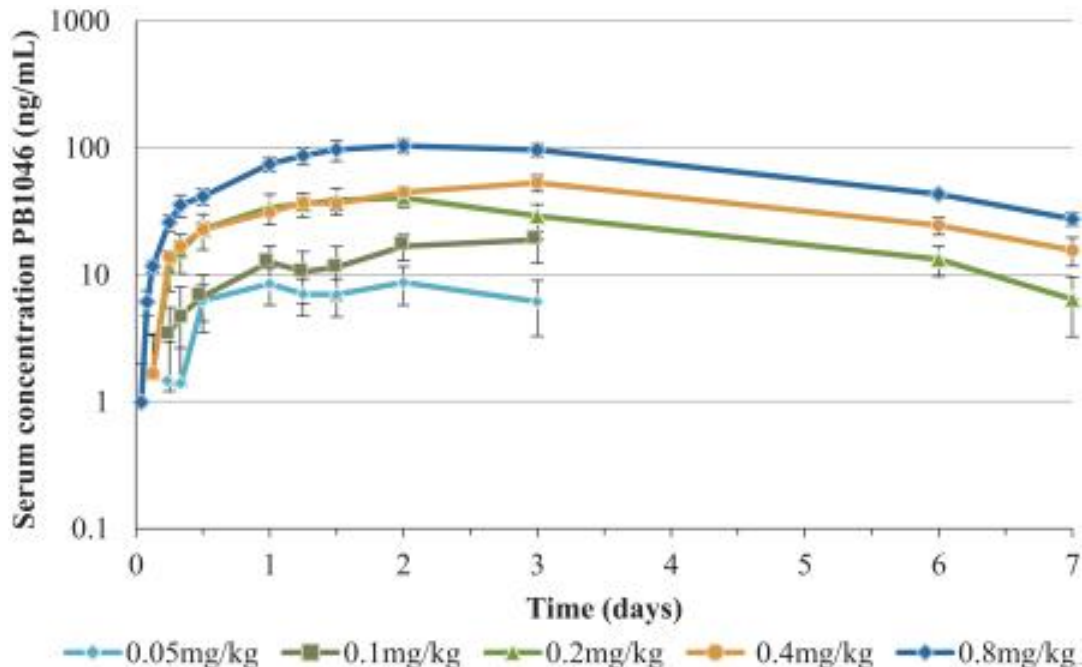
### ***PB1046 Phase 2b Clinical Trial***

We are conducting a randomized, double-blinded, controlled Phase 2b trial in approximately 60 patients with PAH who are New York Heart Association functional class II or III, with an open-label extension. In this trial, patients receive weekly subcutaneous injections of PB1046, in addition to their oral standard-of-care medications, for 16 weeks. These patients initially receive a dose of 0.2 mg/kg of PB1046, to be escalated and ultimately increased to a maximum dose of 2.0 mg/kg, as tolerated. Because in earlier clinical trials we have observed an association between PB1046 dosing and injection-site erythema, in lieu of a completely inactive placebo we instead use a blinded control that has a very low dose of PB1046 that is below a level likely to have therapeutic benefit, but still produces local vasodilation at the injection site in most subjects. The primary endpoint is the change in pulmonary vascular resistance as measured by invasive right heart catheterization. Secondary endpoints include six minute walk distance, respiratory function and biomarkers for cardiac function. Safety endpoints include incidence and severity of AEs and immunogenicity. Six minute walk distance is an important clinical endpoint that the FDA has previously used as the basis for approval of other PAH drugs. We have temporarily paused enrollment of new patients in this trial as a precaution to minimize potential exposure of this patient population at high risk of serious illness from COVID-19. However, we have also informed investigators that they may continue dosing PB1046 and performing assessments for current trial participants if they deem it appropriate and such activities are permitted by their respective institutions. Additionally, we continue to identify new trial sites for future initiation. Although we have been targeting to report results from this trial in the fourth quarter of 2020, we believe that the COVID-19 outbreak will temporarily prevent us from being able to initiate new trial sites and enroll new patients, likely delaying our ability to report the results of this trial into 2021.

### Phase 1 Single Ascending Dose Clinical Trial

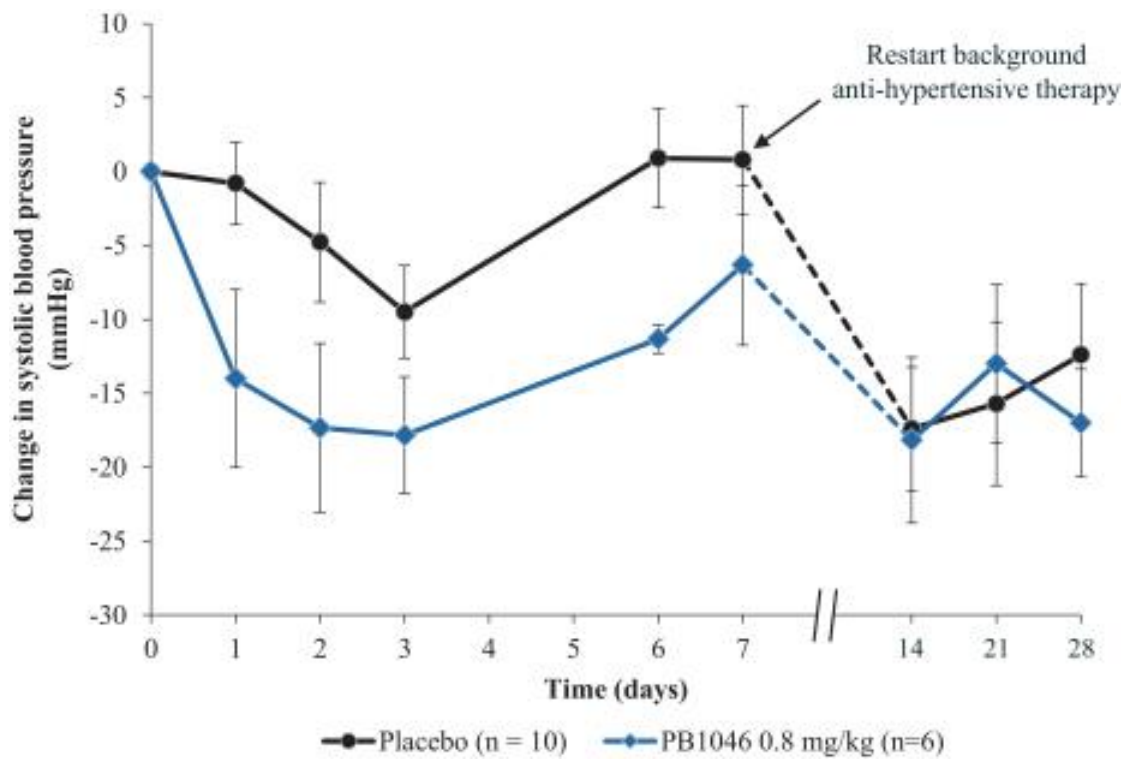
We completed a single ascending dose Phase 1 clinical trial of subcutaneously injected PB1046 in 30 patients with hypertension to assess the safety and pharmacokinetics of PB1046 and to demonstrate early proof of concept. In this clinical trial, the patients stopped taking their standard-of-care anti-hypertensive medications for 14 days before receiving either placebo or a single ascending dose of PB1046 of between 0.05 mg/kg and 0.8 mg/kg. Consistent with our expectation for slow release of ELP fusion proteins, the half-life of PB1046 was approximately 60 hours and serum levels of PB1046 exhibited a prolonged pharmacokinetic profile extending to at least seven days following a single subcutaneous dose, as illustrated below. This is in contrast to the pharmacokinetics of native VIP in which serum levels of VIP disappear within minutes. We believe these results support once-weekly subcutaneous dosing of PB1046.

**Pharmacokinetics of single subcutaneous doses of PB1046 in a Phase 1 dose escalation trial**



The pharmacodynamic activity of PB1046 was assessed by measurements of changes in blood pressure. In the highest dose cohort, we observed that systolic and diastolic blood pressure in patients receiving PB1046 were reduced within one day and remained below levels seen in placebo-treated patients for seven days, as illustrated below. At seven days, all patients resumed their standard hypertension medications and subsequent blood pressures, and the magnitude of reduction in blood pressure compared to baseline were similar whether they had received PB1046 or placebo.

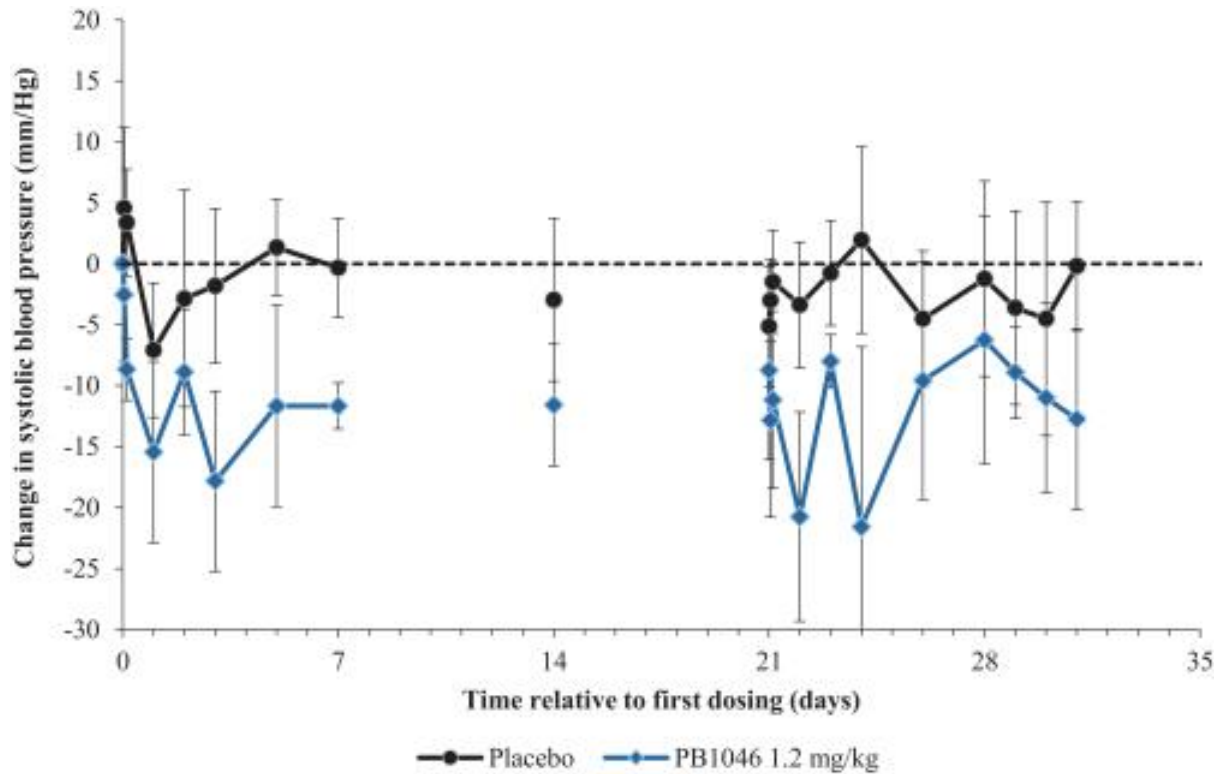
**Mean change in systolic blood pressure in a Phase 1 trial following single subcutaneous dose of PB1046**



#### Phase 1b/2a Multiple Ascending Dose Clinical Trial

We conducted a double-blinded, multiple ascending dose Phase 1b/2a trial in 29 patients with heart failure with reduced ejection fraction, or HFrEF, in order to assess the safety and long-acting pharmacokinetic and pharmacodynamic activity of subcutaneously injected PB1046 in patients with cardiovascular disease. In HFrEF, the heart muscle is not able to contract adequately and therefore expels less oxygen-rich blood into the body. In this clinical trial, patients remained on their standard-of-care heart failure medications and received either weekly placebo or weekly doses of PB1046 of between 0.2 mg/kg and 1.2 mg/kg for four weeks. This clinical trial reproduced the safety, pharmacokinetic and pharmacodynamic observations of the single-dose trial, and we observed that once-weekly dosing was well tolerated. No drug-related SAEs were reported, and there were no reported instances of hypotension, excluding mild orthostatic hypotension in four subjects, which did not appear to be dose related. Of the 22 subjects who received active study drug, all experienced injection-site erythema reaching severe toxicity due to the size of the erythema, and three subjects discontinued treatment due to the erythema. We observed that patients in the highest dose cohort had a statistically significant reduction in blood pressure compared to placebo that was sustained throughout the dosing period, with p-value of 0.043, as illustrated below. A result is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. The conventional method for determining the statistical significance of a result is known as the “p-value,” which represents the probability that random chance caused the result (for example, a p-value = 0.01 means that there is a 1% probability that the difference between the control group and the treatment group is purely due to random chance). Generally, a p-value less than 0.05 is considered statistically significant.

### Mean change in systolic blood pressure in a Phase 1b/2a trial following four weekly subcutaneous doses of PB1046



Based on the results of this clinical trial, and an assessment of a number of clinical and commercial factors, we determined that our initial indication for PB1046 would be PAH.

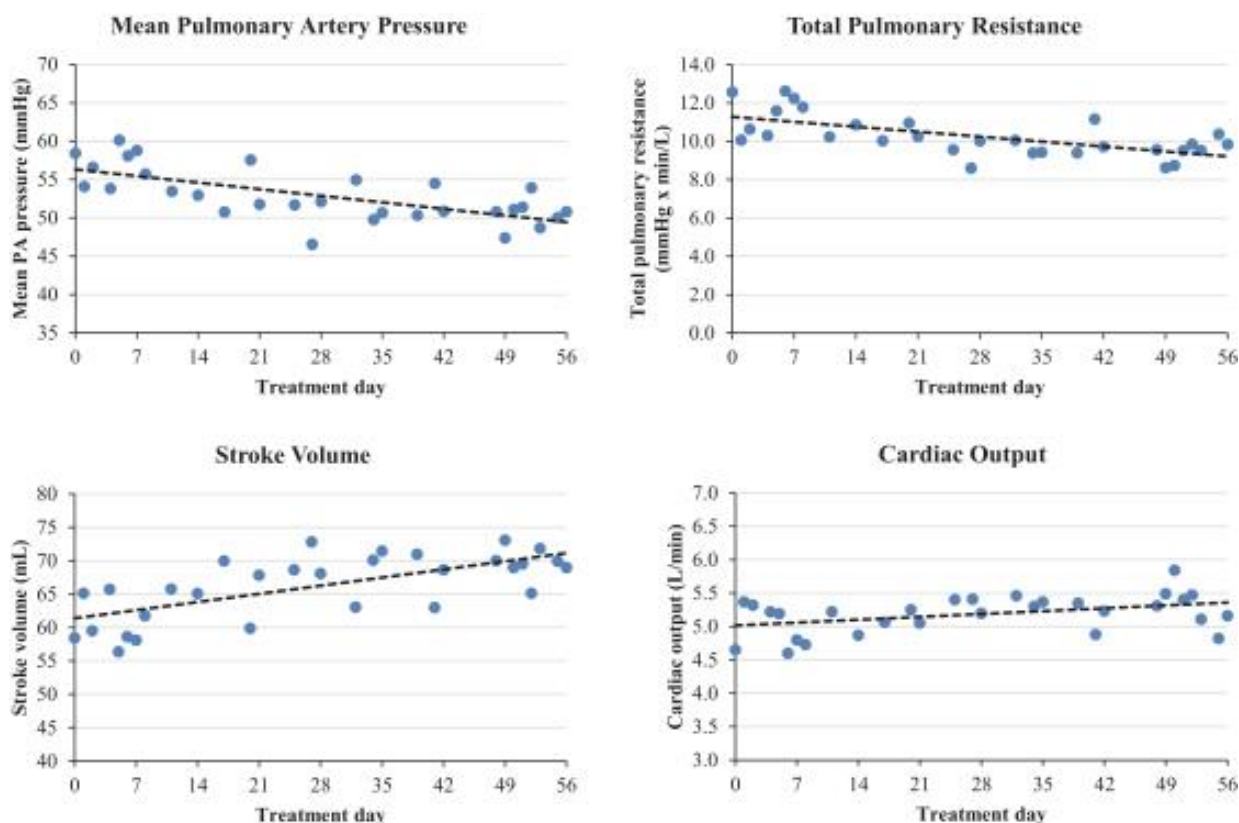
#### *Phase 1b/2a CardioMEMS Pilot Clinical Trial*

Prior to launching a large Phase 2b trial in patients with PAH, the FDA requested that we explore the safety and hemodynamics of PB1046 in patients with PAH. To achieve this objective, we initiated a pilot Phase 1b/2a clinical trial in a small population of PAH patients who had an implanted CardioMEMS device. The patients enrolled in this trial were difficult-to-treat patients with long histories of PAH who were no longer responding to their current therapies. These patients initially received a dose of 0.2 mg/kg of PB1046, which was escalated weekly as tolerated and could be increased to a maximum dose of 2.0 mg/kg, while remaining on their existing therapies.

In the first two patients dosed in this clinical trial, we observed changes in parameters that are important to PAH patients, including that patients' pulmonary arterial pressure and pulmonary resistance decreased over time while cardiac stroke volume and overall cardiac output increased. Results for one of the patients in this trial are illustrated below. The results from the second patient were generally consistent with this patient. These observations are consistent with our expectations for a VIP-based therapy. These patients had continued improvements over a period of 60 days, which we believe suggest that, in addition to its vasodilatory activity, PB1046 may also have more long-term effects on blood vessel and cardiac remodeling. These patients also opted into a trial protocol extension.



## Representative CardioMEMS data from one PAH patient receiving weekly doses of PB1046



In subsequent discussions with the FDA, the safety profile of our Phase 1b/2a clinical trial and the available data from this pilot clinical trial were reviewed, and the FDA determined that our data were sufficient to enable initiation of a Phase 2b clinical trial. Accordingly, we do not intend to enroll additional patients in this pilot clinical trial.

### Safety Overview from Clinical Trials of PB1046

There were no drug-related SAEs reported for any of the patients who have received PB1046. When PB1046 was administered subcutaneously, it was almost always associated with a mild- to moderate- injection-site erythema, or patch of redness, which on average appeared at about 12 hours after injection. The injection-site erythema was not judged by the investigator to be an allergic type reaction; rather, in the investigator's view, it was likely to be associated with the activity of VIP binding to receptors in the skin, resulting in local vasodilation. Additionally, 70% of patients receiving a subcutaneous injection of PB1046 experienced mild pain or tenderness at the injection site, which occurred hours to days after injection and on average lasted about one week. One-third of the patients also experienced mild pruritus, or itching, at the site of injection. We believe that these events are primarily due to the fused VIP peptide since similar events were not observed in clinical trials of other constructs that contain the ELP domain. None of the injection site reactions were judged to be serious. We observed a similar tolerability profile in the Phase 1 clinical trial of PB1046. Notably, there were no events of symptomatic hypotension related to PB1046 in any of the subjects who have received PB1046.

### Preclinical Studies

Published independent research indicates that patients with PAH have both reduced levels of VIP in the lung and in circulation as well as increased levels of VPAC2 receptors in lung tissue. Mice bred to be VIP-deficient spontaneously express symptoms of moderately severe PAH. Repeated treatment of these mice with VIP corrected the key characteristics of the disease including right heart dysfunction, vascular remodeling and lung inflammation. In the monocrotaline-induced PAH rat model, an experimental model of PAH, VIP was active in preventing, and partially reversing, the symptoms of PAH. Combination therapy with VIP and the endothelin receptor antagonist bosentan was shown to be more active than either drug

alone. Furthermore, in multiple preclinical studies we have demonstrated the benefits of PB1046 in cardiomyopathies, due to its ability to induce heart contractility and relaxation effects without an increase in myocardial oxygen demand.

### **Potential Applications of PB1046 in Other Indications**

The biological activities associated with VIP have the potential to provide therapeutic benefit to patients with other diseases. We believe that PB1046 provides a mechanism to bring these VIP-based therapies forward in the following indications:

- **DMD-associated Cardiomyopathy.** Cardiac dysfunction is a very common manifestation of DMD and a common cause of death for individuals with this condition. The ability of PB1046 to increase contractibility of cardiac muscles presents the possibility that it could provide therapeutic benefit to these patients. We observed that PB1046 slowed deterioration in cardiac function and preserved skeletal muscle function in a mouse model of DMD. In addition to direct effects on cardiac function, we believe decreased fibrosis also contributed to the positive effects of PB1046 on both cardiac and skeletal muscle in this model. The FDA has granted orphan drug designation for PB1046 for the treatment of cardiomyopathy associated with DMD.
- **Cystic Fibrosis.** VIP has been shown to stimulate the processing of the cystic fibrosis transmembrane regulator, or CFTR, the protein defective in patients with cystic fibrosis, or CF. In mice lacking the gene for VIP, CFTR is not located at the cell surface, where it is required to function properly, but accumulates within the cell. These mice have lung abnormalities that resemble CF and treatment with VIP peptide restored CFTR to the cell surface and corrected the lung tissue abnormalities. Treatment of human epithelial cells containing the most common CFTR mutation found in CF patients (F508del) with PB1046 *in vitro* has been observed to increase CFTR activity, providing further support that PB1046 may have potential as a treatment for patients with CF.

### **PB6440 for Treatment-Resistant Hypertension**

PB6440 is a selective aldosterone synthase inhibitor that we are developing as an orally administered treatment for resistant hypertension. The mineralocorticoid hormone aldosterone is a critical regulator of fluid and electrolyte balance in the body and, as such, can play an important role in the development of high blood pressure or hypertension. Elevated aldosterone levels are associated with resistant hypertension, congestive heart failure and chronic kidney disease. Agents that block the action of mineralocorticoids at the receptor level, such as spironolactone, have been shown to lower blood pressure, including in patients with resistant hypertension. However, use of these agents is limited by adverse side effects. Inhibition of the production of aldosterone through inhibition of the enzyme responsible for its synthesis, aldosterone synthase (CYP11B2), is an alternative approach to treatment of hypertension. However, development of aldosterone synthase inhibitors is challenging because of a closely-related enzyme, steroid 11 $\beta$ -hydroxylase (CYP11B1), which many potential compounds also inhibit. In preclinical studies, PB6440 was observed to be a highly potent and selective inhibitor of aldosterone synthase and demonstrated a dose-dependent aldosterone reduction without a significant increase in 11-deoxycorticosterone or deoxycortisol in both rodent and primate models. The oral bioavailability and pharmacokinetic profiles appear suitable for once-daily oral dosing in humans. We currently plan to initiate clinical development of PB6440 pending the completion of nonclinical IND-enabling studies planned for 2020, which are expected to be followed by an IND filing and a first-in-human trial in early 2021.

### **ELP Technology**

Our proprietary ELP technology is based on recombinant biopolymers called ELPs, which comprise individual subunits or building blocks derived from a five-amino acid repeat motif found in the human protein elastin. This five-amino acid motif is repeated multiple times to form the ELP biopolymer. We produce our ELP-based products by engineering *E. coli* to produce a single protein comprising the active peptide or protein fused to the ELP biopolymer. This molecule is active as a fusion protein and does not require cleavage or release of the peptide. ELP fusion proteins are produced in the soluble fraction of *E. coli*, which allows for ease of scale-up and purification.

Fusion to ELPs significantly improves the stability of peptides and proteins and enables use of natural or minimally altered peptide sequences. We believe these fusion proteins retain similar potency to the native molecule while being protected from degradation by enzymes in circulation. Additionally, we have observed that the fusion protein maintains the solubility and long half-life of the ELP, in many cases allowing for long-term liquid stability, which is important for injectable products.

ELP fusion proteins can undergo a reversible phase transition, in which ELP fusion proteins aggregate and form a sustained-release depot under the skin. This phase transition is driven by changes in temperature. At lower temperatures ELP fusion proteins are completely soluble, while at warmer temperatures the ELP fusion proteins are in a gel-like state. This allows the ELP fusion proteins to be easily handled and administered subcutaneously using standard, fine gauge needles and syringes. Once the ELP fusion protein is exposed to body heat, it forms a drug depot that slowly releases soluble ELP fusion protein into circulation. By modifying the amino acid sequence of the individual subunits and by varying its overall length, we can engineer our ELP fusion proteins to be released on timescales extending to a week or longer.

Product candidates based on our ELP technology, including prior product candidates for which we have ceased development in order to focus on the development of therapies for cardiopulmonary diseases, have been evaluated in over 500 patients with no known drug-related SAEs.

### ***Preclinical Programs***

We continue to invest in applying our ELP technology to the development of novel product candidates. Our focus is on peptides and proteins that are scientifically or clinically validated but where a suboptimal half-life, stability and delivery limit their potential therapeutic applications.

Our more advanced ELP preclinical programs include:

- ***Glucagon-like peptide-2.*** Glucagon-like peptide-2, or GLP-2, stimulates growth of intestinal villi, increasing their ability to absorb nutrients. GLP-2 is a potential treatment for patients with short bowel syndrome, Crohn's disease or mucositis in patients undergoing cancer treatment. Teduglutide, currently marketed under the brand name Gattex, is an FDA-approved therapy based on GLP-2 that requires daily injections. In animal models, our GLP-2-ELP product candidate provided sustained levels of GLP-2, resulting in greater efficacy than teduglutide with less frequent dosing.
- ***C-type natriuretic peptide.*** C-type natriuretic peptide, or CNP, is a regulator of bone growth and can rescue defects in fibroblast growth factor 3 that cause achondroplasia resulting in dwarfism. Native CNP has a half-life of less than three minutes, limiting its use as a direct therapeutic. We are developing our CNP-ELP product candidate to deliver therapeutic levels of CNP with once weekly subcutaneous injections. In a mouse model, we observed a demonstrated effect on linear growth when our CNP-ELP product candidate was injected once every four days.

### **License, Co-Development and Other Agreements**

#### ***MedImmune Limited License Agreement***

In November 2017, we entered into an exclusive license agreement with MedImmune, a wholly-owned subsidiary of AstraZeneca, or the MedImmune License. Pursuant to the MedImmune License, MedImmune granted us an exclusive, worldwide license under certain patent rights owned or controlled by MedImmune to develop and commercialize any products covered by the MedImmune License, or the MedImmune licensed products, for the treatment, palliation, diagnosis or prevention of any human disorder or condition. The in-licensed patent rights are generally directed to antibodies that bind to ticagrelor and methods of use and include two issued patents in the United States, three pending patent applications in the United States and 13 pending foreign applications. The last patent is expected to expire in 2036 without extension. We have the right to sublicense the licensed technology to third parties subject to certain conditions as specified in the MedImmune License. Under the MedImmune License, we grant to MedImmune a worldwide, non-exclusive, royalty-free, irrevocable license and right of reference solely to exploit any drug product containing ticagrelor or any invention, discovery, development or modification with respect to any drug product containing ticagrelor.

Under the terms of the MedImmune License, we have paid or are required to pay:

- an upfront fee of \$0.1 million;
- quarterly fees relating to technical services provided by MedImmune;
- up to \$18.0 million upon the achievement of certain clinical and regulatory milestones;
- up to \$50.0 million upon the achievement of certain commercial milestones; and
- mid-single digit to low-teen royalty percentages on net sales of MedImmune licensed products, subject to reduction in specified circumstances.

From the inception of the MedImmune License through December 31, 2019, we have paid \$1.6 million under the MedImmune License, related to third-party product storage costs and a milestone payment.

The MedImmune License requires us to use commercially reasonable efforts to develop, obtain and maintain regulatory approval for and commercialize the MedImmune licensed products throughout the term of the MedImmune License. We have the first right, but not the obligation, to control prosecution of the in-licensed patents. In addition, our rights under the MedImmune License are not assignable without the prior written consent of MedImmune, except to a third-party acquirer by our merger or sale of our stock or assets or to an affiliate of our company.

Unless earlier terminated, the MedImmune License automatically expires on the date on which we no longer owe any royalty payments to MedImmune under the MedImmune License, which date will occur on the later of (1) the tenth anniversary of the first commercial sale of the MedImmune licensed products, (2) the expiration of the last in-licensed patent in 2036 and (3) the expiration of regulatory exclusivity under the MedImmune License. The MedImmune License may be terminated prior to its expiration:

- by mutual written consent of us and MedImmune;
- by either party upon the other party's material breach of the MedImmune License that is not cured within the specified cure period based on the nature of such breach;
- by either party in the event of either party's bankruptcy, insolvency or certain similar occurrences;
- by MedImmune if we bring any action or proceeding challenging the validity or enforceability of any of the licensed patents;
- by us, under specified circumstances, if we believe in good faith that there is (1) an issue with respect to the safety or efficacy of PB2452 or any MedImmune licensed product containing PB2452 or (2) an issue with respect to the commercial viability of any MedImmune licensed products, in each case subject to dispute resolution by an independent expert; and
- by us, with respect to a particular country or region, if any product containing ticagrelor is withdrawn by a regulatory authority in such country or region.

Upon termination of the MedImmune License, we grant to MedImmune an exclusive, royalty-free, sublicensable license under our patent rights and know-how to use, sell, have sold, offer for sale, develop, make, have made, manufacture, commercialize, have used, import, export, transport, distribute, promote, market or otherwise dispose certain compounds or products covered by the MedImmune License.

In January 2020, in connection with our entering the SFJ Agreement, we entered into an amendment to the exclusive license agreement pursuant to which MedImmune consented to a potential assignment of the MedImmune License and transfer of our business related to PB2452 to SFJ in the event of the occurrence of certain program transfer events, should they ever occur.

#### ***Co-Development Agreement for PB2452 with SFJ Pharmaceuticals***

In January 2020, we entered into the SFJ Agreement, pursuant to which SFJ will provide us funding to support the global development of PB2452 as a reversal agent for the antiplatelet drug ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. Under the SFJ Agreement, SFJ has agreed to pay us up to \$120.0 million to support the clinical development of PB2452. SFJ paid us an initial \$10.0 million in March 2020 after we obtained the consent of Silicon Valley Bank, or SVB, to grant SFJ a security interest in all of the assets owned or controlled by us that are necessary for the manufacture, use or sale of PB2452. SFJ will pay us an additional \$80.0 million through cost reimbursements followed by six equal quarterly payments beginning with the quarter ending September 30, 2020 through the quarter ending December 31, 2021, and up to an additional \$30.0 million upon the achievement of specified milestones with respect to our clinical development of PB2452.

During the term of the SFJ Agreement, we will have primary responsibility for clinical development and regulatory activities for PB2452 in the United States and the European Union, while SFJ will have primary responsibility for clinical development and regulatory activities for PB2452 in China and Japan and will provide clinical trial operational support in the European Union. We have agreed to use commercially reasonable efforts to conduct and complete our Phase 3 clinical trial of PB2452 and to file a BLA or its foreign equivalent within specified timelines with each of the FDA and the European Medicines Agency, or the EMA. We have formed a joint steering committee with SFJ to oversee and manage the collaboration, including our Phase 3 program and the regulatory process.

Under the terms of the SFJ Agreement, following the FDA approval of a BLA for PB2452, we will pay SFJ an initial payment of \$5.0 million and an additional \$325.0 million in the aggregate in seven additional annual payments. If the EMA, or the national regulatory authority in certain European countries, authorizes a marketing approval for PB2452, we will pay SFJ an initial payment of \$5.0 million and an additional \$205.0 million in the aggregate in seven additional annual payments. If either the Pharmaceuticals and Medical Devices Agency of Japan, or the PMDA, or the National Medical Products Administration of China, or the NMPA, approves a marketing application for PB2452, we will pay SFJ an initial payment of \$1.0 million and then an additional \$59.0 million in the aggregate in eight additional annual payments.

Within 120 days following approval of a BLA, or its equivalent, for PB2452 in one of the jurisdictions described above, we have the right, at our option, to make a one-time cash payment to SFJ to buy out all or a portion of the future unpaid approval payments for such jurisdiction (i.e., the U.S. Approval Payments, EU Approval Payments or Japan/China Approval Payments, as applicable) for a price reflecting a mid-single-digit discount rate. Within 120 days following a change of control of our company, we or our successor have the right, at its option, to make a one-time cash payment to SFJ to buy out all or a portion of the future unpaid approval payments in any of the jurisdictions in which a BLA, or its equivalent, for PB2452 was approved prior to the change of control for a price reflecting a mid-single-digit discount rate, provided that SFJ has not previously assigned the right to receive such payments to a third party, in which event we or our successor shall not have such right.

Under the SFJ Agreement, we granted SFJ a security interest in all of the assets we own or control that are necessary for the manufacture, use or sale of PB2452, or PB2452 Intellectual Property. In connection with the grant of the security interest, we agreed to certain affirmative and negative covenants, including restrictions on our ability to pay dividends, incur additional debt or enter into licensing transactions with respect to the PB2452 Intellectual Property. In addition, we agreed that the security interest granted to SFJ will be a first-priority security interest, subject only to the lien of SVB for our existing indebtedness to SVB.

Upon execution of the SFJ Agreement, we issued to SFJ a ten-year warrant exercisable for 2,200,000 shares of our common stock at an exercise price per share of \$6.50. The warrant is exercisable as follows: (i) 1,100,000 shares may be exercised at any time after the effective date of the SFJ Agreement, provided that SFJ may not sell such exercised shares until one year after such effective date, and (ii) the remaining 1,100,000 shares may be exercised at any time at SFJ's election if the results of our Phase 3 trial meet the interim primary endpoint as set forth in the Phase 3 trial protocol.

In the event that (i) we fail to pay any amounts payable to SFJ under the SFJ Agreement within a specified time period, (ii) we are in default of our obligations, subject to certain exclusions, under the MedImmune License, or (iii) either (a) we determine it is probable that we will be unable to meet our obligations as they become due within one year after the date that our financial statements for the then-current quarter are issued, or available to be issued or (b) a "going concern" footnote is included in any of our financial statements, and, in either case ((a) or (b)), we fail to remedy such going concern condition as specified in the SFJ Agreement, SFJ may elect to have our business related to PB2452 transferred to SFJ. We refer to such events (i), (ii) or (iii) as the Potential Program Transfer Events. If our business related to PB2452 is transferred to SFJ, we will not share in any revenues from the commercialization of PB2452 until SFJ has received a 300% return on its investment in PB2452, after which we will be entitled to a mid-single-digit royalty on net sales of PB2452 in the United States and certain European countries, and after SFJ has received an aggregate 500% return on its investment in PB2452, we will be entitled to a mid-single-digit royalty on net sales of PB2452 in the rest of the world.

The SFJ Agreement expires upon the payment of all approval payments owing to SFJ, unless earlier terminated. The SFJ Agreement may be terminated by us at will at any time after SFJ has paid or incurred a total of \$60.0 million of PB2452 development costs and before receipt of any BLA, or its equivalent, approval for PB2452 from the FDA, the EMA, the PMDA or the NMPA. SFJ may terminate the SFJ Agreement (i) upon the occurrence of a material adverse event, as defined in the SFJ Agreement, (ii) upon a change of control of us, (iii) if (a) we are enjoined from further developing or commercializing PB2452 in any of the United States, certain European countries, China, Japan or Hong Kong or (b) the future value of PB2452 is materially adversely affected due to (1) certain third-party patents that would be infringed by the manufacture, use, sale, offer for sale or import of PB2452 in any of the United States, certain European countries or China, Japan or Hong Kong or (2) invalidity or unenforceability of all patent rights controlled by us covering PB2452 as a reversal agent for the antiplatelet drug ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure in any of the United States, certain European countries, Japan, China or Hong Kong, we refer to each of (a) and (b) as an Adverse Patent Impact, if we do not cure the Adverse Patent Impact within six months of notice from SFJ, or (iv) if SFJ disagrees with certain decisions made by us as part of the joint steering committee. The SFJ Agreement may be terminated by either party (i) upon a material breach of the SFJ Agreement by the other party, (ii) if PB2452 fails to receive regulatory approval from at least one of the FDA, the EMA, the PMDA or the NMPA after completion of the Phase 3 trial of PB2452, submission of BLAs, or their equivalents, to such agencies and the use of commercially reasonable efforts to obtain approval of such BLAs, or their equivalents, (iii) if the Phase 3 trial of PB2452 is completed or terminated and either (a) the primary endpoint in the Phase 3 trial is not achieved or (b) SFJ reasonably determines that the results of the trial do not support

regulatory approval, (iv) upon the bankruptcy of the other party, (v) if the independent data monitoring committee for the Phase 3 trial of PB2452 recommends termination of the trial for safety or health reasons or for futility or the parties mutually agree that a material health or safety concern exists, or (vi) upon a breach by the other party involving improper payments or a violation of anti-corruption policies, unless such breach can be cured without having a materially adverse impact on the probability of completing clinical trials of PB2452 or obtaining regulatory approval for PB2452.

In certain instances, upon the termination of the SFJ Agreement, we will be obligated to pay SFJ a multiple of the amounts paid or incurred by SFJ under the SFJ Agreement, including specifically:

- 300% of such amounts (1) in the event that SFJ terminates the SFJ Agreement due to a material uncured breach of the SFJ Agreement by us or our bankruptcy, (2) if we terminate the SFJ Agreement at will prior to the first regulatory approval of PB2452, or (3) if the SFJ Agreement is terminated due to a safety concern and such termination either (a) arose from our gross negligence, or (b) is due to a serious safety issue that was known to us on the date of the SFJ Agreement but the data demonstrating such serious safety issue were not disclosed to SFJ or publicly known prior to the date of the SFJ Agreement;
- 150% of such amounts if SFJ terminates the SFJ Agreement (1) upon a change of control of us or (2) upon a breach involving improper payments or a violation of anti-corruption policies by us, unless such breach can be cured without having a materially adverse impact on the probability of completing clinical trials of PB2452 or obtaining regulatory approval for PB2452;
- 100% of such amounts in the event of a termination due to an Adverse Patent Impact; and
- 100% of such amounts (plus an amount reflecting interest on such amounts) at an annual rate of 25% in the event of termination by SFJ due to disagreement with certain decisions made by us as part of the joint steering committee.

In addition, if following termination of the SFJ Agreement we continue to develop PB2452 and obtain BLA, or its equivalent, approval in the United States, the European Union, Japan or China, we will make the applicable approval payments for such jurisdiction to SFJ as if the SFJ Agreement had not been terminated, less any payments made upon termination, except that if we terminate the SFJ Agreement for SFJ's failure to make any payment to us when due, or SFJ terminates the SFJ Agreement due to a material adverse event, as defined in the SFJ Agreement, then our obligation to make such approval payments would be reduced by 50%.

#### ***Duke License Agreement***

In October 2006, we entered into an exclusive license agreement, which was most recently amended in April 2019, with Duke, or the Duke License. Pursuant to the Duke License, Duke granted to us an exclusive, worldwide license under certain patent rights owned or controlled by Duke, and a non-exclusive, worldwide license under certain know-how of Duke, to develop and commercialize any products or processes covered by the Duke License, or the Duke licensed products, relating to ELPs. The in-licensed patent rights are generally directed to providing extended exposure for proteins and peptides administered through subcutaneous injections and include 13 registered patents in the United States, 12 registered patents in foreign jurisdictions, four pending patent applications in the United States and six pending foreign applications. The last patent is expected to expire in 2030 without extension.

We have the right to sublicense the Duke licensed products to third parties subject to certain conditions specified in the Duke License. In May 2017, certain patent rights under the Duke License reverted to Duke, and Duke subsequently granted to us a non-exclusive license under such patent rights to develop and commercialize any products or processes involving such patent rights. We also granted back to Duke an exclusive sublicense under certain patent rights licensed to us under the Duke License and a non-exclusive license under certain patent rights owned or controlled by us, in each case to exploit compounds developed using our proprietary ELP technology.

Under the terms of the Duke License, we have paid or are required to pay:

- an upfront fee of \$37,000;
- amendment fees of \$0.2 million related to subsequent amendments of the Duke License;
- additional licensing fees of \$0.2 million;
- up to \$2.2 million in clinical and regulatory milestone fees;

- up to \$0.4 million in commercial milestone fees;
- low single-digit royalty percentages on net sales of Duke licensed products, with minimum aggregate royalty payments of \$0.2 million payable following our achievement of certain commercial milestones; and
- up to the greater of \$0.3 million or a low double-digit percentage of the fees we receive from a third party in consideration of forming a strategic alliance with respect to certain patent rights covered under the Duke License.

In consideration for license rights granted to us, we initially issued Duke 24,493 shares of our common stock. Until we reached a certain stipulated equity milestone, which we reached in October 2007, we were obligated to issue additional shares of common stock to Duke from time to time so that its aggregate ownership represented 7.5% of our issued and outstanding capital stock.

From the inception of the Duke License through December 31, 2019, we have incurred royalty costs of \$0.3 million under the Duke License. As of May 2017, Duke is required to pay us a percentage of revenue that it receives from granting a license or sublicense with respect to certain products covered under the Duke License. As of December 31, 2019, Duke has not paid us any of such fees. We also must pay Duke the first \$1.0 million of non-royalty payments we receive from a sublicensee, and thereafter a low double-digit percentage of any additional non-royalty payments we receive.

The Duke License requires us to use commercially reasonable efforts to develop, obtain and maintain regulatory approval for and commercialize the Duke licensed products according to a particular development schedule throughout the term of the Duke License. We are required to apply for, prosecute and maintain all United States and foreign patent rights under the Duke License. In addition, our rights under the Duke License are not assignable without the prior written consent of Duke, except to a third-party acquirer by our merger or sale of our stock or assets, or to an affiliate of our company.

Unless earlier terminated, the Duke License automatically expires on the date on which all patent rights granted under the Duke License expire, or upon our bankruptcy, insolvency or certain similar occurrences. The Duke License may be terminated prior to its expiration:

- by mutual written consent of us and Duke;
- by us upon three months' written notice to Duke;
- by either party upon the other party's illegal conduct or guilty plea with respect to intentional fraud, willful misconduct or felony;
- by either party upon the other party's material breach of the Duke License that is not cured within the specified cure period based on the nature of such breach; and
- by Duke upon our decision to cease commercial development of the patent rights covered by the Duke License for a material period of time.

Upon termination of the Duke License, we grant to Duke an exclusive, royalty-free, sublicensable license under our patent rights and know-how to use any intellectual property developed by us in the course of exercising our rights under the Duke License.

#### ***Viamet Asset Purchase Agreement***

In January 2020, we entered into an asset purchase agreement, or the PB6440 Agreement, with Viamet Pharmaceuticals Holdings, LLC and its wholly-owned subsidiary, Selenity Therapeutics (Bermuda), Ltd., or the Sellers, pursuant to which we acquired all of the assets and intellectual property rights related to PB6440, the Sellers' proprietary CYP11B2 inhibitor compound (formerly known as SE-6440 or VT-6440) and certain other CYP11B2 inhibitor compounds that are covered by the patent rights acquired by us under the PB6440 Agreement, or together, the Compounds. The acquired patent rights include 19 issued or pending United States and foreign patents and patent applications, with the last issued patent acquired expected to expire in 2037. Under the terms of the PB6440 Agreement, we paid the Sellers an upfront fee of \$0.1 million upon the closing of the transaction, and we are required to pay the Sellers up to \$5.1 million upon the achievement of certain development and intellectual property milestones with respect to certain product candidates that contain a Compound, up to \$142.5 million upon the achievement of certain commercial milestones with respect to any approved product that contains a Compound, and low- to mid-single digit royalty percentages on the net sales of approved products that contain a Compound, subject to customary reductions and offsets in specified circumstances.

## **Manufacturing**

Our large molecule clinical and preclinical product candidates PB2452, PB1046 and our ELP preclinical and research and development pipeline candidates are currently manufactured using a microbial expression system. Our manufacturing utilizes a straight-forward *E. coli* fermentation process with a simple column chromatography-based purification process. Our small molecule candidate, PB6440 is manufactured through chemical synthesis. We believe that these manufacturing processes will enable our product candidates to be manufactured efficiently for clinical and commercial applications. We do not have any cGMP manufacturing facilities. Instead, we utilize third parties for the cGMP manufacture of our product candidates for clinical trials, and we intend to continue to use third parties in the near term for the future clinical development and, if they are approved, commercial manufacture of our drug products. Our contract manufacturers are FDA-inspected establishments that have a history of supplying products to the pharmaceutical industry in accordance with cGMP.

### **PB2452**

PB2452 bulk drug substance, provided to us pursuant to the MedImmune License, was filled and released for use in our initial clinical trials. The PB2452 drug substance was manufactured by Wacker Biotech GmbH, or Wacker, a third-party contract manufacturer, utilizing Wacker's proprietary *E. coli* strain. Manufacturing has continued at Wacker to generate drug supply for our ongoing clinical trials. We have also engaged BioVectra, Inc., or BioVectra, to serve as our contract manufacturer of PB2452 for our ongoing clinical trials. We intend to engage BioVectra for commercial-scale production of PB2452, if approved. As we advance PB2452 through clinical development, we may establish additional supply agreements for the manufacture of PB2452 in order to meet our expected needs for potential commercial demand.

### **PB1046 and our ELP Preclinical Pipeline**

To date, we have relied on a non-proprietary *E. coli* strain for the production of PB1046 and our preclinical ELP pipeline candidates. Third-party manufacturers have performed the cGMP manufacturing of the drug product. Due to efficiencies achieved to date, we intend to utilize this non-proprietary strain for future manufacturing. As we advance PB1046 and other preclinical product candidates through development, we intend to establish additional supply agreements and/or technology transfer agreements in order to meet our expected needs for future clinical trials and potential commercial demand.

### **PB6440**

PB6440 is a small molecule candidate manufactured through chemical synthesis. Third-party manufacturers will perform the cGMP manufacturing of the drug. As we advance PB6440 through development, we intend to establish additional supply agreements and/or technology transfer agreements in order to meet our expected needs for future clinical trials and potential commercial demand.

## **Sales and Marketing**

We retain worldwide commercial rights to all of our product candidates. Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to commercialize PB2452, if approved, independently in the United States because we believe the patient populations and medical specialists for these indications are sufficiently concentrated to allow us to effectively promote these products with a targeted sales team. We may explore, and selectively pursue, strategic collaborations or partnerships with third parties to commercialize PB1046, if approved, in the United States and any approved products outside of the United States in order to maximize the commercial potential of our products.

## **Competition**

The pharmaceutical industry is subject to rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing treatments and new treatments that may become available in the future.

Our current and potential future competitors have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors. Accordingly, our competitors may be more successful than us in obtaining regulatory approval for therapies and in achieving widespread market acceptance of their drugs.



It is also possible that the development of a cure or more effective treatment method for the disorders we are targeting by a competitor could render our current or future drug candidates non-competitive or obsolete or reduce the demand for our drug candidates before we can recover our development and commercialization expenses.

#### **PB2452**

There are currently no other known reversal agents approved or in clinical development for ticagrelor or any other antiplatelet drugs. In the European Union, an extracorporeal whole blood purification adsorber device is available that may be useful for non-specific removal of ticagrelor during some cardiac procedures when used in conjunction with cardiopulmonary bypass. Upon approval, PB2452 would be the only therapeutic agent available for specific reversal of ticagrelor. As a result, market acceptance of PB2452, if approved, will depend heavily on the continued market acceptance and use of ticagrelor. Ticagrelor competes against other commercially available antiplatelet therapies, including other P2Y<sub>12</sub> receptor antagonists, many of which are available as generic drugs and are therefore currently significantly less expensive than ticagrelor. New antiplatelet therapies may also be developed in the future, including other reversible P2Y<sub>12</sub> receptor antagonists and other antiplatelet therapies, which could also have reversal agents, that could displace ticagrelor as the preferred antiplatelet agent for ACS.

#### **PB1046**

Although we anticipate that PB1046 may be used as a complement to patients' existing therapies, we expect to compete with existing treatments for PAH patients with class II through class IV symptoms that target the endothelin, nitric oxide and prostacyclin pathways, as well as any generic equivalents that may be developed. In addition to currently approved drugs within these classes, we are also aware of a number of PAH therapies in clinical development, including:

- *Ralinepag*, an oral IP prostacyclin receptor agonist being developed by Arena Pharmaceuticals;
- *Trevyent*, a formulation of treprostinil being developed by United Therapeutics;
- *Bardoxolone methyl*, an oral therapy being developed by Reata Pharmaceuticals for connective tissue disease-associated PAH;
- *LIQ861*, a powder formulation of treprostinil designed for deep-lung delivery using a disposable, dry powder inhaler being developed by Liquidia Technologies;
- *CAM2043*, a liquid crystal gel formulation of treprostinil as a once-weekly subcutaneous depot injection being developed by Camurus;
- *Treprostinil Technosphere*, an inhaled, dry powder formulation of treprostinil being developed by MannKind Corporation;
- *Beraprost sodium 314d modified release*, a single isomer oral prostacyclin analogue being developed by Lung Biotechnology PBC;
- *Sotatercept*, being developed by Acceleron;
- *GB002*, being developed by Gossamer Bio;
- *INS1009*, an inhaled nanoparticle formulation of a treprostinil prodrug being developed by Insmid Incorporated; and
- *INOpulse*, inhaled nitric oxide being developed by Bellerophon Therapeutics.

#### **PB6440**

Although we anticipate that PB6440 may be used as a complement to patients' existing antihypertensive therapies, we expect to compete with existing generic treatments for hypertension that target the mineralocorticoid receptor. In addition to the currently approved mineralocorticoid receptor antagonists, eplerenone and spironolactone, we are also aware of a number of therapies in clinical development for the treatment of resistant hypertension with which PB6440 would compete if approved including:

- *Aprocitan*, orally active dual endothelin receptor antagonist that is being developed by Janssen Biotech;
- *Firibastat*, a selective and specific inhibitor of Aminopeptidase A being developed by Quantum Genomics; and

- *CIN-107*, an aldosterone synthase inhibitor being developed by Cincor Pharmaceuticals.

## **Intellectual Property**

Our commercial success depends in part upon our ability to obtain and maintain proprietary protection for PB2452, PB1046, PB6440 and future product candidates and related discoveries and our ELP technology; to operate without infringing on or otherwise violating the proprietary rights of others; and to prevent others from infringing or otherwise violating our proprietary rights. We seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our ELP technology, our product candidates and other proprietary technologies, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

The term of individual patents varies depending on the date of filing of the patent application and the legal term of patents in the countries in which they are obtained. Generally, patents issued from regularly filed applications in the United States are granted a term of 20 years from the earliest filing date of a non-provisional application. In addition, in certain instances, a patent term can be adjusted to recapture a portion of the delay by the United States Patent and Trademark Office in issuing the patent. In addition, a patent term may be extended to recapture a portion of the patent term effectively lost as a result of the FDA regulatory review period of the drug covered by the patent. The patent term extension based upon delay by the FDA can be up to five years beyond the expiration of the patent, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and the extension may only apply to one patent that covers the approved drug (and to only those patent claims covering the approved drug or a method for using it). There can be no assurance that any such patent term adjustment or extension will be obtained. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically in countries that we file, the patent term is 20 years from the earliest filing date of a non-provisional patent application. However, the actual protection afforded by a patent varies on a product-by-product basis and 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.

Furthermore, we rely upon trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our commercial partners and selected consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

As of December 31, 2019, our patent estate contained at least 19 patent families that we own or in-license that protect various aspects of our ELP technology or our product candidates. We own or have rights in 22 United States patents, over 18 United States patent applications, over 60 foreign patents and over 60 foreign patent applications.

### ***PB2452***

With regard to PB2452, we in-licensed one patent family. As of December 31, 2019, this patent family includes two issued United States patents with composition of matter claims covering PB2452 that are expected to expire in 2035 and 2036 without taking patent term extensions into account, three pending United States patent applications and 13 pending foreign applications, that if issued, would expire in 2035.

### ***PB1046***

As of December 31, 2019, our portfolio of owned and in-licensed patents and patent applications relating to PB1046 consists of six issued patents in the United States, five pending applications in the United States, 48 granted foreign patents and 16 pending foreign applications with claims directed to compositions of matter covering PB1046 and methods of use thereof, including use in PAH, cystic fibrosis and cardiomyopathy associated with DMD, that we expect to expire between 2027 and 2036, without taking patent term extensions into account.

Upon acquiring the intellectual property rights of PB6440 in January 2020, we acquired three patent families relating to aldosterone synthase inhibitors, which consist of two granted patents in the United States, two pending applications in the United States and 14 pending foreign applications. The granted United States patents are expected to expire in 2037 without taking patent term extensions into account.

### **ELP Technology**

As of December 31, 2019, we owned two patent families relating to our ELP technology, which consist of one granted patent in the United States, one pending application in the United States and six pending foreign applications. The granted patent expires in 2021 without taking patent term extensions into account.

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

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practices, or GLP, regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

### **Preclinical and Clinical Development**

Prior to beginning the first clinical trial with a product candidate, 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 GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, 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 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 trial 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 trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial 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 trials and clinical trial results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product 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.
- Phase 2—The investigational product 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 investigational product 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, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must 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, must develop methods for testing the identity, strength, quality and purity of the final product or, for biologics, the safety, purity and potency. Additionally, 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.

### ***BLA Submission and Review***

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is

safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, 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 a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. 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 a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

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 BLA with a Risk Evaluation and Mitigation Strategy, or 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 product 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 require one or more Phase 4 post-marketing 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.

### ***Accelerated Approval Program***

Any marketing application for a biologic submitted to the FDA for approval may be eligible for FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For biologic products, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive 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 accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

### ***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent 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 orphan drug designation are tax credits for certain research and a waiver of the BLA application 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 orphan designation. In addition, 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.

### ***Breakthrough Therapy Designation***

To qualify for the Breakthrough Therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a Breakthrough Therapy product candidate receives: intensive guidance on an efficient drug development program; intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review; and rolling review. Breakthrough Therapy designation does not change the standards for approval but may expedite the development or approval process.

### ***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 user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic 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, which impose certain 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 AEs 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 a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;

- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of 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 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. Such off-label uses are common across medical specialties. 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.

### ***Biosimilars and Reference Product Exclusivity***

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and impact of the BPCIA is subject to significant uncertainty.

### ***Federal and State Fraud and Abuse, Data Privacy and Security and Transparency Laws and Regulations***

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state healthcare laws and regulations restrict business practices in the biopharmaceutical industry. These laws may impact, among other things, our current and future business operations, including our clinical research activities and proposed sales, marketing and education programs and constrain the business or financial arrangements and relationships with healthcare providers and other parties through which we market, sell and distribute our products for which we obtain marketing approval. These laws include anti-kickback and false claims laws and regulations, data privacy and security and transparency laws and regulations, including, without limitation, those laws described below.

The federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Further, 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 False Claims Act and the civil monetary penalties statute.

The federal civil and criminal false claims laws, including the False Claims Act, which prohibit, among other things, any individual or entity from knowingly presenting or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the United States government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of products for unapproved, and thus non-reimbursable, uses.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, 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.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization on certain health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates, independent contractors that perform certain services involving the use or disclosure of individually identifiable health information. 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 HIPAA and seek attorneys’ fees and costs associated with pursuing federal civil actions.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

We may also be subject to state and foreign law equivalents of each of the above federal laws; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; 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 that otherwise restrict payments that may be made to healthcare providers; state and local laws that require the registration of pharmaceutical sales representatives; as well as state and foreign laws that govern 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 HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory



exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations 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 these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

We are also subject to additional federal laws, such as the United States Foreign Corrupt Practices Act, or the FCPA, which prohibits, any United States individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. In many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers would be subject to regulation under the FCPA. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

### ***Coverage and Reimbursement***

Market acceptance and sales of any drug products depend in part on coverage and the extent to which adequate reimbursement for drug products will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Coverage and reimbursement for our product also depends on coverage and adequate reimbursement for the procedures using PB2452 as a ticagrelor reversal agent and PB1046 for the treatment of PAH. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. Even if the procedure using our product is covered, third-party payors may package the cost of the drug into the procedure payment and not separately reimburse the physician for the costs associated with our product. A decision by a third-party payor not to cover or separately reimburse for our products could reduce physician utilization of our products once approved. Additionally, in the United States, there is no uniform policy of coverage and reimbursement among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided is made on a payor-by-payor basis. One payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage and adequate reimbursement.

Third-party payors determine which medical procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure and may be unwilling to undergo such procedures in the absence of such coverage and adequate reimbursement.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental, nor investigational.

Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our product candidates, to the extent that customers who are prescribed our product candidates, if approved, are not separately reimbursed for the cost of the product candidates. An example of payment updates is the Medicare program updates to physician payments, which is done on an annual basis. In the past, when the

application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, ended the use of the statutory formula and introduced a merit-based incentive bonus program for Medicare physicians, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

### ***Impact of Healthcare Reform on our Business***

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of drug product candidates, restrict or regulate post-approval activities and affect the profitable sale of drug product candidates.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the United States pharmaceutical industry. The ACA, among other things: (1) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (2) expanded the entities eligible for discounts under the 340B drug pricing program; (3) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP; (4) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (5) addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (6) introduced a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% 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; (7) created 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 (8) established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug.

There remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, 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." 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. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In December 2018, CMS published a new 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. On December 14, 2018, a Texas United States District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the United States Court of Appeals for the 5th Circuit upheld the District Court ruling 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 United States Supreme Court granted two petitions to review the ruling of the 5th Circuit, and a decision is expected sometime in 2021. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

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 pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2029 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug 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. The Department of Health and Human Services has solicited feedback on some of these measures and, implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although these and other measures may require additional authorization to become effective, Congress and the Trump administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented 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.

## **Employees**

As of December 31, 2019, we had approximately 40 employees. All of our employees are located in the United States. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

## **Corporate Information**

We were incorporated under the laws of the State of Delaware in January 2002. Our principal executive offices are located at 1 Great Valley Parkway, Suite 30, Malvern, Pennsylvania 19355. Our telephone number is (610) 981-6500. Our common stock is listed on the Nasdaq Global Market under the symbol "PHAS."

## **Available Information**

Our internet website address is [www.phasebio.com](http://www.phasebio.com). In addition to the information contained in this Annual Report, information about us can be found on our website. Our website and information included in or linked to our website are not part of this Annual Report.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or the SEC. The SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is [www.sec.gov](http://www.sec.gov).

## **Item 1A. Risk Factors.**

*The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time*

to time. You should carefully consider the risks described below, in addition to the other information contained in this Annual Report on Form 10-K and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

### **Risks Related to Our Financial Position and Capital Needs**

***We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.***

We are a clinical-stage biopharmaceutical company with a limited operating history.

Since our inception, we have incurred significant net losses. Our net loss was \$39.2 million for the year ended December 31, 2019. As of December 31, 2019, we had an accumulated deficit of \$162.2 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Since inception, we have financed our operations primarily with proceeds raised in our initial public offering, private placements of convertible debt and convertible preferred stock and borrowings under our term loan. In future periods we expect to receive up to \$120.0 million from the SFJ Agreement. We have no products approved for commercialization and have never generated any revenue from product sales.

We have devoted substantially all of our financial resources and efforts to the development of our clinical and preclinical product candidates and our proprietary half-life extending elastin-like polypeptide, or ELP, technology, including conducting preclinical studies and clinical trials. We expect to continue to incur significant expenses and operating losses over the next several years. We expect that it could be several years, if ever, before we have a commercialized product. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue our ongoing clinical trials of PB2452 and PB1046, as well as initiate and complete additional clinical trials, as needed;
- seek to expand our geographical reach through the SFJ Agreement and the corresponding clinical development support fees that we will incur;
- pursue regulatory approvals for PB2452 as a reversal agent for the antiplatelet drug ticagrelor and PB1046 for the treatment of PAH;
- develop PB6440 for treatment-resistant hypertension;
- seek to discover and develop additional clinical and preclinical product candidates;
- scale up our clinical and regulatory capabilities;
- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval, including PB2452 and PB1046;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate any revenue or revenue that is significant enough to achieve profitability.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***We have a limited operating history and no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.***

We commenced operations in 2002, and our operations to date have been largely focused on raising capital and developing our clinical and preclinical product candidates and our proprietary ELP half-life extending technology, including undertaking preclinical studies and conducting clinical trials. To date, we have not yet demonstrated our ability to successfully complete pivotal clinical trials, obtain regulatory approvals, manufacture a product on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful 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 or a history of successfully developing and commercializing products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to develop commercial capabilities, and we may not be successful in doing so.

***We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.***

Our operations have consumed substantial amounts of cash since inception. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect to continue to incur significant expenses and operating losses over the next several years as we complete our ongoing clinical trials of our product candidates, initiate future clinical trials of our product candidates, seek marketing approval for PB2452 as a ticagrelor reversal agent and PB1046 for the treatment of PAH, develop PB6440 for treatment-resistant hypertension and advance any of our other product candidates we may develop or otherwise acquire. In addition, our product candidates, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for a number of years, if at all. If we obtain marketing approval for PB2452, PB1046, PB6440 or any other product candidates that we develop or otherwise acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company.

As of December 31, 2019, we had cash and cash equivalents of \$74.0 million. We believe that our existing cash and cash equivalents as of December 31, 2019, in addition to the \$10.0 million received in March 2020 and the \$80.0 million in anticipated proceeds that we will receive pursuant to the SFJ Agreement, will be sufficient to fund our operating expenses and capital requirements into the second half of 2021. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional product candidates, and changes in regulation. Our future capital requirements will depend on many factors, including:

- the progress and results of our ongoing and planned future clinical trials of PB2452 and PB1046 and our development of PB6440 and other preclinical programs;
- the timing and amount of any payments we receive under the SFJ Agreement;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for any future product candidates we may decide to pursue;
- the extent to which we develop, in-license or acquire other product candidates and technologies;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;

- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish collaborations to commercialize PB1046 in the United States;
- our ability to establish collaborations to commercialize PB2452, PB1046, PB6440 or any of our other product candidates outside the United States; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

We will require additional capital to commercialize PB2452, PB1046 and PB6440. If we receive regulatory approval for either of these product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Further, 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. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

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

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, government or private party grants, debt financings and license and collaboration agreements. Except with respect to the funding obligations pursuant to the SFJ Agreement, we do not currently have any other committed external source of funds. 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 of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For example, under the SFJ Agreement, we granted SFJ a first-priority security interest in all of our assets related to PB2452, subject only to the lien of SVB for existing indebtedness to SVB. In connection with the grant of the security interest, we agreed to certain affirmative and negative covenants, including restrictions on our ability to pay dividends, incur additional debt or enter into licensing transactions with respect to intellectual property related to PB2452. Similarly, our loan and security agreement with Silicon Valley Bank, or SVB, and WestRiver Innovation Lending Fund VIII, L.P., or WestRiver, is secured by a security interest in substantially all of our current and future assets. We are also obligated to comply with various other customary covenants, including restrictions on our ability to encumber our intellectual property assets. The security interests granted to SFJ, SVB and WestRiver may preclude future debt financing or make the terms of such financings less favorable.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates, grant licenses on terms that may not be favorable to us or commit to future payment streams. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***If we receive regulatory approval for PB2452, or if the SFJ Agreement is terminated, we will be required to make substantial payments to SFJ pursuant to the SFJ Agreement. If we do not have sufficient funding or cash flow from our business to meet our payment obligations under the SFJ Agreement, SFJ could exercise its remedies as a holder of a first-priority security interest in our assets and our business could be materially harmed.***

On January 9, 2020, we entered into the SFJ Agreement, pursuant to which SFJ will provide up to \$120 million to support the global development of PB2452. If we receive regulatory approval for PB2452 as a reversal agent for the antiplatelet drug ticagrelor, we will be required to make substantial payments to SFJ pursuant to the SFJ Agreement. Our ability to make these required payments depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to meet our obligations under the SFJ Agreement. If we are unable to generate such cash flow or to obtain additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources on acceptable terms or at all, we could default on our payment obligations to SFJ. We have granted SFJ a first-priority security interest in all

of our assets related to PB2452, subject only to the lien of SVB for existing indebtedness to SVB. If we are unable to meet our payment obligations to SFJ, SFJ may exercise its remedies as a holder of a first-priority security interest, which would result in a loss of our assets and our business would be materially harmed.

In addition, in the event that (i) we fail to pay any amounts payable to SFJ under the SFJ Agreement within a specified time period, (ii) we are in default of our obligations (subject to certain exclusions) under the MedImmune License or (iii) either (a) we determine it is probable that we will be unable to meet our obligations as they become due within one year after the date that our financial statements for the then-current quarter are issued, or available to be issued or (b) a “going concern” footnote is included in any of our financial statements, and, in either case ((a) or (b)), we fail to remedy such going concern condition as specified in the agreement, SFJ may elect to have our business related to PB2452 transferred to SFJ. If our business related to PB2452 is transferred to SFJ, we will not share in any revenues from the commercialization of PB2452 until SFJ has received a 300% return on its investment in PB2452, after which we will be entitled to a mid-single-digit royalty on net sales of PB2452 in the United States and certain European countries, and after SFJ has received an aggregate 500% return on its investment in PB2452, we will be entitled to a mid-single-digit royalty on net sales of PB2452 in the rest of the world.

In the event that the SFJ Agreement is terminated, we will be obligated to make substantial payments to SFJ. If following termination of the SFJ Agreement we continue to develop PB2452 and obtain BLA approval in the United States, the European Union, Japan or China, we will be obligated to pay applicable approval payments for any such jurisdiction to SFJ as if the SFJ Agreement had not been terminated, less any payments made upon termination, except in limited circumstances. Further, if our business related to SFJ is transferred to SFJ in the event that we breach certain provisions of the SFJ Agreement, we will not share in any revenues from the commercialization of PB2452 until SFJ has received an at least 300% return on its investment in PB2452. See “Business - License, Co-Development and Other Agreements - Co-Development Agreement for PB2452 with SFJ Pharmaceuticals.” Such payment obligations could have significant consequences for our stockholders and our business, results of operations and financial condition and could force us to delay or terminate development of PB2452 or other product candidates.

### **Risks Related to the Development of Our Product Candidates**

***We currently have only two clinical-stage product candidates, PB2452, a ticagrelor reversal agent, and PB1046 for the treatment of PAH. If we are unable to successfully develop, receive regulatory approval for and commercialize our product candidates for these or any other indications, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed.***

We currently have no products that are approved for commercial sale. We currently have only two clinical-stage product candidates, PB2452 and PB1046. To date, we have not yet conducted any pivotal clinical trials. We have not completed the development of any product candidates, and we may never be able to develop marketable products.

We have invested substantially all of our efforts and financial resources in the development of our clinical and preclinical product candidates and our proprietary ELP technology. Our ability to generate revenue from our product candidates, which we do not expect will occur for several years, if ever, will depend heavily on the successful development, regulatory approval and eventual commercialization of our product candidates. The success of PB2452, PB1046, PB6440 or any other product candidates that we develop or otherwise may acquire will depend on several factors, including:

- timely and successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- successful enrollment and completion of clinical trials;
- with respect to PB2452, the success of our collaboration with SFJ;
- successful development of, or making arrangements with third-party manufacturers for, our commercial manufacturing processes for any of our product candidates that receive regulatory approval;
- receipt of timely marketing approvals from applicable regulatory authorities;
- launching commercial sales of products, if approved;
- acceptance of our products, if approved, by patients, the medical community and third-party payors, for their approved indications;
- the prevalence and severity of adverse events experienced with PB2452, PB1046, PB6440 or any other product candidates;

- the availability, perceived advantages, cost, safety and efficacy of alternative therapies for any product candidate, and any indications for such product candidate, that we develop, specifically, alternative antiplatelet therapies to ticagrelor, including therapies that may be developed with a reversal agent, alternative reversal agents for ticagrelor or alternative treatments for PAH or treatment-resistant hypertension;
- our ability to produce PB2452, PB1046, PB6440 or any other product candidates we develop on a commercial scale;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product candidates and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including current good manufacturing practices, or cGMPs, and complying effectively with other procedures; and
- maintaining a continued acceptable safety, tolerability and efficacy profile of the products following approval.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for PB2452, PB1046, PB6440 or any other product candidate we develop, we may not be able to continue our operations.

***The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed.***

The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, and the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. PB2452 and PB1046 are currently our only clinical-stage product candidates. We have not obtained regulatory approval for any product candidate, and it is possible that we may never obtain regulatory approval for PB2452, PB1046, PB6440 or any product candidates we may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any drug product candidates in the United States until we receive regulatory approval of a BLA, or a new drug application, or NDA, from the FDA. To date, we have only had limited discussions with the EMA and other comparable foreign authorities regarding regulatory approval for PB2452, PB1046 or any other product candidate outside of the United States.

Prior to obtaining approval to commercialize any drug product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe, pure and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs.

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

We have invested a significant portion of our time and financial resources in the development of our clinical and preclinical product candidates, including PB2452, PB1046 and PB6440. Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize PB2452, PB1046, PB6440 and any future product candidates in a timely manner.

Even if we eventually complete clinical testing and receive approval of a BLA, NDA or foreign marketing application for PB2452, PB1046, PB6440 or any future product candidates, the FDA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials,



including post-marketing clinical trials. The FDA or the applicable foreign regulatory agency also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA or applicable foreign regulatory agency may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, the FDA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

***Based on feedback from the FDA, we intend to seek regulatory approval of PB2452 in the United States through an accelerated approval process. If we are not successful with this process, the development and commercialization of PB2452 could be delayed, abandoned or significantly more costly.***

The FDA's accelerated approval regulations allow drugs that are being developed to treat an unmet medical need to be approved substantially based on evidence of an effect on a surrogate biomarker endpoint that is considered reasonably likely to predict clinical benefit, rather than a clinical endpoint such as survival or irreversible morbidity. Based on feedback from the FDA, our strategy is to use an accelerated approval pathway that may require that our Phase 3 clinical trial of PB2452 be ongoing at the time of BLA approval. To support our BLA submission for accelerated approval, the FDA recommended an interim analysis of biomarker data from an initial subset of 100 patients, with approximately 50 patients with uncontrolled major or life-threatening bleeding and approximately 50 patients requiring urgent surgery or an invasive procedure, in our Phase 3 trial, together with safety data from our Phase 2 clinical trials. After we submit our BLA with data from the first 100 patients, we intend to complete the Phase 3 trial and establish a post-approval registry in accordance with FDA requirements. If the FDA requires the completion of the Phase 3 trial prior to the submission of a BLA, the development and commercialization timeline of PB2452 will be delayed. Further, the FDA may determine that the trials conducted by us were insufficient to support approval for all or some of the proposed indications, require us to conduct extensive post-approval studies or require us to make modifications to our ongoing Phase 3 clinical trial after approval and marketing.

***Clinical product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs and experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

In order to obtain FDA approval to market a new biological or drug product we must demonstrate proof of safety, purity and efficacy in humans. The risk of failure for product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety, purity, potency, and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing or at any time during the trial process. The outcome of preclinical testing and early clinical trials may not be predictive of the results 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 products.

We have not completed all clinical trials required for the approval of any of our product candidates. We cannot assure you that any clinical trial that we are conducting, or may conduct in the future, will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

We may incur additional costs and experience delays in ongoing clinical trials for our product candidates, and we do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

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 favorable or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

***Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials.***

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in

regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

***Interim “top-line” and preliminary results 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 publish interim top-line or preliminary results from our clinical trials. Interim results 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. Preliminary or top-line results 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, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

***Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.***

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication.

If our product candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an institutional review board may also require that we suspend, discontinue, or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the product candidate.

Additionally, if one or more of our product candidates receives marketing approval, and we or others identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the labels;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- we may not be able to achieve or maintain third-party payor coverage and adequate reimbursement; and
- our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or foreign regulatory agency in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

***As an organization, we have never conducted pivotal clinical trials, and we may be unable to do so for any product candidates we may develop.***

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, EMA or other regulatory agencies to market PB2452, PB1046, PB6440 or any future product candidate. Carrying out pivotal clinical

trials is a complicated process. As an organization, we have not previously conducted any later stage or pivotal clinical trials. In order to do so, we will need to expand our clinical development and regulatory capabilities, and we may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our pivotal clinical trials. See “— Risks Related to our Dependence on Third Parties —We will rely on third parties to conduct our future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.” In particular, pursuant to the SFJ Agreement, SFJ will have primary responsibility for clinical development and regulatory activities for PB2452 in China and Japan and will provide clinical trials operational support in the European Union. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA or NDA submission and approval of PB2452, PB1046, PB6440 or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates.

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

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or foreign regulatory authorities. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the eligibility criteria for the trial in question;
- the size of the patient population and process for identifying patients;
- the perceived risks and benefits of the product candidate in the trial;
- the availability of competing commercially available therapies and other competing drug candidates’ clinical trials;
- the willingness of patients to be enrolled in our clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- potential disruptions caused by the COVID-19 pandemic, including difficulties in initiating clinical sites, enrolling participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we rely on and expect to continue to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

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

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential 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 processes and product characteristics. 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 other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval.

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 commence sales and generate revenue.

***Our clinical development of PB2452 depends on the continued use of ticagrelor as an antiplatelet therapy.***

We are developing PB2452 as a ticagrelor reversal agent for the treatment of patients on ticagrelor with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. If previously unknown safety risks related to ticagrelor are discovered that would affect its use as an antiplatelet therapy, or if market acceptance of ticagrelor significantly changes, we may pause or stop development of PB2452, which would significantly and adversely affect our business prospects.

***ELP is a novel technology, which makes it difficult to predict the time, risks and cost of development and of subsequently obtaining regulatory approval of our ELP product candidates.***

PB1046 and certain other preclinical product candidates are based on our proprietary ELP technology. Some of our future success depends on the successful development of this technology and products based on it. To our knowledge, no regulatory authority has granted approval to any person or entity, including us, to market and commercialize therapeutics using our novel ELP technology. We may never receive approval to market and commercialize any product candidate that utilizes ELP.

If we uncover any previously unknown risks related to our ELP technology, or if we experience unanticipated problems or delays in developing our ELP product candidates, we may be unable to complete our clinical trials and preclinical studies, meet the obligations of our license agreements or commercialize our product candidates on a timely or profitable basis. If serious adverse events or unacceptable side effects are observed in clinical trials or preclinical studies of a product candidate based on our ELP technology, our ability to develop other product candidates based on our ELP technology would be adversely affected.

***We may be unable to obtain or maintain orphan drug designations or exclusivity for PB1046 or other product candidates, which could limit the potential profitability of such product candidates.***

Regulatory authorities in some jurisdictions, including the United States, designate drugs intended for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Generally, a product that has orphan drug designation and subsequently receives the first FDA approval for the disease for which it has such designation is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. 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 orphan designation.

The FDA has granted two orphan drug designations for PB1046: one for the treatment of PAH and a second for cardiomyopathy associated with DMD. We may seek orphan drug designation for future indications for PB1046 or for other product candidates. Even if we were to obtain orphan drug designation for a product candidate, we may not obtain orphan exclusivity and that exclusivity may not effectively protect the drug from the competition of different drugs for the same condition, which could be approved during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer or more effective or makes a major contribution to patient care. Orphan drug exclusive marketing rights in the United States also 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 quantity of the drug to meet the needs of patients with the rare disease or condition. The failure to obtain an orphan drug designation for any product candidates we may develop, the inability to maintain that designation for the duration of the applicable period, or the inability to obtain or maintain orphan drug exclusivity could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

***Breakthrough Therapy designation by the FDA and PRIME designation by the EMA for PB2452, or any other product candidate, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that the product candidate will receive marketing approval.***

We have received a Breakthrough Therapy designation for PB2452 for the reversal of ticagrelor's antiplatelet activity and may, in the future, apply for Breakthrough Therapy designation for other product candidates. A Breakthrough Therapy is defined as a product candidate 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 product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates 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 a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

Access to the PRIME initiative is granted by the EMA to support the development and accelerate the review of new therapies to treat patients with unmet medical need. The receipt of this access for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional EMA procedures and, in any event, does not assure ultimate approval by the EMA. In addition, even though PB2452 has been granted access to PRIME, the EMA may later decide that it no longer meets the conditions for such access.

***We may not be successful in our efforts to increase our pipeline of product candidates, including by pursuing additional indications for our current product candidates or in-licensing or acquiring additional product candidates for other diseases.***

A key element of our strategy is to build and expand our pipeline of product candidates, including by developing PB1046 for the treatment of other orphan conditions, and PB6440 for treatment-resistant hypertension and identifying other product candidates using our ELP technology. In addition, we may in-license or acquire additional product candidates for other diseases. We may not be able to identify or develop product candidates that are safe, tolerable and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify, in-license or acquire may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

***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.***

Because we have limited financial and management resources, we focus on development programs and product candidates that we identify for specific indications. As such, we are currently primarily focused on the development of PB2452 as a ticagrelor reversal agent, PB1046 for the treatment of PAH and PB6440 for treatment-resistant hypertension. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for PB1046 that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. 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 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 to such product candidate.

***The ongoing COVID-19 pandemic could adversely impact our business, including our clinical trials.***

In December 2019, a novel strain of coronavirus, SARS-CoV-2, was reported to have surfaced in Wuhan, China and to cause a severe respiratory illness now known as COVID-19. Since then, COVID-19 has spread to multiple countries,

including the United States and several European countries, including countries in which we have ongoing and planned clinical trials. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government imposed travel restrictions on travel between the United States, Europe, Canada and other countries. Further, the President of the United States declared the COVID-19 pandemic a national emergency, invoking powers under the Stafford Act, the legislation that directs federal emergency disaster response. We may experience disruptions due to the COVID-19 pandemic that could severely impact our business and clinical trials, including:

- delays, difficulties or a suspension in enrolling patients in our ongoing and planned clinical trials;
- delays, difficulties or a suspension in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- interruptions in our ability to manufacture and deliver drug supply for trials;
- 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 monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others; and
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

For our clinical trials that are planned to be conducted at sites in countries that are experiencing heightened impact from COVID-19, in addition to the risks listed above, we may also experience the following adverse impacts:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA to accept data from clinical trials in these affected geographies.

As we advance our clinical programs for PB2452 and PB1046 with site activations and patient enrollment, we remain in close contact with our CROs, clinical sites and suppliers to attempt to assess the impacts that COVID-19 may have on our clinical trials and current timelines and to consider whether we can implement appropriate mitigating measures to help to lessen such impacts. At this time, however, we cannot currently fully forecast the scope of impacts that COVID-19 may have on our ability to initiate trial sites, enroll and assess patients, supply study drug and report trial results. To date, we have temporarily paused enrollment of new patients in the PB1046 Phase 2b clinical trial as a precaution to minimize potential exposure of this patient population at high risk of serious illness from COVID-19. Although we have been targeting to report results from this trial in the fourth quarter of 2020, we believe that the COVID-19 outbreak will temporarily prevent us from being able to initiate new trial sites and enroll new patients, likely delaying our ability to report the results of this trial into 2021.

The global COVID-19 pandemic continues to rapidly evolve. The extent to which COVID-19 may impact our business and clinical trials will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, 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 United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.***

Following the result of a referendum in 2016, the United Kingdom, or UK, left the European Union, or EU, on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed to by the UK and the EU, the UK will be subject to a transition period until December 31, 2020, or the Transition Period, during which EU rules will continue to apply. Negotiations between the UK and the EU are expected to continue in relation to the customs and trading relationship between the UK and the EU following the expiry of the Transition Period.

Since a significant proportion of the regulatory framework in the UK applicable to our business and our product candidates is derived from EU directives and regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU. For example, as a result of the uncertainty surrounding Brexit, the EMA relocated to Amsterdam from London. Following the Transition Period, the UK will no longer be covered by the centralized procedures for obtaining EU-wide marketing and manufacturing authorizations from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products will be required in the UK, the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK or the EU and limit our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the EU, or we may incur expenses in establishing a manufacturing facility in the EU in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK or the EU for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

### **Risks Related to the Commercialization of Our Product Candidates**

#### ***Market acceptance of PB2452, if approved, will depend heavily on the continued market acceptance and use of ticagrelor.***

The commercial success of PB2452 as a ticagrelor reversal agent, if approved, is dependent on the continued market acceptance and use of ticagrelor as an antiplatelet therapy. Ticagrelor competes against other commercially available antiplatelet therapies, including other P2Y<sub>12</sub> receptor antagonists, many of which are available as generic drugs and therefore significantly less expensive than ticagrelor. New antiplatelet therapies may also be developed in the future, including other P2Y<sub>12</sub> receptor antagonists and other antiplatelet therapies, which could also have reversal agents, that could displace ticagrelor as the American College of Cardiology, American Heart Association and European Society of Cardiology's preferred antiplatelet agent for acute coronary syndrome or otherwise reduce ticagrelor's market position. Any such changes in the market acceptance and use of ticagrelor would significantly harm our business, results of operations and prospects for PB2452.

#### ***Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.***

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA or foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force in the United States;
- the strength of marketing and distribution support;



- the availability of third-party coverage and adequate reimbursement for PB2452, PB1046, PB6440 and any other product candidates, once approved;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

***If we are unable to establish sales, marketing and distribution capabilities for PB2452, PB1046, PB6440 or any other product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.***

We do not have sales or marketing infrastructure. To achieve commercial success for PB2452, PB1046, PB6440 or any other product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***We face substantial competition, which may result in a smaller than expected commercial opportunity and/or others discovering, developing or commercializing products before or more successfully than we do.***

The life sciences industry is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical and specialty pharmaceutical companies, compounding facilities, academic institutions and governmental agencies and public and private research institutions.

There are currently no other known reversal agents approved or in clinical development for ticagrelor or any other antiplatelet drugs. In the European Union, an extracorporeal whole blood purification adsorber device is available that may be useful for non-specific removal of ticagrelor during some cardiac procedures when used in conjunction with cardiopulmonary bypass. Upon approval, PB2452 would be the only therapeutic agent available for specific reversal of ticagrelor. There can be no assurance that competitors will not seek to develop a competing product. Moreover, the success of PB2452, if approved, will be dependent on the continued success of ticagrelor. See “—Market acceptance of PB2452, if approved, will depend heavily on the continued market acceptance and use of ticagrelor.”

We are aware of several other products and product candidates as potential treatments for PAH that would compete with PB1046. Although we anticipate that PB1046 may be used as a complement to patients’ existing therapies, we expect to compete with existing treatments for PAH patients with Class II-IV symptoms that target the endothelin, nitric oxide and prostacyclin pathways, as well as any generic equivalents that may be developed. In addition to currently approved drugs

within these classes, we are also aware of a number of PAH therapies in clinical development with which PB1046 would compete if approved.

We are aware of several other products and product candidates as potential treatments for treatment-resistant hypertension that could compete with PB6440. Although we anticipate that PB6440 may be used as a complement to patients' existing antihypertensive therapies, we expect to compete with existing generic treatments for hypertension that target the mineralocorticoid receptor. In addition to the currently approved mineralocorticoid receptor antagonists, eplerenone and spironolactone, we are also aware of a number of therapies in clinical development for the treatment of resistant hypertension with which PB6440 would compete if approved.

In addition, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects, are more convenient or are less expensive than PB2452, PB1046, PB6440 or any other product that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our product, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

***The success of PB2452 as a ticagrelor reversal agent, PB1046 for the treatment of PAH, PB6440 for treatment-resistant hypertension or any future product candidate, will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these procedures.***

We believe our success depends on obtaining and maintaining coverage and adequate reimbursement for PB2452 as a ticagrelor reversal agent, PB1046 for the treatment of PAH, PB6440 for treatment-resistant hypertension and/or procedures utilizing PB2452, PB1046, PB6440 or any other product candidate, and the extent to which patients will be willing to pay out-of-pocket for such products and procedures, in the absence of reimbursement for all or part of the cost. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. Even if the procedure using our product is covered, third-party payors, such as Medicare, Medicaid, managed care organizations, and private health insurers, may package the cost of the drug into the procedure payment and not separately reimburse the physician for the costs associated with our product. A decision by a third-party payor not to cover or separately reimburse for our products could reduce physician utilization of our products once approved. Additionally, in the United States, there is no uniform policy of coverage and reimbursement among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. One payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage, and adequate reimbursement.

Third-party payors determine which products and procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure, including costs associated with products used during the procedure, and may be unwilling to undergo such procedures in the absence of such coverage and adequate reimbursement. Physicians may be unlikely to offer procedures for such treatment if they are not covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for our stated indications unless coverage is provided and reimbursement is adequate.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental, nor investigational.

Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. An example of payment rate updates occurs in the Medicare program updates to physician payments, which is done on an annual basis. In the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, ended the use of the statutory formula and introduced a merit-based incentive bonus program for Medicare physicians, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models and the Merit-based Incentive Payment System. In November 2019, CMS issued a rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Any resulting decrease in payment under the merit-based reimbursement system may adversely affect our revenue and results of operations. In addition, the Medicare physician fee schedule has been adapted by some private payors into their plan-specific physician payment schedule. We cannot predict how pending and future healthcare legislation will impact our business, and any changes in coverage and reimbursement that further restricts coverage of our product candidates or lowers reimbursement for procedures using our products could harm our business.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our products are used under any foreign reimbursement system.

There can be no assurance that PB2452, PB1046, PB6440 or any other product candidate, if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary, that it will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale.

***The market for PB2452, PB1046, PB6440 or any other product candidates may be smaller than we expect.***

Our estimates of the potential market opportunity for PB2452, PB1046, PB6440 or any other product candidates include several key assumptions based on our industry knowledge, industry publications and third-party research reports. These assumptions include, for PB2452, the number of patients on ticagrelor who will experience uncontrolled major or life-threatening bleeding or who will require urgent surgery or an invasive procedure; for PB1046, the number of patients with PAH; and for PB6440, the number of patients with treatment-resistant hypertension, as well as the estimated reimbursement levels for each product candidate if approved. However, there can be no assurance that any of these assumptions are, or will remain, accurate. If the actual market for PB2452, PB1046, PB6440 or for any other product candidates we may develop is smaller than we expect, our revenues, if any, may be limited and it may be more difficult for us to achieve or maintain profitability.

***Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently hold \$5,000,000 in product liability insurance coverage in the aggregate, with a per incident limit of \$5,000,000, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

***Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity.***

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability and damage to our reputation, and the further development of our product candidates could be delayed.

**Risks Related to Our Dependence on Third Parties**

***We rely on third parties to conduct a significant portion of our existing clinical trials and potential future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.***

To date, we have generally engaged CROs to conduct our ongoing clinical trial of PB2452 and to assist in conducting portions of our ongoing clinical trial of PB1046. We expect to engage CROs for future clinical trials for PB2452, PB1046, PB6440 or other product candidates that we may progress to clinical development. In addition, pursuant to the SFJ Agreement, SFJ will have primary responsibility for clinical development and regulatory activities for PB2452 in China and Japan and will provide clinical trials operational support in the European Union. We expect to continue to rely on third parties, including clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, the performance of our CROs may also be interrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic.

In addition, 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 clinical programs. 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, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

We rely on these parties for execution of our preclinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and

reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA 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 by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

In addition, principal investigators for our 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. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA 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 and may ultimately lead to the denial of marketing approval of PB2452, PB1046, PB6440 or any other product candidates.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

***We contract with third parties for the manufacture of PB2452 and PB1046 for clinical drug supply and expect to continue to do so for commercialization if approved. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not have any cGMP manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the cGMP manufacture of PB2452, PB1046, PB6440 and any other product candidates that we may pursue, for clinical development as well as for commercial manufacture of PB2452, PB1046, PB6440 and any other product candidates which we may pursue, if we receive marketing approval. We also rely on a proprietary *E. coli* strain owned by Wacker Biotech GmbH, or Wacker, which we have licensed for the production of PB2452. Our reliance on Wacker's *E. coli* strain increases the risk that we will not have sufficient quantities of PB2452 or be able to obtain quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts. We will continue to rely on Wacker to manufacture our clinical supply of PB2452 for our ongoing clinical trials. We have also engaged BioVectra, another cGMP contract manufacturer, for our ongoing clinical trials and we intend to use BioVectra for commercial production of PB2452, if approved.

With respect to PB2452, to date we have only relied upon Wacker for manufacture of drug substance for use in our initial clinical trials. As we scale our manufacturing of PB2452 to meet potential commercial demand, if PB2452 is approved, we have initiated a technology transfer of our current manufacturing process for PB2452 to BioVectra. We have engaged BioVectra to manufacture drug substance for our ongoing clinical trials and intend to engage BioVectra to manufacture commercial supply of PB2452, if approved. We will need to perform analytical and other tests to demonstrate that the new materials produced by Wacker, BioVectra, or any other future third-party manufacturer that we engage, are comparable in all respects to the product utilized in our previous clinical trials. There is no assurance that any such product will pass the required comparability testing, that any other future third-party manufacturer that we engage will be successful in producing PB2452 or that any materials produced by Wacker, BioVectra or any other third-party manufacturer that we engage will have the same effect in patients that we have observed to date with respect to materials used in our previous clinical trials. Moreover, if supplies are interrupted or produced in poor yield or quality, it would materially harm our business. BioVectra will be required to scale up the manufacturing process to meet our future needs of PB2452 for later-stage clinical development and, if approved, commercialization. If BioVectra is unable to successfully scale up the manufacturing process, we would need to find alternative manufacturing facilities or an alternative manufacturing process, which we may not be able to do on a timely basis or on commercially reasonable terms, if at all, and which could adversely affect the clinical development of PB2452.

We also expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of PB2452, PB1046, PB6440 and any other product candidates for which we obtain marketing approval. The facilities used by our contract manufacturers to manufacture our product candidates must be inspected by the FDA or other regulatory authorities after we submit our BLA or comparable marketing application to the FDA or other regulatory authority.

We do not have control over a supplier's or manufacturer's compliance with laws, regulations and applicable cGMP standards or similar regulatory requirements and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we may be unable to obtain regulatory approval of our marketing applications. In addition, 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 finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We may be unable to enter into any agreements with future third-party manufacturers or to do so on acceptable terms. Even if we enter into such agreements, qualifying and validating such manufacturers may take a significant period of time and reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the incurrence of upfront scale-up costs prior to commercial approval;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible increase in costs for the raw materials for our product candidates; and
- the possible termination or nonrenewal of any agreement by any third party at a time that is costly or inconvenient for us.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supply of our products.

Our product candidates, and any drugs that we may develop, may compete with other product candidates and drugs for access to manufacturing facilities. The performance of our third-party manufacturers may also be interrupted by production shortages or other supply interruptions resulting from the ongoing COVID-19 pandemic. There are no assurances we would be able to enter into similar commercial arrangements with other manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us in a timely manner. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

***We are collaborating with SFJ for the development of PB2452, and we may seek additional collaborations with third parties for the development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.***

We are collaborating with SFJ for the development of PB2452. We may seek additional third-party collaborators for the development and commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators for any such arrangements include regional and national pharmaceutical companies and biotechnology companies. If we enter into any additional such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or 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 if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If SFJ or any future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

***We may seek to establish additional collaborations, and if we are unable to do so, 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 capital. We are collaborating with SFJ for the development of PB2452. For our other product candidates, we may decide to establish additional collaborations with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any 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 similar regulatory authorities outside the United States, 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 products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. 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.

We may not be able to negotiate additional 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 such 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 revenue.

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

***If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.***

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and our ELP technology. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and product candidates.

As of the date of this Annual Report on Form 10-K, our patent estate contained at least 19 patent families that we own or in-license that protect various aspects of our product candidates or our ELP technology platform. We own or have rights in 22 United States patents, 18 United States patent applications, over 60 foreign patents and over 60 foreign patent applications. We cannot offer any assurances about which of our patent applications will issue, the breadth of any resulting patent or whether any of the issued patents will be found invalid and unenforceable or will be threatened by third parties. We cannot offer any assurances that the breadth of our granted patents will be sufficient to stop a competitor from developing and commercializing a product, including a biosimilar product that would be competitive with one or more of our product candidates. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any of our product candidates. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent prosecution process is expensive and time-consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

In addition to the protection provided by our patent estate, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not amenable to patent protection. Although we generally require all of our employees to assign their inventions to us, and 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 provide any assurances that all such agreements have been duly executed, or that our trade secrets and other confidential proprietary information will not be disclosed. Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products, if approved, and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, our agreements or security measures may be breached, and we may not have adequate remedies for any breach. Also, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a



competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

***Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-United States legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.***

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. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States 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. 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. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we 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. 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 that product 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 and could have a material adverse effect on our business.

***If we fail to comply with our obligations in our current and future intellectual property licenses with third parties or the SFJ Agreement, we could lose rights that are important to our business.***

We are heavily reliant upon licenses to certain patent rights and proprietary technology for the development of PB2452, PB1046 and our ELP technology. These license agreements impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations, our licensors may have the right to terminate our licenses, in which event we might not be able to develop, manufacture or market any product that is covered by the intellectual property we in-license from such licensor and may face other penalties. Such an occurrence would materially adversely affect our business prospects.

Licenses to additional third-party technology and materials that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have a material adverse effect on our business and financial condition. Although we control the prosecution, maintenance and enforcement of the licensed and sublicensed intellectual property relating to PB2452, we may require the cooperation of our licensors and any upstream licensor, which may not be forthcoming. Therefore, we cannot be certain that the prosecution, maintenance and enforcement of these patent rights will be in a manner consistent with the best interests of our business. If we or our licensor fail to maintain such patents, or if we or our licensor lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights we may own in the future. Further, if we fail to comply with our development obligations under our license agreements, we may lose our patent rights with respect to such agreement on a territory-by-territory basis, which would affect our patent rights worldwide.

Termination of our current or any future license agreements would reduce or eliminate our rights under these agreements and may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Any of the foregoing could prevent us from commercializing our other product candidates, which could have a material adverse effect on our operating results and overall financial condition.

In addition, intellectual property rights that we in-license in the future may be sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

Further, we have granted SFJ a security interest in all of our assets related to PB2452, pursuant to the SFJ Agreement. If we are unable to meet our payment obligations to SFJ, SFJ may exercise its remedies as a holder of a first priority security interest, which would result in a loss of our PB2452 intellectual property rights and our business would be materially harmed.

***Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents.***

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act included a number of significant changes to United States patent law. These included provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contained new statutory provisions that require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. It is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, 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 future patents. Further, the United States 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 actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, 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. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

***We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe the patents we have applied for. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In an infringement proceeding, a court may decide that the patent claims we are asserting are invalid and/or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover the technology in question. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-

examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, 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 our product candidates. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patent applications. An unfavorable outcome could require us to cease using the related technology or force us to take a license under the patent rights of the prevailing party, if available. Furthermore, our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

***We may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our product candidates.***

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain.***

As our current and future product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. We cannot provide any assurance that our current and future product candidates do not infringe other parties' patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and future product candidates, including interference or derivation proceedings before the USPTO. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize PB2452, PB1046, PB6440 or any future product candidates. In order to successfully challenge the validity of any such United States patent in federal court, we would need to overcome a presumption of validity. As this burden is high and requires us to present clear and convincing evidence as to the invalidity of any such United States patent claim, there is no assurance that a court of competent jurisdiction would agree with us and invalidate the claims of any such United States patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future.

While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that one of our product candidates infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court orders, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed the patent at issue. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

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

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

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

We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents, or other intellectual property. We may 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. Although it is our policy to require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. 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 such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

If we rely on third parties to manufacture or commercialize PB2452, PB1046, PB6440 or any future product candidates, or if we collaborate with additional third parties for the development of PB2452, PB1046, PB6440 or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

***We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.***

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as that in the United States or Europe. These products may compete with our product candidates, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, which could make it difficult for us to stop the infringement of our future patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, 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. Accordingly, our efforts to 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.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and/or applications and any patent rights we may obtain in the future. Furthermore, the USPTO and various non-United States government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse of a patent or patent application can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market, which could have a material adverse effect on our business.

***Any trademarks we have obtained or may obtain may be infringed or otherwise violated, or successfully challenged, resulting in harm to our business.***

We expect to rely on trademarks as one means to distinguish our product candidates, if approved for marketing, from the drugs of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. Any of the foregoing events may have a material adverse effect on our business.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to or otherwise competitive with our product candidates but that are not covered by the claims of our current or future patents;
- an in-license necessary for the manufacture, use, sale, offer for sale or importation of one or more of our product candidates may be terminated by the licensor;
- we or future collaborators might not have been the first to make the inventions covered by our issued or future issued patents or our pending patent applications;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or in-license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or in-license may not provide coverage for all aspects of our product candidates in all countries;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

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

***Our relationships with customers, healthcare providers, physicians and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities 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 in return for, or to induce, either the referral of an individual, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for 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. The term “remuneration” has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, provides that 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 federal False Claims Act;
- the federal civil and criminal false claims laws, including, without limitation, the federal False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim

includes “any request or demand” for money or property presented to the United States federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of products for unapproved, and thus non-reimbursable, uses;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes which prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on health plans, healthcare clearinghouses and certain healthcare providers, known as “covered entities”, and their respective HIPAA “business associates”, and independent contractors that perform certain services involving the use or disclosure of individually identifiable health information. 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 HIPAA and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the State Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (1) payments or other “transfers of value” made to physicians, as defined by such law, and teaching hospitals, and (2) ownership and investment interests held by physicians and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws and regulations; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; 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 that otherwise restrict payments that may be made to healthcare providers; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws that govern 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 HIPAA, thus complicating compliance efforts. For example, the General Data Protection Regulation (EU) 2016/679, or GDPR, which went into effect on May 25, 2018, imposes privacy and security obligations on any entity that collects and/or processes health data from individuals located in the European Union. Under the GDPR, fines of up to 20 million Euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance. In addition, on June 28, 2018, California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent state privacy legislation in the United States, which could increase our potential liability and adversely affect our business. As well as complicating our compliance efforts, non-compliance with these laws could result in penalties or significant legal liability.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes,



regulations 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 these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

***Even if we obtain regulatory approval for PB2452, PB1046, PB6440 or any future product candidates, they will remain subject to ongoing regulatory oversight.***

Even if we obtain any regulatory approval for PB2452, PB1046, PB6440 or any future product candidates, such product candidates, once approved, will be subject to ongoing regulatory requirements applicable to manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and submitting of safety and other post-market information, among other things. Any regulatory approvals that we receive for PB2452, PB1046, PB6440 or any future product candidates may also be subject to a risk evaluation and mitigation strategy, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or requirements that we conduct potentially costly post-marketing testing, including Phase 4 trials, and in the event that we receive accelerated approval of PB2452, the completion of a Phase 3 trial, and surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We will further be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports.

Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We will also have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we will not be allowed to promote our products for indications or uses for which they do not have approval, commonly known as off-label promotion. The holder of an approved BLA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process.

In addition, drug manufacturers are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of PB2452, PB1046, PB6440 or any future product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA, NDA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;

- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize PB2452, PB1046, PB6440 or any future product candidates and harm our business, financial condition, results of operations and prospects.

***Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.***

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the United States pharmaceutical industry. The ACA, among other things: (1) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (2) expanded the entities eligible for discounts under the 340B drug pricing program; (3) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP; (4) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (5) addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (6) introduced a new Medicare Part D coverage gap discount program in which manufacturers must now agree to offer 70% 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; (7) created 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 (8) established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug.

There remain judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision that 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." 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. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In December 2018, CMS published a new 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. On December 14, 2018, a Texas United States District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the United States Court of Appeals for the 5th Circuit upheld the District Court ruling 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. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

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 pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2029, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a plan to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug 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. The Department of Health and Human Services has started soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented 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.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. The Trump administration has also taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the 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 requirements will be interpreted and 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 the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for PB2452, PB1046, PB6440 or any future product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of PB2452, PB1046, PB6440 or other product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

***Our business activities will be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.***

As we expand our business activities outside of the United States, including our clinical trial efforts, we will be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

**Risks Related to Employee Matters and Managing Our Growth**

***Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on the management, development, clinical, financial and business development expertise of our executive officers, particularly Jonathan P. Mow, our Chief Executive Officer. Each of our executive officers may currently terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

***We expect to expand our clinical development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

As of December 31, 2019, we had approximately 40 employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of

clinical product development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non-compliance 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 may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, 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 individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct, 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 be in compliance with such 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 civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

### **Risks Related to Ownership of Our Common Stock and Our Status as a Public Company**

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

Prior to our initial public offering, there was no public market for our common stock, and we cannot assure you that an active trading market for our shares will continue to develop or be sustained. As a result, it may be difficult for you to sell shares at an attractive price or at all.

***The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.***

Our stock price has been, and may continue to be, volatile. Since our IPO, our common stock has traded at prices ranging from \$2.55 to \$16.65 per share. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- the commencement, enrollment or results of our clinical trials of PB2452, PB1046, PB6440 or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for PB2452, PB1046, PB6440 or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results from, delays in or termination of clinical trials;

- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- unanticipated serious safety concerns related to the use of PB2452, PB1046, PB6440 or any other product candidate;
- changes in financial estimates by us or by any equity research analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- progress under our collaboration with SFJ for the development of PB2452;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

The stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

***If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about 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 equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

***A significant portion of our total outstanding shares are available for immediate resale. This could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

In addition, we have filed registration statements on Form S-8 registering the issuance of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options and the restrictions of Rule 144 in the case of our affiliates.

Additionally, the holders of approximately 7.0 million shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

***The issuance of additional stock in connection with financings, acquisitions, investments, our equity incentive plan or otherwise will dilute all other stockholders.***

Our certificate of incorporation authorizes us to issue up to 200,000,000 shares of common stock and up to 10,000,000 shares of preferred stock with such rights and preferences as may be determined by our board of directors. Subject to compliance with applicable rules and regulations, in the future we may issue common stock or other securities convertible into shares of our common stock from time to time in connection with a financing, acquisition, investment, our equity incentive plan or otherwise. The number of new shares of our common stock issued in connection with raising additional capital could constitute a material portion of the then outstanding shares of our common stock, which could result in substantial dilution to our existing stockholders and cause the market price of our common stock to decline.

***Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.***

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- stockholders will not be entitled to remove directors other than by a 66 2/3% vote and only for cause;
- stockholders will not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

***Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.***

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates beneficially own a significant percentage of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

***We are an “emerging growth company” and a “smaller reporting company” and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.***

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from 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 in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.***

We are subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting.



We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the Securities and Exchange Commission, or the SEC, or other regulatory authorities.

***We have broad discretion in the use of our cash and cash equivalents.***

We have broad discretion over the use of our cash and cash equivalents, including the net proceeds from our recent public offerings. You may not agree with our decisions, and our use of these cash and cash equivalents may not yield any return on your investment. We expect to use our existing cash and cash equivalents to advance PB2452, PB1046 and PB6440, fund development of our ELP technology and preclinical programs and for working capital and general corporate purposes. In addition, we may use a portion of our cash and cash equivalents to pursue our strategy to in-license or acquire additional product candidates. Our failure to apply our cash and cash equivalents effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these cash and cash equivalents. You will not have the opportunity to influence our decisions on how to use these cash and cash equivalents.

***New or future changes to tax laws could materially adversely affect our company.***

On December 22, 2017, President Trump signed into law H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018", informally titled the Tax Cuts and Jobs Act, or the Tax Act, which significantly revises the United States Internal Revenue Code of 1986, as amended. Future guidance from the United States Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our United States operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future United States tax expense. The foregoing items, as well as any other future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition, or results of operations. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation.

***Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.***

We are subject to taxation in more than one tax jurisdiction. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from jurisdiction to jurisdiction, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

***We might not be able to utilize a significant portion of our net operating loss carryforwards.***

At December 31, 2019, we had federal and state net operating loss, or NOL, carryforwards of \$149.0 million, \$153.4 million, respectively. The federal NOLs generated prior to 2018 may be used to offset up to 100% of future taxable income and will begin to expire in 2022, unless previously utilized. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the Tax Act. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use

its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.***

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of the SFJ Agreement preclude us from paying dividends, and any existing or future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

***We have begun incurring increased costs and demands upon management as a result of being a public company.***

As a public company listed in the United States, we are incurring significant additional legal, accounting and other costs, which we anticipate could be between \$2.0 million and \$3.0 million annually. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expense and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

***Our amended and restated certificate of incorporation provides 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 certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (4) any action asserting a claim governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides 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.

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 such lawsuits against us and our directors, officers and other employees. For example, stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery and federal district courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. If a court were to find either choice of forum provision contained in our amended

and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Recently, the Court of Chancery of the State of Delaware issued an opinion invalidating the federal district court exclusive forum provision, which decision has been appealed. In light of that recent decision, we will not attempt to enforce this provision of our amended and restated certificate of incorporation, unless the decision is reversed on appeal. As a result, we may incur additional costs associated with resolving disputes that would otherwise be restricted by that provision in other jurisdictions, which could seriously harm our business. However, if the decision is reviewed on appeal and ultimately overturned by the Delaware Supreme Court, we would enforce the federal district court exclusive forum provision.

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

None.

**Item 2. Properties.**

We lease 16,000 square feet of research and development and administrative space in Malvern, Pennsylvania, pursuant to a lease agreement that expires in September 2023. We also lease 4,000 square feet of administrative space in San Diego, California, pursuant to a lease agreement that expires in October 2022. We believe that our existing facilities are suitable and adequate to meet our current needs. We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

**Item 3. Legal Proceedings.**

We are not subject to any material legal proceedings. From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

**Item 4. Mine Safety Disclosures.**

Not applicable.

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

**Market Information for Common Stock**

Our common stock is listed on The Nasdaq Global Market under the symbol “PHAS.”

**Holders of Record**

As of March 26, 2020, we had 56 holders of record of our common stock, which excludes stockholders whose shares were held in nominee or street name by brokers. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

**Dividend Policy**

We have never paid cash dividends on any of our capital stock and currently intend to retain our future earnings, if any, to fund the development and growth of our business.

**Unregistered Sales of Equity Securities**

In October 2019, in connection with our existing term loan, we issued to each of Silicon Valley Bank and WestRiver Innovation Lending Fund VIII, L.P. warrants to purchase an aggregate of 12,131 shares of common stock with an exercise price of \$3.88. The issuance of these warrants was exempt from registration under Section 4(a)(2) of the Securities Act.

In January 2020, in connection with the execution of the SFJ Agreement, we issued to SFJ a ten-year warrant exercisable for 2,200,000 shares of common stock with an exercise price of \$6.50. The issuance of this warrant was exempt from registration under Section 4(a)(2) of the Securities Act.

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

None.

**Item 6. Selected Financial Data.**

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

**Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.**

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations included in this Annual Report on Form 10-K.*

**Overview**

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases, with an initial focus on cardiopulmonary indications. Our lead product candidate, PB2452, is a novel reversal agent for the antiplatelet drug ticagrelor, which we are developing for the reversal of the antiplatelet effects of ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. Based on feedback from the FDA we intend to seek approval of PB2452 in the United States through an accelerated approval process. In our completed Phase 2a clinical trial of PB2452, we observed immediate and complete reversal of ticagrelor’s antiplatelet activity within five minutes following initiation of infusion and sustained reversal for over 20 hours.

We are developing PB2452 with SFJ pursuant to the SFJ Agreement. Under the SFJ Agreement, SFJ has agreed to pay us up to \$120.0 million to support the clinical development of PB2452. During the term of the SFJ Agreement, we will

have primary responsibility for clinical development and regulatory activities for PB2452 in the United States and the European Union, while SFJ will have primary responsibility for clinical development and regulatory activities for PB2452 in China and Japan and will provide clinical trials operations support in the European Union.

The FDA granted Breakthrough Therapy designation for PB2452 in April 2019. The EMA granted PB2452 PRIME designation in February 2020. Based on feedback from the FDA, we intend to submit a BLA for potential accelerated approval based on an interim analysis of the first approximately 100 patients treated in our Phase 3 trial, with approximately 50 patients with uncontrolled major or life-threatening bleeding and approximately 50 patients requiring urgent surgery or an invasive procedure. We recently commenced our pivotal Phase 3 clinical trial. Based on an 18-month estimated enrollment timeline for the first 100 patients in the Phase 3 trial, we are targeting to submit our BLA for PB2452 in the second half of 2022. To support full approval for patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure, the FDA recommended enrollment of 200 total patients in the Phase 3 trial. After we submit our BLA with data from the first 100 patients, we intend to complete the Phase 3 trial and establish a post-approval registry in accordance with FDA requirements. The CHMP of the EMA has also generally agreed with our proposed development plan for PB2452.

Our second product candidate, PB1046, is a once-weekly fusion protein currently in a Phase 2b clinical trial for the treatment of PAH. PB1046 utilizes our ELP technology, which also serves as an engine for our preclinical pipeline. We have temporarily paused enrollment of new patients in this trial as a precaution to minimize potential exposure of this patient population at high risk of serious illness from COVID-19. However, we have also informed investigators that they may continue dosing PB1046 and performing assessments for current trial participants if they deem it appropriate and such activities are permitted by their respective institutions. Additionally, we continue to identify new trial sites for future initiation. Although we have been targeting to report results from this trial in the fourth quarter of 2020, we believe that the COVID-19 outbreak will temporarily prevent us from being able to initiate new trial sites and enroll new patients, likely delaying our ability to report the results of this trial into 2021. We are also developing our preclinical product candidate, PB6440, for treatment-resistant hypertension. We retain worldwide commercial rights to all of our product candidates.

We have a limited operating history. Since our inception in 2002, our operations have focused on developing our clinical and preclinical product candidates and our proprietary ELP technology, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials and preclinical studies. We do not have any product candidates approved for sale and have not generated any revenue from product sales. Since inception, we have financed our operations primarily through the sale of equity and debt securities and our term loans with SVB and WestRiver.

In 2018, we received \$60.7 million in aggregate net proceeds from our IPO and the sale of Series D convertible preferred stock and \$4.0 million in borrowings under our term loan with SVB. In April 2019, we received \$46.3 million in net proceeds from an underwritten public offering of our common stock. In May 2019, we received an additional \$2.5 million under our term loan with SVB and WestRiver, or our 2019 Loan, and in October 2019, we received an additional \$5.0 million under our 2019 Loan. In January 2020, we entered into the SFJ Agreement pursuant to which SFJ has agreed to provide us up to \$120.0 million of funding to support the clinical development of PB2452. In March 2020, SFJ paid us an initial \$10.0 million. SFJ will pay us an additional \$80.0 million through cost reimbursements followed by six equal quarterly payments beginning with the quarter ending September 30, 2020 through the quarter ending December 31, 2021, and up to an additional \$30.0 million upon the achievement of specified clinical development milestones with respect to our ongoing Phase 3 clinical trial of PB2452.

Since our inception, we have incurred significant operating losses. Our net loss was \$39.2 million for the year ended December 31, 2019. As of December 31, 2019, we had an accumulated deficit of \$162.2 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially in connection with our ongoing activities, as we:

- continue our ongoing clinical trials of PB2452 and PB1046, as well as initiate and complete additional clinical trials, as needed;
- seek to expand our geographical reach through the SFJ Agreement and the corresponding clinical development support fees that we will incur;
- pursue regulatory approvals for PB2452 as a reversal agent for the antiplatelet drug ticagrelor and PB1046 for the treatment of PAH;
- develop PB6440 for treatment-resistant hypertension;
- seek to discover and develop additional clinical and preclinical product candidates;
- scale up our clinical and regulatory capabilities;

- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval, including PB2452 and PB1046;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

## Recent Developments

### *Co-Development Agreement with SFJ*

In January 2020, we entered into the SFJ Agreement with SFJ, pursuant to which SFJ has agreed to pay us up to \$120.0 million to support the clinical development of PB2452. In March 2020, SFJ paid us an initial \$10.0 million. SFJ will fund \$80.0 million of development expenses through the end of 2021 and up to an additional \$30.0 million based on us meeting specific, pre-defined clinical milestones for PB2452. During the term of the SFJ Agreement, we will have primary responsibility for clinical development and regulatory activities for PB2452 in the United States and the European Union, while SFJ will have primary responsibility for clinical development and regulatory activities for PB2452 in China and Japan and will provide clinical trials operations support in the European Union. Refer to "Item 1. Business" under the subheading *Business - License, Co-Development and Other Agreements - Co-Development Agreement for PB2452 with SFJ Pharmaceuticals* in this annual report.

### *PB6440 Asset Purchase Agreement*

In January 2020, we entered into an asset purchase agreement with Viamet and Selenity to acquire all of the assets and intellectual property rights related to PB6440, a novel oral aldosterone synthase inhibitor, which we plan to develop for treatment-resistant hypertension. Refer to "Item 1. Business" under the subheading *Business - License, Co-Development and Other Agreements - Viamet Asset Purchase Agreement* in this annual report.

### *Commencement of Pivotal Phase 3 Clinical Trial for PB2452*

We recently commenced our pivotal Phase 3 clinical trial. Based on feedback from the FDA, we intend to submit a BLA for potential accelerated approval based on an interim analysis of the first approximately 100 patients treated in our Phase 3 trial, with approximately 50 patients with uncontrolled major or life-threatening bleeding and approximately 50 patients requiring urgent surgery or an invasive procedure. After we submit our BLA with data from the first 100 patients, we intend to complete the Phase 3 trial and establish a post-approval registry in accordance with FDA requirements.

## FINANCIAL OVERVIEW

### Components of Operating Results

#### *Revenue*

#### *Grant Revenue*

Grant revenue is derived from government grants that support our efforts on specific research projects. We recognize grant revenue when there is reasonable assurance of compliance with the conditions of the grant and reasonable assurance that the grant revenue will be received.

### *Revenue Under Collaborative Agreement*

Revenue under collaborative agreement is derived from an agreement with our collaboration partner, ImmunoForge Co., Ltd., or ImmunoForge. We have granted ImmunoForge a license to develop certain compound indications in exchange for an upfront license payment and event-based payments subject to ImmunoForge's achievement of specified development, regulatory and sales-based milestones. In addition, we are entitled to royalties if products under the collaboration are commercialized. We recognize revenue for upfront amounts when the license is transferred to ImmunoForge. Development milestones and other fees are recognized as revenue when it is probable that the amount will not result in a significant reversal of revenue in the future. Sales-based milestones and royalties cannot be recognized until the underlying sales occur.

### *Research and Development Expense*

Research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our clinical trials and preclinical studies;
- manufacturing and supply scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial supply and potential commercial supply, including manufacturing validation batches;
- clinical development support fees that we incur related to the SFJ Agreement;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- expenses relating to regulatory activities; and
- laboratory materials and supplies used to support our research activities.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expense to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct our later-stage clinical trials for PB2452 and PB1046, develop PB6440, conduct other preclinical studies and clinical trials and prepare regulatory filings and, if we receive regulatory approval for one or more product candidates, prepare for commercialization efforts.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of our product candidates, or when, if ever, material net cash inflows may commence from those candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- delays in regulators or institutional review boards authorizing us or our investigators to commence our clinical trials or in our ability to negotiate agreements with clinical trial sites or contract research organizations;
- our ability to secure adequate supply of product candidates for our trials;
- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- any side effects associated with our product candidates;
- the duration of patient follow-up; and
- the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may

never succeed in achieving regulatory approval for our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of our product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Product commercialization will take several years and millions of dollars in development costs.

#### *General and Administrative Expense*

General and administrative expense consists principally of salaries and related costs for personnel in executive and administrative functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expense includes professional fees for legal, accounting and tax-related services and insurance costs.

We anticipate that our general and administrative expense will increase as we continue to operate as a public reporting company and continue to develop PB2452, PB1046, PB6440 and our future product candidates. We believe that these increases likely will include increased costs for director and officer liability insurance, costs related to the hiring of additional personnel and increased fees for outside consultants, lawyers and accountants. We also expect to incur increased costs to comply with corporate governance, internal controls, investor relations, disclosure and similar requirements applicable to public reporting companies.

#### *Interest Expense*

Interest expense consists of interest expense on our convertible promissory notes and term loan. Following the conversion of the convertible promissory notes into shares of redeemable convertible Series D preferred stock in August 2018, we no longer recognize interest on the convertible promissory notes. We recognize interest on our term loan with SVB and WestRiver.

#### *Change in Fair Value of Warrant and Derivative Liabilities*

Change in fair value of warrant and derivative liabilities reflects the revaluation at each reporting date of our redeemable convertible preferred stock warrants and the conversion option on our convertible promissory notes, respectively. Following the conversion of our convertible promissory notes to preferred stock in August 2018, the conversion of all outstanding shares of our preferred stock into common stock, and the corresponding conversion of all outstanding preferred stock warrants into common stock warrants, in connection with the closing of our IPO in October 2018, we no longer remeasure the warrant liability or derivative liability for periods following the closing of the IPO.

### **License, Co-Development and Other Agreements**

#### *MedImmune Limited License Agreement*

In November 2017, we entered into the MedImmune License with MedImmune. Pursuant to the MedImmune License, MedImmune granted us an exclusive, worldwide license under certain patent rights owned or controlled by MedImmune to develop and commercialize the MedImmune Licensed Products, for the treatment, palliation, diagnosis or prevention of any human disorder or condition. Under the MedImmune License, we paid MedImmune an upfront fee of \$0.1 million. We are also required to pay MedImmune: quarterly fees relating to technical services provided by MedImmune; up to \$18.0 million in clinical and regulatory milestone fees, \$1.0 million of which was incurred in the second quarter of 2019; up to \$50.0 million in commercial milestone fees; and mid-single digit to low-teen royalty percentages on net sales of MedImmune Licensed Products, subject to reduction in specified circumstances. In addition, the MedImmune License offers an option for third-party product storage costs. From the inception of the MedImmune License through December 31, 2019, we have incurred costs of \$1.6 million under the MedImmune License.

#### *Co-Development Agreement with SFJ Pharmaceuticals*

In January 2020, we entered into the SFJ Agreement, pursuant to which SFJ will provide us funding to support the global development of PB2452 as a reversal agent for the antiplatelet drug ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. Under the SFJ Agreement, SFJ has agreed to pay us up to \$120.0 million to support the clinical development of PB2452. SFJ paid us an initial \$10.0 million in March 2020 after we obtained the consent of Silicon Valley Bank, or SVB, to grant SFJ a security interest in all of the assets owned or controlled



by us that are necessary for the manufacture, use or sale of PB2452. SFJ will pay us an additional \$80.0 million through cost reimbursements followed by six equal quarterly payments beginning with the quarter ending September 30, 2020 through the quarter ending December 31, 2021 and up to an additional \$30.0 million upon the achievement of specified milestones with respect to our clinical development of PB2452. During the term of the SFJ Agreement, we will have primary responsibility for clinical development and regulatory activities for PB2452 in the United States and the European Union, while SFJ will have primary responsibility for clinical development and regulatory activities for PB2452 in China and Japan and will provide clinical trials operational support in the European Union.

Under the terms of the SFJ Agreement, following the FDA approval of a BLA for PB2452, we will pay SFJ an initial payment of \$5.0 million and an additional \$325.0 million in the aggregate in seven additional annual payments. If the EMA or the national regulatory authority in certain European countries approve a BLA for PB2452, we will pay SFJ an initial payment of \$5.0 million and an additional \$205.0 million in the aggregate in seven additional annual payments. If either the PMDA of Japan or the NMPA of China approves a marketing application for PB2452, we will pay SFJ an initial payment of \$1.0 million and then an additional \$59.0 million in the aggregate in eight additional annual payments.

Within 120 days following approval of a BLA for PB2452 in one of the jurisdictions described above, we have the right, at our option, to make a one-time cash payment to SFJ to buy out all or a portion of the future unpaid approval payments for such jurisdiction (i.e., the U.S. Approval Payments, EU Approval Payments or Japan/China Approval Payments, as applicable) for a price reflecting a mid-single-digit discount rate. Within 120 days following a change of control of our company, we or our successor have the right, at its option, to make a one-time cash payment to SFJ to buy out all or a portion of the future unpaid approval payments in any of the jurisdictions in which a BLA for PB2452 was approved prior to the change of control for a price reflecting a mid-single-digit discount rate, provided that SFJ has not previously assigned the right to receive such payments to a third party (in which event we or our successor shall not have such right).

If following termination of the SFJ Agreement we continue to develop PB2452 and obtain BLA approval in the United States, the European Union, Japan or China, we will make the applicable approval payments for such jurisdiction to SFJ as if the SFJ Agreement had not been terminated, less any payments made upon termination, except that if we terminate the SFJ Agreement for SFJ's failure to make any payment to us when due, or SFJ terminates the SFJ Agreement due to a material adverse event, as defined in the SFJ Agreement, then our obligation to make such approval payments would be reduced by 50%.

#### *Duke License Agreement*

In October 2006, we entered into the Duke License with Duke, which we most recently amended in April 2019. Pursuant to the Duke License, Duke granted us an exclusive, worldwide license under certain patent rights owned or controlled by Duke, and a non-exclusive, worldwide license under certain know-how of Duke, to develop and commercialize the Duke licensed products relating to ELPs. Under the Duke License, we paid Duke an upfront fee of \$37,000, additional fees in connection with amendments to the Duke License of \$0.2 million and other additional licensing fees of \$0.2 million. In consideration for license rights granted to us, we initially issued Duke 24,493 shares of our common stock. Until we reached a certain stipulated equity milestone, which we reached in October 2007, we were obligated to issue additional shares of common stock to Duke from time to time so that its aggregate ownership represented 7.5% of our issued and outstanding capital stock. We are also required to pay Duke: up to \$2.2 million in regulatory and clinical milestone fees; up to \$0.4 million in commercial milestone fees; low single-digit royalty percentages on net sales of Duke licensed products, with minimum aggregate royalty payments of \$0.2 million payable following our achievement of certain commercial milestones; and up to the greater of \$0.3 million or a low double-digit percentage of the fees we receive from a third party in consideration of forming a strategic alliance with respect to certain patent rights covered under the Duke License. We also must pay Duke the first \$1.0 million of non-royalty payments we receive from a sublicensee, and thereafter a low double-digit percentage of any additional nonroyalty payments we receive, subject to certain conditions. From the inception of the Duke License through December 31, 2019, we have incurred royalty costs of \$0.3 million under the Duke License. We are also required to apply for, prosecute and maintain all United States and foreign patent rights under the Duke License.

#### *Wacker License Agreement*

In April 2019, we entered into a license agreement, or the Wacker License Agreement, with Wacker Biotech GmbH, or Wacker, pursuant to which Wacker granted us an exclusive license under certain of Wacker's intellectual property rights to use Wacker's proprietary *E. coli* strain for the manufacture of PB2452 worldwide outside of specified Asian countries and to commercialize PB2452, if approved, manufactured by us or on our behalf using Wacker's proprietary *E. coli* strain throughout the world. We have the right to grant sublicenses under the license, subject to certain conditions as specified in the Wacker License Agreement. Under the terms of the agreement, we are required to pay a fixed, nominal per-unit royalty, which is subject to adjustment, and an annual license fee in a fixed Euro amount in the low to mid six digits. The agreement will be in

force for an indefinite period of time, and upon the expiration of our royalty obligations, the license will be considered fully paid and will convert to a non-exclusive license. Either party may terminate the Wacker License Agreement for breach if such breach is not cured within a specified number of days. We incurred \$0.2 million in costs under the Wacker License Agreement for the year ended December 31, 2019.

#### *Viamet Asset Purchase Agreement*

In January 2020, we entered into the PB6440 Agreement with Viamet Pharmaceuticals Holdings, LLC and its wholly-owned subsidiary, Selenity Therapeutics (Bermuda), Ltd., or the Sellers, pursuant to which we acquired all of the assets and intellectual property rights related to the Sellers' proprietary CYP11B2 inhibitor compound, formerly known as SE-6440 or VT-6440, and certain other CYP11B2 inhibitor compounds that are covered by the patent rights acquired by us under the PB6440 Agreement, or together, Compounds. Under the terms of the PB6440 Agreement, we paid the Sellers an upfront fee of \$0.1 million upon the closing of the transaction, and we are required to pay the Sellers up to \$5.1 million upon the achievement of certain development and intellectual property milestones with respect to certain product candidates that contain a Compound, up to \$142.5 million upon the achievement of certain commercial milestones with respect to any approved product that contains a Compound and low- to mid-single digit royalty percentages on the net sales of approved products that contain a Compound, subject to customary reductions and offsets in specified circumstances. We incurred \$0.1 million in costs under the PB6440 Agreement for the year ended December 31, 2019.

## **Results of Operations**

### ***Comparison of the Years Ended December 31, 2019 and 2018***

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,		Change
	2019	2018	
<b>Revenue:</b>			
Grant revenue	\$ 1,786	\$ 668	\$ 1,118
Revenue under collaborative agreement	575	—	575
Total revenue	2,361	668	1,693
<b>Operating expenses:</b>			
Research and development	30,911	15,455	15,456
General and administrative	11,186	4,857	6,329
Total operating expenses	42,097	20,312	21,785
Loss from operations	(39,736)	(19,644)	(20,092)
<b>Other income (expense):</b>			
Interest income	1,582	387	1,195
Interest expense	(1,076)	(3,924)	2,848
Foreign exchange loss	(17)	—	(17)
Change in fair value of warrant liability	—	11	(11)
Change in fair value of derivative liability	—	(676)	676
Total other income (expense)	489	(4,202)	4,691
Net loss	\$ (39,247)	\$ (23,846)	\$ (15,401)

#### *Revenue*

Grant revenue was \$1.8 million for the year ended December 31, 2019, compared to \$0.7 million for the year ended December 31, 2018. The increase was due to higher costs that qualified for grant reimbursement under our SBIR grants for the development of PB1046 during the year ended December 31, 2019. We began incurring costs that qualified for grant reimbursement in August 2018 and continued to incur costs throughout 2019. Revenue under collaborative agreement was \$0.6 million for the year ended December 31, 2019, compared to zero for the year ended December 31, 2018. The increase of \$0.6 million was related to revenue from our agreement with ImmunoForge, which was entered into in 2019.

### Research and Development Expense

Research and development expense was \$30.9 million for the year ended December 31, 2019, compared to \$15.5 million for the year ended December 31, 2018. The increase of \$15.5 million was primarily attributable to increased clinical and drug production activities related to PB2452, increased personnel costs due to additional headcount, increased costs associated with our general research efforts and increased clinical activity related to PB1046.

The following table summarizes our research and development expense by functional area for the years ended December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,		Change
	2019	2018	
Preclinical and clinical development	\$ 24,368	\$ 11,857	\$ 12,511
Compensation and related benefits	4,725	2,789	1,936
Stock-based compensation	286	124	162
Facilities expense	766	463	303
Other	766	222	544
Total research and development expense	<u>\$ 30,911</u>	<u>\$ 15,455</u>	<u>\$ 15,456</u>

The following table summarizes our research and development expense by product candidate for the years ended December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,		Change
	2019	2018	
External research and development expense by program			
PB2452	\$ 16,660	\$ 6,726	\$ 9,934
PB1046	6,069	4,542	1,527
Unallocated research and development expense:			
Compensation and stock-based compensation	5,011	2,913	2,098
Other research and development	3,171	1,274	1,897
Total research and development expense	<u>\$ 30,911</u>	<u>\$ 15,455</u>	<u>\$ 15,456</u>

### General and Administrative Expense

General and administrative expense was \$11.2 million for the year ended December 31, 2019, compared to \$4.9 million for the year ended December 31, 2018. The increase of \$6.3 million was primarily attributable to an increase in professional services related to consulting services and legal services, an increase in personnel expense due to additional headcount and additional expenses associated with being a public company.

### Interest Income

Interest income was \$1.6 million for the year ended December 31, 2019, compared to \$0.4 million for the year ended December 31, 2018. The increase of \$1.2 million was attributable to higher balances of cash and cash equivalents during 2019.

### Interest Expense

Interest expense was \$1.1 million for the year ended December 31, 2019, compared to \$3.9 million for the year ended December 31, 2018. Interest expense for the year ended December 31, 2019 was attributable to interest on the 2019 Loan. Interest expense for the year ended December 31, 2018 was primarily attributable to interest from borrowings pursuant to our convertible promissory notes, which were outstanding during 2018. These notes were converted into shares of redeemable convertible Series D stock in August 2018.

### Change in Fair Value of Derivative Liability

Change in fair value of derivative liability resulted in no expense for the year ended December 31, 2019, compared to \$0.7 million of expense for the year ended December 31, 2018. The conversion option related to our convertible promissory notes was subject to remeasurement at each reporting period, with changes in fair value recorded in the statement of operations. The convertible promissory notes converted into redeemable convertible preferred stock in August 2018 upon the sale of the Series D redeemable convertible preferred stock and, accordingly, we no longer remeasure the fair value of the derivative liability.

### **Liquidity and Capital Resources**

Since our inception, we have not generated any revenue from product sales and have incurred net losses and negative cash flows from our operations. We have financed our operations since our inception primarily through public offerings of our common stock, private placements of convertible debt and convertible preferred stock and borrowings under our term loans. In future periods, we expect to receive up to \$120.0 million from the SFJ Agreement.

In October 2017, we entered into a loan and security agreement, or the SVB Loan, with SVB, which provided that we could borrow up to \$7.5 million.

In August 2018, we received \$17.7 million in net proceeds from the sale of our Series D redeemable convertible preferred stock. Concurrent with this financing, all of our outstanding convertible promissory notes, and accrued interest thereon, were converted into 2.1 million shares of Series D redeemable convertible preferred stock.

In October 2018, we completed our IPO of our common stock, which resulted in the issuance and sale of 9.9 million shares of common stock at a public offering price of \$5.00 per share, generating net proceeds of approximately \$43.0 million after deducting underwriting discounts and commissions and other offering costs. Upon closing of the IPO, all outstanding shares of our redeemable convertible preferred stock were converted into an aggregate of 13.2 million shares of common stock.

In March 2019, we entered into the 2019 Loan with SVB and WestRiver, pursuant to which we could borrow up to \$15.0 million, issuable in three separate tranches. As of December 31, 2019, we had drawn on all three tranches under the 2019 Loan in the amounts of \$7.5 million, \$2.5 million and \$5.0 million.

In April 2019, we completed an underwritten public offering of our common stock, which resulted in the issuance and sale of an aggregate of 4,124,475 shares of common stock at a public offering price of \$12.00 per share, generating net proceeds of \$46.3 million after deducting underwriting discounts and commissions and other offering costs.

In December 2019, we filed a shelf registration statement on Form S-3, or the 2019 Shelf Registration Statement, which became effective in January 2020. The 2019 Shelf Registration Statement permits: (i) the offering, issuance and sale by us of up to a maximum aggregate offering price of \$200.0 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination; and (ii) the offering, issuance and sale by us of up to a maximum aggregate offering price of \$60.0 million of our common stock that may be issued and sold under an “at-the-market” sales agreement, or ATM, with Citigroup Global Markets Inc. and William Blair & Company, L.L.C. No securities have been sold under the 2019 Shelf Registration Statement.

In January 2020, we entered into the SFJ Agreement, pursuant to which SFJ agreed to provide funding to support the development of PB2452 as a reversal agent for the antiplatelet drug ticagrelor. Pursuant to the SFJ Agreement, SFJ has agreed to pay us up to \$120.0 million, including an initial payment of \$10.0 million paid in March 2020, an additional \$80.0 million through cost reimbursements followed by six equal quarterly payments beginning with the quarter ending September 30, 2020 through the quarter ending December 31, 2021 and up to an additional \$30.0 million upon the achievement of specific clinical development milestones with respect to our ongoing Phase 3 clinical trial of PB2452.

As of December 31, 2019, we had cash and cash equivalents of \$74.0 million.

The following table summarizes our cash flows for each of the periods set forth below (in thousands):

	Year Ended December 31,	
	2019	2018
Net cash used in operating activities	\$ (39,594)	\$ (17,053)
Net cash used in investing activities	(960)	(119)
Net cash provided by financing activities	53,528	64,797
Net increase in cash and cash equivalents	\$ 12,974	\$ 47,625

### *Operating Activities*

Net cash used in operating activities was \$39.6 million during the year ended December 31, 2019. The use of cash primarily related to our net loss of \$39.2 million, adjusted for non-cash charges primarily related to \$1.4 million in stock-based compensation expense, \$0.5 million for non-cash interest expense and a \$2.4 million change in our operating assets and liabilities. The change in our operating assets and liabilities was principally due to a \$2.0 million increase in prepaid expense and other assets and an increase in other receivables of \$1.0 million, partially offset by a \$0.8 million increase in accounts payable, all as a result of increased clinical activities for our ongoing clinical trials of PB2452 and PB1046.

Net cash used in operating activities was \$17.1 million during the year ended December 31, 2018. The use of cash primarily related to our net loss of \$23.8 million, adjusted for non-cash charges primarily related to \$3.7 million for non-cash interest expense, \$0.7 million for the change in the fair value of the derivative liability and a \$2.0 million change in our operating assets and liabilities. The change in our operating assets and liabilities was principally due to a \$3.3 million increase in accounts payable and accrued expenses, partially offset by a \$1.0 million increase in prepaid expenses, all as a result of increased clinical activities for our ongoing clinical trials of PB2452 and PB1046.

### *Investing Activities*

Net cash used in investing activities was \$1.0 million for the purchase of property and equipment during the year ended December 31, 2019. Net cash used in investing activities was \$0.1 million for the purchase of property and equipment during the year ended December 31, 2018.

### *Financing Activities*

Net cash provided by financing activities was \$53.5 million during the year ended December 31, 2019, due primarily to the receipt of \$46.3 million in net proceeds from the April 2019 underwritten public offering and borrowings of \$8.1 million on the 2019 Loan, partially offset by \$0.9 million for partial repayment of the SVB Loan. Net cash provided by financing activities was \$64.8 million during the year ended December 31, 2018, consisting primarily of \$43.0 million in net proceeds from our initial public offering, \$17.7 million from the issuance of the Series D redeemable convertible preferred stock and \$4.0 million in proceeds from the SVB Loan.

### *Funding Requirements*

To date, we have not generated any revenues from the commercial sale of approved drug products, and we do not expect to generate substantial revenue for at least the next several years. If we fail to complete the development of our product candidates in a timely manner or fail to obtain their regulatory approval, our ability to generate future revenue will be compromised. We do not know when, or if, we will generate any revenue from our product candidates, and we do not expect to generate significant revenue unless and until we obtain regulatory approval of, and commercialize, our product candidates. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of and seek marketing approval for our product candidates. In addition, if we obtain approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We believe that our existing cash and cash equivalents as of December 31, 2019, in addition to the \$10.0 million received in March 2020 and the \$80.0 million in anticipated proceeds that we will receive pursuant to the SFJ Agreement, will be sufficient to fund our operating expenses and capital requirements into the second half of 2021. We intend to devote our existing cash and cash equivalents to advance our clinical and preclinical development programs. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of product candidates.

Our future capital requirements will depend on many factors, including:

- the progress and results of our ongoing and planned future clinical trials of PB2452, PB1046, PB6440 and our other preclinical programs;
- the timing and amount of payments we receive under the SFJ Agreement;

- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for any future product candidates we may decide to pursue;
- the extent to which we develop, in-license or acquire other product candidates and technologies;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish collaborations to commercialize PB1046 in the United States;
- our ability to establish collaborations to commercialize PB2452, PB1046 or any of our other product candidates outside of the United States; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available in the near term, if at all.

Our future commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the terms of these equity securities or this debt may restrict our ability to operate. Any future debt financing and equity financing, if available, may involve agreements that include covenants limiting and restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, entering into profit-sharing or other arrangements or declaring dividends. If we raise additional funds through government or private grants, collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Further, 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.

#### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the SEC rules and regulations.

#### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting policies, or GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with GAAP, we evaluate our estimates and judgments on an ongoing basis.

Significant estimates include assumptions we have used in the determination of accrued research and development costs. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our financial statements. See Note 2 to the financial statements appearing elsewhere in this Annual Report for a discussion of our significant accounting policies.

### ***Accrued Research and Development Expense***

The majority of our operating expenses to date have been incurred in research and development activities. As part of the process of preparing our financial statements, we are required to estimate expenses resulting from obligations under contracts with vendors, consultants and research organizations, in connection with conducting clinical and preclinical activities. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. We reflect preclinical study and clinical trial expenses in our financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the preclinical study or clinical trial as measured by the timing of various aspects of the preclinical study or clinical trial, or related activities. Our accrual estimates are determined through review of the underlying contracts along with preparation of financial models taking into account discussions with research and other key personnel as to the progress of preclinical studies or clinical trials, or other services being conducted. During the course of a preclinical study or clinical trial, we will adjust the rate of expense recognition if actual results differ from our original estimates.

### **Recent Accounting Pronouncements**

See Note 2 to the financial statements appearing elsewhere in this Annual Report for information concerning recent accounting pronouncements.

### **JOBS Act Transition Period**

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation, (i) not providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) not complying with any requirement that may be adopted by the Public Company Accounting Oversight Board. We will remain an emerging growth company until the earliest to occur of (1) the last day of the fiscal year (a) ending December 31, 2023, which is the end of the fiscal year following the fifth anniversary of the completion our initial public offering, (b) in which we have total annual gross revenues of at least \$1.07 billion or (c) in which we are deemed to be a “large accelerated filer” under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We are a “smaller reporting company” (and may continue to qualify as such even after we no longer qualify as an emerging growth company) and accordingly may provide less public disclosure than larger public companies, including the inclusion of only two years of audited financial statements and only two years of related selected financial data and management’s discussion and analysis of financial condition and results of operations disclosure. As a result, the information that we provide to our stockholders may be different than what they might receive from other public reporting companies in which they hold equity interests.

### **Effect of Inflation**

Inflation did not have a significant impact on our net sales, revenues or income from continuing operations in 2019 or 2018.

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

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

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

The information required by this Item 8 is set forth in our financial statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

#### **Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.**

None.

#### **Item 9A. Controls and Procedures.**

##### *Disclosure Controls and Procedures*

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and our principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

With respect to the year ended December 31, 2019, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2019 to provide reasonable assurance that the information required to be disclosed by us in this Annual Report was (a) reported within the time periods specified by SEC rules and regulations and (b) communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding any required disclosure.

##### *Management's Report on Internal Control Over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control - Integrated Framework* (2013 framework) (COSO). Based on its assessment, management believes that, as of December 31, 2019, our internal control over financial reporting is effective at the reasonable assurance level.

This Annual Report does not include an attestation report of our independent registered public accounting firm as allowed by the SEC's transition period for emerging growth companies.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to



the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal year ended December 31, 2019 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

None.

## PART III

We will file a definitive Proxy Statement for our 2020 Annual Meeting of Stockholders, or the Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2020 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

### **Item 10. Directors, Executive Officers and Corporate Governance.**

The information required by this Item 10 will be included in our Proxy Statement under the captions “Information Regarding the Board of Directors and Corporate Governance,” “Election of Directors,” “Executive Officers” and “Delinquent Section 16(a) Reports” and is incorporated herein by reference.

### **Item 11. Executive Compensation.**

The information required by this Item 11 will be included in our Proxy Statement under the captions “Executive Compensation” and “Director Compensation” and is incorporated herein by reference.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this Item 12 will be included in our Proxy Statement under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance under Equity Compensation Plans” and is incorporated herein by reference.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this Item 13 will be included in our Proxy Statement under the captions “Transactions with Related Persons and Indemnification” and “Independence of the Board of Directors” and is incorporated herein by reference.

### **Item 14. Principal Accounting Fees and Services.**

The information required by this Item 14 will be included in our Proxy Statement under the caption “Ratification of Selection of Independent Registered Public Accounting Firm” and is incorporated herein by reference.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules.**

**(a)(1) Financial Statements**

See the Index to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K.

**PhaseBio Pharmaceuticals, Inc.**

**Index to Financial Statements**

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## Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors  
PhaseBio Pharmaceuticals, Inc.:

### *Opinion on the Financial Statements*

We have audited the accompanying balance sheets of PhaseBio Pharmaceuticals, Inc. (the Company) as of December 31, 2019 and 2018, the related statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years then ended, in conformity with U.S. generally accepted accounting principles.

### *Change in Accounting Principle*

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Update 2016-02, *Leases*, and related amendments.

### *Basis for Opinion*

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

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

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

/s/ KPMG LLP

We have served as the Company's auditor since 2010.

Philadelphia, Pennsylvania  
March 30, 2020

**PHASEBIO PHARMACEUTICALS, INC.**  
**BALANCE SHEETS**  
(in thousands, except share and per share amounts)

	December 31,	
	2019	2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 74,025	\$ 61,031
Restricted cash	—	20
Other receivables	1,233	233
Prepaid expenses and other assets	3,565	1,344
<b>Total current assets</b>	<b>78,823</b>	<b>62,628</b>
Property and equipment, net	1,924	355
Operating lease right-of-use assets	1,715	—
Other assets	32	43
<b>Total assets</b>	<b>\$ 82,494</b>	<b>\$ 63,026</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Current portion of long-term debt	\$ 2,378	\$ —
Accounts payable	2,921	1,806
Accrued expenses and other current liabilities	3,180	2,771
<b>Total current liabilities</b>	<b>8,479</b>	<b>4,577</b>
Long-term debt, net	12,326	7,500
Operating lease liabilities, net	1,508	—
Other long-term liabilities	203	—
Deferred rent	—	22
<b>Total liabilities</b>	<b>22,516</b>	<b>12,099</b>
Commitments and contingencies ( <i>Note 7</i> )		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2019 and 2018; zero shares issued and outstanding at December 31, 2019 and 2018	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at December 31, 2019 and 2018; 28,796,371 shares issued and 28,766,404 shares outstanding at December 31, 2019; 24,528,242 shares issued and 24,498,275 shares outstanding at December 31, 2018	29	25
Treasury stock, at cost, 29,967 shares as of December 31, 2019 and 2018	(24)	(24)
Additional paid-in capital	222,131	173,837
Accumulated deficit	(162,158)	(122,911)
<b>Total stockholders' equity</b>	<b>59,978</b>	<b>50,927</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 82,494</b>	<b>\$ 63,026</b>

*See accompanying notes to financial statements.*

**PHASEBIO PHARMACEUTICALS, INC.**  
**STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2019	2018
Revenue:		
Grant revenue	\$ 1,786	\$ 668
Revenue under collaborative agreement	575	—
Total revenue	2,361	668
Operating expenses:		
Research and development	30,911	15,455
General and administrative	11,186	4,857
Total operating expenses	42,097	20,312
Loss from operations	(39,736)	(19,644)
Other income (expense):		
Interest income	1,582	387
Interest expense	(1,076)	(3,924)
Foreign exchange loss	(17)	—
Change in fair value of warrant liability	—	11
Change in fair value of derivative liability	—	(676)
Total other income (expense)	489	(4,202)
Net loss	\$ (39,247)	\$ (23,846)
Net loss per common share, basic and diluted	\$ (1.43)	\$ (4.49)
Weighted average common shares outstanding, basic and diluted	27,493,558	5,305,062

*See accompanying notes to financial statements.*

**PHASEBIO PHARMACEUTICALS, INC.**  
**STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)**  
(in thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Stockholders' Equity (Deficit)						
			Common Stock		Treasury Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
<b>Balance at December 31, 2017</b>	9,131,999	\$ 89,634	775,755	\$ 1	(29,967)	\$ (24)	\$ 1,672	\$ (99,065)	\$ (97,416)
Issuance of redeemable preferred stock	1,842,959	14,890	—	—	—	—	—	—	—
Issuance of redeemable preferred stock upon conversion of promissory notes	2,080,209	19,778	—	—	—	—	—	—	—
Exercises of warrants for preferred stock	144,948	1,212	—	—	—	—	—	—	—
Accretion of redeemable preferred stock to redemption value	—	95	—	—	—	—	(95)	—	(95)
Conversion of redeemable convertible preferred stock warrants into common stock warrants	—	—	—	—	—	—	3,346	—	3,346
Conversion of redeemable convertible preferred stock into common stock	(13,200,115)	(125,609)	13,225,048	13	—	—	125,596	—	125,609
Issuance of common stock in initial public offering, net	—	—	9,864,666	10	—	—	42,964	—	42,974
Exercises of warrants for common stock, net	—	—	619,086	1	—	—	(70)	—	(69)
Exercises of stock options	—	—	43,687	—	—	—	92	—	92
Stock-based compensation	—	—	—	—	—	—	332	—	332
Net loss	—	—	—	—	—	—	—	(23,846)	(23,846)
<b>Balance at December 31, 2018</b>	—	—	24,528,242	25	(29,967)	(24)	173,837	(122,911)	50,927
Issuance of common stock warrants	—	—	—	—	—	—	355	—	355
Issuance of common stock in public offering, net	—	—	4,124,475	4	—	—	46,273	—	46,277
Exercises of stock options	—	—	143,654	—	—	—	245	—	245
Stock-based compensation	—	—	—	—	—	—	1,421	—	1,421
Net loss	—	—	—	—	—	—	—	(39,247)	(39,247)
<b>Balance at December 31, 2019</b>	—	\$ —	28,796,371	\$ 29	(29,967)	\$ (24)	\$ 222,131	\$ (162,158)	\$ 59,978

*See accompanying notes to financial statements.*



**PHASEBIO PHARMACEUTICALS, INC.**  
**STATEMENTS OF CASH FLOWS**  
(in thousands)

	Year Ended December 31	
	2019	2018
<b>Operating activities</b>		
Net loss	\$ (39,247)	\$ (23,846)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	174	105
Stock-based compensation	1,421	332
Non-cash interest expense	500	3,664
Change in fair value warrant liability	—	(11)
Change in fair value derivative liability	—	676
Changes in operating assets and liabilities:		
Other receivables	(1,000)	(233)
Prepaid expenses and other assets	(1,954)	(1,017)
Accounts payable	802	1,337
Accrued expenses	(327)	1,923
Deferred rent	37	17
Net cash used in operating activities	(39,594)	(17,053)
<b>Investing activities</b>		
Purchases of property and equipment	(960)	(119)
Net cash used in investing activities	(960)	(119)
<b>Financing activities</b>		
Proceeds from issuance of common stock, net	46,277	42,974
Payments of deferred stock offering costs	(145)	—
Proceeds from issuance of redeemable convertible preferred stock, net	—	17,712
Long-term borrowings, net	8,089	3,995
Proceeds from exercise of stock options	245	92
Proceeds from exercise of warrants	—	24
Repayments of long-term debt	(938)	—
Net cash provided by financing activities	53,528	64,797
Net increase in cash and cash equivalents	12,974	47,625
Cash, cash equivalents and restricted cash at the beginning of the year	61,051	13,426
Cash, cash equivalents and restricted cash at the end of the year	\$ 74,025	\$ 61,051
<b>Supplemental disclosure for cash flow</b>		
Cash paid for interest	\$ 576	\$ 260
<b>Supplemental disclosure of cash flow information</b>		
Accrued interest on term loan refinanced to principal	\$ 308	\$ —
Debt refinanced through new term loan	\$ 6,563	\$ —
Right-of-use asset and lease liabilities recorded upon adoption of ASC 842	\$ 1,991	\$ —
Conversion of redeemable convertible preferred stock into common stock	\$ —	\$ 125,609
Conversion of convertible promissory notes into redeemable convertible preferred stock	\$ —	\$ 19,778
Warrant liability converted to redeemable convertible preferred stock upon the exercise of warrants	\$ —	\$ 4,297
Issuance of warrants in conjunction with debt	\$ 355	\$ 2,822
Conversion of redeemable convertible preferred stock warrants into common stock warrants	\$ —	\$ 3,346
Accretion of redeemable convertible preferred stock	\$ —	\$ 95
Deferred stock offering costs in accounts payable	\$ 110	\$ —
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 823	\$ 39

*See accompanying notes to financial statements.*

**1. Organization and Description of Business**

*Description of Business*

PhaseBio Pharmaceuticals, Inc. (the "Company") was incorporated as a Delaware corporation on January 10, 2002. The Company is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases. The Company's lead product candidate, PB2452, is a novel reversal agent for the antiplatelet drug ticagrelor, which the Company is developing for the reversal of the antiplatelet effects of ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. The Company's second product candidate, PB1046, is a once-weekly fusion protein currently in a Phase 2b clinical trial for the treatment of pulmonary arterial hypertension. PB1046 utilizes the Company's proprietary half-life extending elastin-like polypeptide technology, which also serves as the engine for future product pipeline candidates.

*Liquidity*

The Company has experienced net losses and negative cash flows from operations since its inception and, as of December 31, 2019, had an accumulated deficit of \$162.2 million. The Company expects to continue to incur net losses for at least the next several years. As of December 31, 2019, the Company had cash and cash equivalents of \$74.0 million and working capital of \$70.3 million. In January 2020, the Company entered into a co-development agreement ("SFJ Agreement") with SFJ Pharmaceuticals X, Ltd., an SFJ Pharmaceuticals Group company ("SFJ") pursuant to which SFJ will provide funding and operational support for the clinical development of PB2452. Management believes that its existing cash and cash equivalents as of December 31, 2019, in addition to the \$10.0 million received in March 2020 and the \$80.0 million in anticipated proceeds that the Company will receive pursuant to the SFJ Agreement, will be sufficient to fund operating expenses and capital requirements into the second half of 2021.

The Company currently has an effective shelf registration statement on Form S-3 ("2019 Shelf Registration Statement") on file with the Securities and Exchange Commission ("SEC"), which expires January 2023. The 2019 Shelf Registration Statement currently permits the offering, issuance and sale by the Company of up to an aggregate offering price of \$200.0 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination, of which \$60.0 million may be offered, issued and sold in "at-the-market" sales pursuant to an equity distribution agreement with Citigroup Global Markets Inc. and William Blair & Company, L.L.C ("Equity Distribution Agreement"). No securities have been sold under the 2019 Shelf Registration Statement and no shares have been sold pursuant to the Equity Distribution Agreement.

*Basis of Presentation*

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP") and the rules and regulations of the SEC. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB").

The Company manages its operations as a single reportable segment for the purposes of assessing performance and making operating decisions.

**2. Significant Accounting Policies**

*Use of Estimates*

The preparation of the Company's financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to the valuation of redeemable convertible preferred stock warrants prior to the Initial Public Offering ("IPO"), the conversion option on the convertible notes and clinical trial accruals. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results could differ materially from those estimates and assumptions.

*Concentrations of Credit Risk*

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Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains certain deposits in federally insured financial institutions in excess of federally insured limits. The Company could experience losses on the money market funds in the future.

*Cash and Cash Equivalents*

The Company considers all highly liquid investments with an original maturity from the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include cash in readily available checking and money market accounts.

*Restricted Cash*

The Company had restricted cash of \$20,000 as of December 31, 2018, which was held in a certificate of deposit at the Company's bank to secure the Company's corporate credit card. The restriction was removed in June 2019.

*Fair Value of Financial Instruments*

The carrying amounts of other receivables, prepaid expenses and other assets, accounts payable and accrued expenses and other current liabilities are reasonable estimates of their fair value because of the short maturity of these items. Based on the borrowing rates currently available to the Company for loans with similar terms, the Company believes the fair values of the term loan and operating lease liabilities and corresponding right-of-use assets approximate their respective carrying values.

*Property and Equipment*

Property and equipment are recorded at cost and depreciated over the estimated useful lives of the assets (three to five years) using the straight-line method. Leasehold improvements are amortized over the shorter of their estimated useful lives or the lease term.

*Leases*

At lease commencement, the Company records a lease liability based on the present value of lease payments over the expected lease term including any options to extend the lease that the Company is reasonably certain to exercise. The Company calculates the present value of lease payments using an incremental borrowing rate as the Company's leases do not provide an implicit interest rate. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. At the lease commencement date, the Company records a corresponding right-of-use lease asset based on the lease liability, adjusted for any lease incentives received and any initial direct costs paid to the lessor prior to the lease commencement date. The Company may enter into leases with an initial term of 12 months or less ("Short-Term Leases"). For any Short-Term Leases, the Company records the rent expense on a straight-line basis and does not record the leases on the balance sheet. The Company had no Short-Term Leases as of December 31, 2019 and 2018.

After lease commencement, the Company measures its leases as follows: (i) the lease liability based on the present value of the remaining lease payments using the discount rate determined at lease commencement and (ii) the right-of-use lease asset based on the remeasured lease liability, adjusted for any unamortized lease incentives received, any unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease agreement. Any lease incentives received and any initial direct costs are amortized on a straight-line basis over the expected lease term. Rent expense is recorded on a straight-line basis over the expected lease term.

*Long-Lived Assets*

The Company regularly reviews the carrying value and estimated lives of all of its long-lived assets, including property and equipment and right-of-use assets to determine whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. The determinants used for this evaluation include management's estimate of the asset's ability to generate net positive cash flow in future periods as well as the strategic significance of the assets to the Company's business objectives. Should an impairment exist, the impairment loss would be measured based on the extent that the estimated fair value is less than its carrying value. The Company did not recognize any impairment losses in the years ended December 31, 2019 and 2018.

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*Preferred Stock Warrant Liability*

The Company previously issued freestanding warrants to purchase shares of its redeemable convertible preferred stock. Since the underlying redeemable convertible preferred stock was classified outside of permanent equity, those warrants were classified as liabilities in the accompanying balance sheet. Warrants classified as liabilities were recorded at their estimated fair value on the date of issuance and were revalued at each subsequent balance sheet date, with fair value changes recognized as increases or reductions to other income (expense) in the accompanying statements of operations. The Company estimated the fair value of these warrants using the Black-Scholes option-pricing model.

In connection with the Company's IPO in October 2018, all warrants were either exercised or converted into warrants to purchase common stock, at which time the liability was reclassified to stockholders' equity.

*Preclinical and Clinical Trial Accruals*

The Company accrues and expenses amounts incurred in connection with preclinical studies and clinical trial activities performed by third parties based upon estimates of the proportion of work completed over the life of the individual trial and subject enrollment rates in accordance with agreements with clinical research organizations, contract manufacturing organizations and clinical trial sites. The Company determines the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including the Company's clinical development plan.

Management makes estimates of the Company's accrued expenses as of each balance sheet date in the Company's financial statements based on facts and circumstances known to the Company at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

*Research and Development Expense*

Research and development costs are expensed as incurred.

*Stock-Based Compensation*

The Company measures and recognizes compensation expense for all stock-based compensation based on the estimated fair value at the date of grant. Currently, the Company's stock-based awards consist only of stock options; however, future grants under the Company's equity compensation plan may also consist of shares of restricted stock, restricted stock units, stock appreciation rights, performance awards and performance units. The Company also maintains an employee stock purchase program under which it may issue shares. The Company estimates the fair value of stock options using the Black-Scholes option-pricing model, which requires the use of estimates. The Company recognizes stock-based compensation cost for ratably vesting stock options on a straight-line basis over the requisite service period of the award and records forfeitures in the period in which they occur.

The Black-Scholes option-pricing model requires the input of subjective assumptions, including the risk-free interest rate, the fair value of the underlying common stock (for option grants prior to the IPO), the expected dividend yield of the Company's common stock, the expected volatility of the price of the Company's common stock, and the expected term of the option. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, the Company's stock-based compensation expense could be materially different in the future.

*Income Taxes*

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

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The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits, if any, within income tax expense, and any accrued interest and penalties are included within the related tax liability line.

*Grant Revenue*

Grant revenue is derived from government grants that support the Company's efforts on specific research projects. The Company has determined that the government agencies providing grants to the Company are not customers. The Company recognizes grant revenue when there is reasonable assurance of compliance with the conditions of the grant and reasonable assurance that the grant revenue will be received.

*Revenue Under Collaborative Agreement*

The Company generates revenues from payments received under a collaborative agreement. Under such collaboration agreements, the Company recognizes revenue when it transfers promised goods or services to partners in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with partners, the Company performs the following five steps: (i) identifies the promised goods or services in the contract; (ii) identifies the performance obligations in the contract, including whether they are distinct in the context of the contract; (iii) determines the transaction price, including the constraint on variable consideration; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when (or as) the Company satisfies the performance obligations.

For revenue from such collaborative agreements, the Company generally collects an upfront license payment from the collaboration partner and is also entitled to receive event-based payments subject to the collaboration partner's achievement of specified development, regulatory and sales-based milestones. In addition, the Company is generally entitled to royalties if products under the collaboration are commercialized. Although such agreements are in form structured as collaborative agreements, for accounting purposes they represent contracts with partners that are not subject to accounting literature on collaborative arrangements. If the Company grants to collaboration partners a license to the Company's intellectual property, the Company does not develop assets jointly with the collaboration partner and does not share in significant risks of their development or commercialization activities.

Transaction price for a contract represents the amount to which the Company is entitled in exchange for providing goods and services to the partner. Transaction price does not include amounts subject to uncertainties unless it is probable that there will be no significant reversal of revenue when the uncertainty is resolved. Apart from the upfront license payment, all other fees the Company may earn under such collaborative agreements are subject to significant uncertainties of product development. Achievement of many of the event-based development and regulatory milestones may not be probable until such milestones are actually achieved. This generally relates to milestones such as obtaining marketing authorization approvals and successful completion of clinical trials. With respect to other development milestones, e.g. dosing of a first patient in a clinical trial, achievement could be considered probable prior to its actual occurrence, based on the progress towards commencement of the trial. The Company does not include any amounts subject to uncertainties into the transaction price until it is probable that the amount will not result in a significant reversal of revenue in the future. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price.

Because such agreements generally only have one type of performance obligation, a license, which is generally all transferred at the same time as agreement inception, allocation of the transaction price among multiple performance obligations is not required.

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Upfront amounts allocated to licenses are recognized as revenue when the licenses are transferred to the collaboration partners. Development milestones and other fees are recognized in revenue when their occurrence becomes probable.

*Net Loss Per Share*

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities, which include redeemable convertible preferred stock, warrants and outstanding stock options under the Company's stock option plan, have been excluded from the computation of diluted net loss per share as they would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position.

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive.

	As of December 31,	
	2019	2018
Common stock options	2,577,718	1,545,403
Warrants to purchase common stock	149,595	75,597
Total	2,727,313	1,621,000

*Recent Accounting Pronouncements*

In February 2016, the FASB issued ASU 2016-02, *Leases*. This update amended the current accounting guidance for lease transactions. Under the new guidance, a lessee is required to recognize both assets and liabilities for any leases with terms in excess of twelve months. Additionally, certain qualitative and quantitative disclosures are required in the financial statements. The Company adopted ASU 2016-02 in the first quarter of 2019 using a modified retrospective transition method as of the effective date as permitted by the amendments in ASU 2018-11. As a result, the Company was not required to adjust comparative prior-period financial information for the effects of the standard or make the new required lease disclosures for periods before the date of adoption. The Company elected to adopt the package of transition practical expedients and, therefore, did not reassess (1) whether existing or expired contracts contain a lease, (2) lease classification for existing or expired leases or (3) the accounting for initial direct costs that were previously capitalized. The Company did not elect the practical expedient to use hindsight for leases existing at the adoption date. Further, the Company does not expect the amendments in ASU 2018-01, *Land Easement Practical Expedient* to have an effect on its financial statements because the Company does not enter into land easement arrangements. The adoption of the new leasing standards did not affect retained earnings and other components of equity as of December 31, 2018. Upon adoption in the first quarter of 2019, the Company recorded right-of-use assets and corresponding lease liabilities of \$2.0 million.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement - Disclosure Framework (Topic 820): Changes to the Disclosure Requirements for Fair Value Measurement*. The updated guidance improves the disclosure requirements on fair value measurements. The updated guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted for any removed or modified disclosures. The Company is currently assessing the timing and impact of adopting the updated provisions.

**3. Fair Value Measurement**

Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The Company classifies fair value measurements in one of the following three categories for disclosure purposes:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

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Level 3: Unobservable inputs that are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The Company's cash equivalents are classified using Level 1 inputs within the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

The following table summarizes the Company's assets and liabilities that require fair value measurements on a recurring basis and their respective input levels based on the fair value hierarchy (in thousands):

	Fair Value Measurements at Reporting Date			
	Total	Level 1	Level 2	Level 3
<b>As of December 31, 2019:</b>				
Assets				
Cash equivalents	\$ 73,761	\$ 73,761	\$ —	\$ —
<b>As of December 31, 2018:</b>				
Assets				
Cash equivalents	\$ 59,357	\$ 59,357	\$ —	\$ —

The following tables present activity for the preferred stock warrant liability and the derivative liability measured at fair value using significant unobservable Level 3 inputs during the year ended December 31, 2018 (in thousands):

	Preferred Stock Warrant Liability
Balance at December 31, 2017	1,656
Issuance of warrants	2,822
Exercise of warrants	(1,197)
Changes in fair value reflected as change in fair value of warrant liability	(11)
Conversion to common stock warrants upon IPO	(3,270)
Balance at December 31, 2018	\$ —

	Derivative Liability
Balance at December 31, 2017	3,028
Changes in fair value reflected as change in fair value of derivative liability	676
Extinguishment of derivative upon conversion of convertible promissory notes	(3,704)
Balance at December 31, 2018	\$ —

**4. Property and Equipment**

The following table presents the composition of property and equipment, net as of December 31, 2019 and 2018 (in thousands):

**PHASEBIO PHARMACEUTICALS, INC.**  
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	As of December 31,	
	2019	2018
Lab equipment	\$ 2,112	\$ 1,764
Computer hardware, software and telephone	279	228
Furniture and fixtures	107	98
Leasehold improvements	67	50
Construction in progress	1,318	—
	3,883	2,140
Less accumulated depreciation	(1,959)	(1,785)
Property and equipment, net	\$ 1,924	\$ 355

**5. Accrued Expenses and Other Current Liabilities**

The following table presents the composition of accrued expenses and other current liabilities as of December 31, 2019 and 2018 (in thousands):

	As of December 31,	
	2019	2018
Accrued clinical and related costs	\$ 819	\$ 1,358
Accrued compensation and related costs	1,746	914
Accrued interest	84	194
Operating lease liability, short-term	265	—
Accrued other	266	305
Accrued expenses and other current liabilities	\$ 3,180	\$ 2,771

**6. Debt**

*Convertible Promissory Notes*

In 2017, the Company issued \$14.7 million of convertible promissory notes (the “2017 Notes”) to holders of Series C-1 redeemable convertible preferred stock (“Series C-1”). The 2017 Notes bore interest at the rate of 8% per annum. Upon a subsequent equity financing of at least \$10.0 million prior to the stated maturity date, the 2017 Notes plus accrued interest would automatically convert into shares of the stock issued by the Company in such financing at a price equal to 80% of the lowest issue price.

The 2017 Notes could have converted into a variable number of shares of preferred stock, and accordingly, the Company determined the conversion provision to be a redemption feature. The redemption feature was evaluated as an embedded derivative and bifurcated from the convertible promissory notes due to the substantial premium paid upon redemption and accounted for as a derivative instrument. Upon bifurcating the redemption feature, the Company recorded a debt discount of \$3.0 million that was recognized in interest expense over the term of the 2017 Notes.

In connection with the 2017 Notes, the Company issued warrants to the noteholders to purchase 304,397 shares of Series C-1. The warrants were exercisable for \$0.12 per share and expired upon the earlier of (1) the date of the initial closing of a liquidation event, as defined, (2) the closing of a firm commitment underwritten initial public offering, or (3) January 2024. All warrants were exercised in connection with the closing of the Company’s IPO. The Company recorded a debt discount of \$1.7 million, which represented the estimated fair value of the warrants, upon issuance of the 2017 Notes, which was being amortized to interest expense over the term of the 2017 Notes using the effective-interest method.

In August 2018, the Company sold 1,842,959 shares of Series D redeemable preferred stock (“Series D”) to new and existing investors at a price of \$9.659 per share for net proceeds of \$17.7 million and issued warrants to purchase 368,582 shares of Series C-1 at an exercise price of \$0.12 per share (the “Series D Financing”). Concurrent with the Series D Financing, all of the Company’s previously outstanding 2017 Notes, including accrued interest thereon, were converted into 2,080,209 shares of Series D.

Interest expense, including the debt discount related to the 2017 Notes, was \$3.4 million for the year ended December 31, 2018.



*Term Loans*

*October 2017 Loan Agreement with Silicon Valley Bank*

In October 2017, the Company entered into a Loan and Security Agreement (“SVB Loan”) with Silicon Valley Bank (“SVB”), pursuant to which the Company could borrow up to \$7.5 million, issuable in three separate tranches (“Growth Capital Advances”) of \$3.5 million (“Tranche A”), \$2.0 million (“Tranche B”) and \$2.0 million (“Tranche C”). Each of the Growth Capital Advances were available upon the achievement of certain clinical and regulatory milestones. Under the terms of the SVB Loan, as amended, the Company was required to make interest-only payments through December 31, 2018, followed by an amortization period of 24 months of equal monthly payments of principal plus interest amounts until paid in full. The maturity date of the SVB Loan was December 31, 2020.

In connection with the SVB Loan, the Company issued to SVB a warrant to purchase 49,713 shares of Series C-1 at an exercise price of \$9.659 per share, which became exercisable for common stock following the IPO. The warrant is immediately exercisable and expires on October 18, 2027. The Company was required to make a final payment equal to 7% of the original aggregate principal amount of the Growth Capital Advances at maturity. In November 2017, the Company drew \$3.5 million from Tranche A.

The Company had the option to prepay all, but not less than all, of the borrowed amounts, provided that the Company would have been obligated to pay a prepayment fee equal to (a) 3.0% of the outstanding principal balance of the applicable Growth Capital Advances if prepayment was made prior to the first anniversary of the effective date of the SVB Loan, (b) 2.0% of the outstanding principal balance of the applicable Growth Capital Advances if prepayment was made by the second anniversary of the effective date of the SVB Loan or (c) 1.0% of the outstanding principal balance of the applicable Growth Capital Advances if prepayment was made after the second anniversary of the effective date of the SVB Loan.

The Company repaid the outstanding principal balance and accrued portion of the final payment under the SVB Loan in full using the first tranche from the new term loan entered into in March 2019 (“the 2019 Loan”).

*March 2019 Loan Agreement with Silicon Valley Bank and WestRiver Innovation Lending Fund VIII, L.P.*

In March 2019, the Company entered into the 2019 Loan with SVB and WestRiver Innovation Lending Fund VIII, L.P. (“WestRiver”), pursuant to which the Company could borrow up to \$15.0 million, issuable in three separate tranches (“Advances”), of \$7.5 million (“Tranche 1”), which was issued upon execution of the 2019 Loan, \$2.5 million, which was issued in May 2019 (“Tranche 2”) and \$5.0 million, which was issued in October 2019 (“Tranche 3”), which the Company was required to draw upon the achievement of certain regulatory milestones (the “Tranche 3 Milestones”).

The maturity date of the 2019 Loan is March 1, 2023. Under the terms of the 2019 Loan, the Company is to make interest-only payments through June 30, 2020 with respect to Tranche 1, Tranche 2 and Tranche 3 at a rate equal to the greater of the Prime Rate plus 1.00%, as defined in the 2019 Loan, or 6.5%, followed by an amortization period of 33 months of equal monthly payments of principal plus interest until paid in full. In addition to and not in substitution for the Company’s regular monthly payments of principal plus accrued interest, the Company is required to make a final payment equal to 6% of the aggregate principal amount of the advances (“Final Payment”) on the maturity date.

Upon execution of the 2019 Loan and the draw of Tranche 1, the Company issued to SVB and WestRiver warrants to purchase an aggregate of 37,606 shares of common stock with an exercise price of \$4.73 per share. In May 2019, upon the draw of Tranche 2, the Company issued to SVB and WestRiver warrants to purchase an aggregate of 12,130 shares of common stock with an exercise price of \$10.86 per share. In October 2019, upon the draw of Tranche 3, the Company issued to SVB and WestRiver warrants to purchase an aggregate of 24,262 shares of common stock with an exercise price of \$3.88 per share. All warrants are immediately exercisable and expire ten years from the date of issuance.

Upon execution of the 2019 Loan, the Company drew \$7.5 million from Tranche 1 and repaid the outstanding principal balance and the accrued portion of the Final Payment of the SVB Loan.

The Company’s obligations under the 2019 Loan are secured by a first-priority security interest in substantially all of the Company’s current and future assets. The Company is also obligated to comply with various other customary covenants, including restrictions on the Company’s ability to encumber its intellectual property assets.

The Company recorded a debt discount of \$0.4 million for the estimated fair value of warrants and debt issuance costs upon the borrowing of Tranches 1, 2 and 3, which is being amortized to interest expense over the term of the 2019 Loan

**PHASEBIO PHARMACEUTICALS, INC.**  
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using the effective-interest method. Interest expense, including amortization of debt discount related to the term debt, totaled \$1.1 million and \$0.6 million for the years ended December 31, 2019 and 2018, respectively. The balance of the Final Payment liability was \$0.2 million as of December 31, 2019 and is included in other long-term liabilities on the balance sheet. The Company is in compliance with all covenants under the 2019 Loan as of December 31, 2019.

Based on a 39-month amortization of the outstanding principal amounts for the 2019 Loan, the following table sets forth by year the Company's required future principal payments as of December 31, 2019 (in thousands):

<u>Years Ending December 31,</u>	
2020	\$ 2,528
2021	5,316
2022	5,677
2023	1,479
Thereafter	—
Total principal payments	15,000
Less unamortized loan fees	(296)
Total term loan borrowings	<u>\$ 14,704</u>

**7. Commitments and Contingencies**

*Legal Proceedings*

The Company is not currently a party to any litigation, nor is management aware of any pending or threatened litigation against the Company, that it believes would materially affect the Company's business, operating results, financial condition or cash flows.

**8. Leases**

The Company leases office and research and development facilities and equipment under various non-cancellable operating lease agreements.

In January 2010, the Company entered into a lease for office and laboratory space in Malvern, Pennsylvania (the "Malvern Lease"). The Malvern Lease commenced in March 2010 and was amended to extend its term to July 31, 2018 and again to September 30, 2023, with an option to extend the lease for an additional three years. This lease contains escalating rent payments. In December 2018, the Company entered into a lease for office space in San Diego, California, which expires in October 2022. As of December 31, 2019, the weighted average remaining lease term for the Company's leases was 6.1 years, and the weighted average discount rate used to determine the right-of-use assets and corresponding operating lease liabilities was 6.4%.

Maturities of operating lease liabilities as of December 31, 2019 are as follows:

<u>Year Ending December 31,</u>	
2020	\$ 372
2021	377
2022	363
2023	272
2024	278
Thereafter	498
Total future minimum lease payments	2,160
Less: Present value adjustment	(387)
Operating lease liabilities	<u>\$ 1,773</u>

The Company recognizes rent expense for the operating leases on a straight-line basis. The Company accounts for the difference between the minimum lease payments and the straight-line amount as deferred rent and records it as an offset to operating lease right-of-use assets. Rent expense was \$0.5 million and \$0.4 million for the years ended December 31, 2019 and 2018, respectively.

## 9. Stockholders' Equity

### *Preferred Stock*

The Company issued Series 1 redeemable convertible preferred stock, Series 2 redeemable preferred stock, Series AA redeemable convertible preferred stock, Series B redeemable convertible preferred stock, Series C-1, Series C-2 redeemable convertible preferred stock, Series C-3 redeemable convertible preferred stock, and Series D convertible preferred stock (collectively, "Preferred Stock"). Upon the closing of the IPO in October 2018, all shares of Preferred Stock were automatically converted into an aggregate of 13,225,048 shares of common stock.

### *Initial Public Offering*

In October 2018, the Company completed an IPO of its common stock, which resulted in the issuance and sale of an aggregate of 9,864,666 shares of common stock at a public offering price of \$5.00 per share, generating net proceeds of \$43.0 million after deducting underwriting discounts and commissions and other offering costs.

### *April 2019 Offering*

In April 2019, the Company completed an underwritten public offering of its common stock, which resulted in the issuance and sale of an aggregate of 4,124,475 shares of common stock at a public offering price of \$12.00 per share, generating net proceeds of \$46.3 million after deducting underwriting discounts and commissions and other offering costs.

### *Shelf Registration Statement*

In December 2019, the Company filed the 2019 Shelf Registration Statement on Form S-3, which became effective in January 2020. The 2019 Shelf Registration Statement permits: (i) the offering, issuance and sale by the Company of up to a maximum aggregate offering price of \$200.0 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination; and (ii) the offering, issuance and sale by the Company of up to a maximum aggregate offering price of \$60.0 million of the Company's common stock that may be issued and sold in "at-the-market" sales pursuant to the Equity Distribution Agreement. No securities have been sold under the 2019 Shelf Registration Statement and no shares have been sold pursuant to the Equity Distribution Agreement.

## 10. Stock-Based Compensation

### *Stock Plans*

In July 2018, the Company amended its Amended and Restated 2002 Stock Plan (the "2002 Plan") to reserve an additional 800,000 shares of common stock for issuance under the 2002 Plan.

In October 2018, the Company's board of directors and stockholders adopted and approved the 2018 Equity Incentive Plan (the "2018 Plan"), which is a successor to and continuation of the 2002 Plan. The 2018 Plan became effective upon the execution of the underwriting agreement related to the IPO on October 17, 2018. No further grants will be made under the 2002 Plan.

Initially, the maximum number of shares of the Company's common stock that may be issued under the 2018 Plan was 3,231,626 shares. As of December 31, 2019, the Company had 1,221,879 shares available for grant under the 2018 Plan. The number of shares of common stock reserved for issuance under the 2018 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2019 through January 1, 2028, in an amount equal to 3% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Company's board of directors. Subject to this provision, the Company added 862,992 shares available for grant to the 2018 Plan effective January 1, 2020. The maximum number of shares of the Company's common stock that may be issued on the exercise of incentive stock options under the 2018 Plan is 9,694,878.

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The following table summarizes stock option activity for the 2002 Plan and 2018 Plan for the year ended December 31, 2019:

	Total Options	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at Ended December 31, 2017	1,075,209	\$ 1.60	7.3	\$ 711,328
Granted	563,268	\$ 4.07		
Exercised	(43,687)	\$ 2.12		
Cancelled or expired	(49,387)	\$ 1.65		
Outstanding at December 31, 2018	1,545,403	\$ 2.48	7.6	\$ 1,593,487
Granted	1,260,540	\$ 4.19		
Exercised	(143,654)	\$ 1.71		
Cancelled or expired	(84,571)	\$ 4.65		
Outstanding at December 31, 2019	2,577,718	\$ 3.29	7.9	\$ 7,914,459
Vested and expected to vest at December 31, 2019	2,577,718	\$ 3.29	7.9	\$ 7,914,459
Vested and exercisable at December 31, 2019	1,157,120	\$ 2.25	6.7	\$ 4,469,348

The weighted-average grant date fair value per share of options granted was \$2.62 and \$2.75 for the years ended December 31, 2019 and 2018, respectively. The aggregate intrinsic value of options exercised was \$1.0 million and \$0.2 million for the years ended December 31, 2019 and 2018, respectively.

As of December 31, 2019, the total unrecognized compensation expense related to unvested employee and non-employee stock option awards was \$3.2 million, which was expected to be recognized in expense over a weighted-average period of approximately 2.7 years.

In October 2018, the Company's board of directors and stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"). The ESPP became effective on October 17, 2018. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees and to provide incentives for such individuals to exert maximum efforts toward the Company's success and that of the Company's affiliates. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code for United States employees.

The ESPP authorizes the issuance of 196,000 shares of the Company's common stock under purchase rights granted to the Company's employees or to employees of any of the Company's designated affiliates. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2019 through January 1, 2028, by the lesser of (1) 1% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of the automatic increase, and (2) 490,000 shares; provided that before the date of any such increase, the Company's board of directors may determine that such increase will be less than the amount set forth in clauses (1) and (2). Subject to this provision, the Company added 287,664 shares available for grant to the ESPP effective January 1, 2020. As of December 31, 2019, no shares of common stock have been purchased under the ESPP.

#### *Determining Fair Value of Stock Options*

The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. Certain of these inputs are subjective and generally require judgment to determine.

*Expected Term*—The expected term of stock options represents the weighted average period the stock options are expected to be outstanding. The Company uses the simplified method for estimating the expected term. The simplified method calculates the expected term as the average time-to-vesting and the contractual life of the options.

*Expected Volatility*—Due to the Company's limited operating history and lack of company-specific historical or implied volatility, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available.

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*Risk-Free Interest Rate*—The risk-free rate assumption is based on the United States Treasury instruments, the terms of which were consistent with the expected term of the Company’s stock options.

*Expected Dividend*—The Company has not paid and does not intend to pay dividends.

*Common Stock Valuation*—Due to the absence of a public market trading the Company’s common stock prior to the IPO, it was necessary to estimate the fair value of the common stock underlying the stock-based grants when performing fair value calculations using the Black-Scholes option pricing model. The fair value of the common stock underlying the stock-based grants was assessed for each grant date by the board of directors. All options to purchase shares of common stock have been granted with an exercise price per share no less than the fair value per share of the common stock underlying those options on the date of grant.

In the absence of a public trading market for the Company’s common stock, the Company determined the estimated fair value of its common stock using methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants (“AICPA”) Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation (“AICPA Practice Aid”).

The fair value of each option was estimated on the date of grant using the weighted average assumptions in the table below:

	Year Ended December 31,	
	2019	2018
Risk-free interest rate	2.36%	2.88%
Expected term (in years)	5.9	7.0
Expected volatility	69%	69%
Expected dividend yield	—	—
Fair value of common stock	\$ 4.19	\$ 4.07

Stock-based compensation expense has been reported in the Company’s statements of operations for the years ended December 31, 2019 and 2018 as follows (in thousands):

	Year Ended December 31,	
	2019	2018
General and administrative	\$ 1,135	\$ 208
Research and development	286	124
Total stock-based compensation	\$ 1,421	\$ 332

**11. License Agreements**

*MedImmune Limited*

In November 2017, the Company entered into a license agreement (“MedImmune License”) with MedImmune Limited (“MedImmune”). MedImmune is a wholly-owned subsidiary of AstraZeneca plc (“AstraZeneca”). Pursuant to the terms of the MedImmune License, MedImmune granted the Company exclusive global rights for the purpose of developing and commercializing products under the MedImmune License (“MedImmune licensed product”). In consideration of the license and other rights granted by MedImmune, the Company made an upfront payment of \$0.1 million, which was included as research and development expense for the year ended December 31, 2017. The Company is also obligated to make a series of contingent milestone payments totaling up to an aggregate of \$18.0 million upon the achievement of clinical development and regulatory milestones. During the year ended December 31, 2019, the Company made a \$1.0 million milestone payment to MedImmune, which was recorded as a research and development expense. In addition, the Company will pay MedImmune tiered royalties ranging from mid-single-digit to low-teen percentages of net sales of any MedImmune licensed products and additional payments of up to \$50.0 million in aggregate commercial milestones. The Company also must pay quarterly fees relating to technical services provided by MedImmune. The MedImmune License requires the Company to cooperate with MedImmune on commercial messaging of PB2452 and provides MedImmune with the return of rights to PB2452 if certain commercial diligence requirements are not achieved by the Company. In addition, the MedImmune License offers an option for

third-party product storage costs. The Company incurred an insignificant amount of third-party product storage costs during the years ended December 31, 2019 and 2018. AstraZeneca is a stockholder of the Company.

#### *Duke University*

In October 2006, the Company entered into a license agreement with Duke University (“Duke”) (as amended, the “Duke License”). Pursuant to the Duke License, Duke granted to the Company an exclusive, worldwide license under certain patent rights and a non-exclusive license to know-how owned or controlled by Duke to develop and commercialize any products or processes covered under the Duke License (the “Duke licensed products”). The Duke License was amended in February 2016 to allow Duke to use the Company’s technology in the area of small-molecule oncologics. The Duke License is a worldwide, sublicensable agreement and remains in full effect for the life of the last-to-expire patents included in the patent rights, which is estimated to be 2029. The Company is required to apply for, prosecute and maintain all United States and foreign patent rights under the Duke License.

The Company is obligated to pay up to \$2.2 million upon the achievement of clinical development and regulatory milestones and up to \$0.4 million upon the achievement of commercial milestones. The Duke License may be terminated by Duke if the Company fails to meet certain clinical development and regulatory milestones within specified timeframes. As of December 31, 2019, the Company was in compliance with its development obligations.

The Company is required to use commercially reasonable efforts to develop one or more products or processes and introduce them into commercial markets. Duke will receive low single-digit royalty percentages on net sales of Duke licensed products by the Company or its sublicensee, with minimum aggregate royalties of \$0.2 million payable following the Company’s achievement of certain commercial milestones. No sales of Duke licensed products or services have occurred since the effective date through December 31, 2019.

Certain alliance fee payments up to the greater of \$0.3 million or a low double-digit percentage of the fees the Company receives from a third party in consideration of forming a strategic alliance, may be required depending upon how the patent rights are commercialized. The Company will pay Duke the first \$1.0 million of nonroyalty payments it receives from a sublicensee, and thereafter a specified percentage of any additional nonroyalty payments it receives, subject to certain conditions. If Duke receives revenue as a result of a license or sublicense to a third party in the field of small-molecule oncologics, it will pay the Company a specified percentage of the amount of such revenue in excess of \$1.0 million. Duke is also a stockholder of the Company.

#### *Wacker*

In April 2019, the Company entered into a license agreement (“Wacker License Agreement”), with Wacker Biotech GmbH (“Wacker”), pursuant to which Wacker granted the Company an exclusive license under certain of Wacker’s intellectual property rights to use Wacker’s proprietary *E. coli* strain for the manufacture of PB2452 worldwide outside of specified Asian countries, and to commercialize PB2452, if approved, manufactured by the Company or on the Company’s behalf using Wacker’s proprietary *E. coli* strain throughout the world. The Company has the right to grant sublicenses under the license, subject to certain conditions as specified in the Wacker License Agreement. Under the terms of the agreement, the Company is required to pay a fixed, nominal per-unit royalty, which is subject to adjustment, and an annual license fee in a fixed Euro amount in the low to mid six digits. The agreement will be in force for an indefinite period of time, and upon the expiration of the Company’s royalty obligations, the license will be considered fully paid and will convert to a non-exclusive license. Either party may terminate the Wacker License Agreement for breach if such breach is not cured within a specified number of days. The Company incurred \$0.2 million in costs under the Wacker License Agreement for the year ended December 31, 2019.

## **12. Revenue**

### *Grant revenue*

In February 2018, the Company received Small Business Innovation Research (“SBIR”) grants from the National Institutes of Health in an aggregate amount of \$2.8 million to support the clinical development of PB1046 for the treatment of pulmonary arterial hypertension for the period from February 17, 2018 to July 31, 2020. In connection with the SBIR grants, the United States government will receive a non-exclusive, royalty-free license to use any technology the Company develops under such grants. The Company recognized \$1.8 million and \$0.7 million under the SBIR grants in the year ended December 31, 2019 and 2018, respectively.

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*Revenue Under Collaborative Agreement*

In April 2019, the Company entered into an agreement with ImmunoForge Co., Ltd. (“ImmunoForge”) for the exclusive, worldwide license of PB1023, a long-acting, recombinant glucagon-like peptide-1 analogue, for the treatment of certain diseases, including conditions related to sarcopenia.

The Company received an upfront payment of \$0.2 million upon execution of the contract, \$0.1 million for certain scientific consulting services and is entitled to receive \$0.3 million within one year of the effective date of the agreement. The Company is eligible to receive milestone-based payments and mid-single digit royalty payments on net sales of licensed products, a percentage of which Duke is entitled to receive pursuant to the Duke License. For the year ended December 31, 2019, the Company recognized \$0.6 million in revenue related to the ImmunoForge agreement.

**13. Income Taxes**

The Company’s loss before income taxes was \$39.2 million and \$23.8 million for the years ended December 31, 2019 and 2018, respectively and was generated entirely in the United States. The Company did not record current or deferred income tax expense or benefit during the years ended December 31, 2019 and 2018.

A reconciliation of income tax expense (benefit) to the amount computed by applying the statutory federal income tax rate to the loss from operations is summarized for the years ended December 31, 2019 and 2018, respectively, as follows (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
Income tax benefit at statutory rate	\$ (8,242)	\$ (5,008)
State income tax, net of federal benefit	(3,783)	(1,593)
Permanent items	16	3
Fair value adjustments	—	15
Non-deductible interest expense	—	706
Stock-based compensation	56	45
Orphan drug credit	(925)	(475)
Research and development credits	(763)	(274)
Uncertain tax positions	548	222
Tax Cuts and Jobs Act	—	(15)
Change in state rate	(34)	—
Change in valuation allowance	13,179	6,426
Other	(52)	(52)
	<u>\$ —</u>	<u>\$ —</u>

Significant components of the Company’s deferred tax assets as of December 31, 2019 and 2018 are shown below:

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	As of December 31,	
	2019	2018
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 42,872	\$ 31,744
Research and development and orphan drug credits	6,212	4,615
Accrued expenses	519	332
Intangibles	60	69
Operating lease liabilities	545	—
Other, net	322	54
<b>Total deferred tax assets</b>	<b>50,530</b>	<b>36,814</b>
<b>Deferred tax liabilities:</b>		
Operating lease right-of-use assets	(527)	—
Property and equipment, net	(28)	(18)
<b>Total deferred tax liabilities</b>	<b>(555)</b>	<b>(18)</b>
<b>Net deferred tax assets before valuation allowance</b>	<b>49,975</b>	<b>36,796</b>
Valuation allowance	(49,975)	(36,796)
<b>Net deferred tax assets</b>	<b>\$ —</b>	<b>\$ —</b>

As of December 31, 2019 and 2018, management assessed the realizability of net deferred tax assets and evaluated the need for a valuation allowance against the net deferred tax assets. This evaluation utilizes the framework contained in ASC 740, *Income Taxes*, whereby management considers all available positive and negative evidence as of the balance sheet date to determine whether all or some portion of the Company's net deferred tax assets will be realized. Under this guidance, a valuation allowance must be established for net deferred tax assets when it is more-likely-than-not (a probability level of more than 50%) that the asset will not be realized.

Management followed the guidance in ASC 740, which states that "a cumulative loss in recent years is a significant piece of negative evidence that is difficult to overcome" and concluded that the Company's net deferred tax assets were not realizable as of December 31, 2019 and 2018. Accordingly, a valuation allowance of \$50.0 million and \$36.8 million has been recorded to offset the net deferred tax assets. The change in valuation allowance for the years ended December 31, 2019 and 2018 was an increase of \$13.2 million and an increase of \$6.4 million, respectively.

At December 31, 2019, the Company had federal and state net operating loss ("NOL") carryforwards of \$149.0 million, and \$153.4 million, respectively. The federal NOLs generated prior to 2018 may be used to offset up to 100% of future taxable income and will begin to expire in 2022, unless previously utilized. The federal NOL generated post-2017 of \$57.4 million will be available to offset up to 80% of future taxable income and may be carried forward indefinitely. The Pennsylvania NOLs may be used to offset 40% of future taxable income and will begin to expire in 2029, unless previously utilized.

At December 31, 2019, the Company has federal and Pennsylvania research and development tax credit carryforwards totaling \$3.8 million and \$0.4 million, respectively. The federal and Pennsylvania research and development tax credit carryforwards will begin to expire in 2028 and 2029, respectively, unless previously utilized.

At December 31, 2019, the Company also has federal orphan drug credit carryforwards of \$4.2 million, which will begin to expire in 2036, unless previously utilized.

Through December 31, 2019, the Company has generated a combination of research and development credits and orphan drug credits. Certain of these credits were derived from tax credit studies to document the qualified activities and certain other credits were not derived from studies. For the credits that were calculated through a study, the IRS, on audit, may disagree with the amount of credits calculated. When studies are ultimately performed for the other credits, they may result in an adjustment to those specific credits.

Under the Internal Revenue Code, the utilization of a corporation's net operating loss and tax credit carryforwards may be limited following a greater than 50% change in ownership over a three-year period. Any unused annual limitation may



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be carried forward to future years for the balance of the net operating loss and tax credit carryforward period. Under these rules, prior ownership changes may have created a limitation in the Company's ability to use certain tax carryforwards on a yearly basis. Additionally, certain state operating losses may also be limited, including Pennsylvania, which limits net operating loss carryforward utilization to 40% of apportioned taxable income.

The Company applies the two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount, which is more than 50% likely of being realized upon ultimate settlement. Income tax positions must meet a more likely than not recognition threshold at the effective date to be recognized upon the adoption of ASC 740 and in subsequent periods. This interpretation also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company files income tax returns in the United States federal jurisdiction and various state jurisdictions. Tax years 2016 and forward remain open for examination for federal tax purposes and tax years 2016 and forward remain open for examination for the Company's more significant state tax jurisdictions. To the extent utilized in future years' tax returns, net operating loss carryforwards at December 31, 2019 will remain subject to examination until the respective tax year is closed.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits for the years ended December 31, 2019 and 2018 (in thousands):

	<b>Year Ended December 31</b>	
	<b>2019</b>	<b>2018</b>
Gross unrecognized tax benefits at the beginning of the year	\$ 1,809	\$ 1,293
Increases related to current year positions	645	362
Increases related to prior year positions	106	154
Decreases related to prior year positions	—	—
Expiration of unrecognized tax benefits	—	—
Gross unrecognized tax benefits at the end of the year	<u>\$ 2,560</u>	<u>\$ 1,809</u>

Due to the Company's valuation allowance, none of the unrecognized tax benefits, if recognized, would affect the Company's effective tax rate.

As of December 31, 2019, and 2018, the Company had unrecognized tax benefits of \$2.6 million and \$1.8 million, respectively. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. During the years ended December 31, 2019 and 2018, the Company did not accrue any interest and penalties on uncertain tax positions. The Company does not expect its unrecognized tax benefits to change significantly within the next 12 months.

**14. Employee Retirement Plan**

The Company has an employee retirement plan pursuant to Section 401(k) of the Internal Revenue Code. All employees are eligible to participate, provided they meet the requirements of this plan. The Company is not required to make matching contributions under the plan; however, in 2019, the Company began making matching contributions. The Company voluntarily contributed \$0.1 million to the plan for the year ended December 31, 2019.

**15. Related Party Transactions**

As described above in Note 11, the Company is party to the MedImmune License. AstraZeneca, the parent company of MedImmune, is a related party of the Company.

**16. Subsequent Events**

*Co-Development Agreement for PB2452 with SFJ Pharmaceuticals*

In January 2020, the Company entered into the SFJ Agreement, pursuant to which SFJ will provide funding to the Company to support the global development of PB2452 as a reversal agent for the antiplatelet drug ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. Under the SFJ Agreement, SFJ has agreed to pay the Company up to \$120.0 million to support the clinical development of PB2452. In March 2020, SFJ

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paid the Company an initial \$10.0 million. SFJ will pay the Company an additional \$80.0 million through cost reimbursements followed by six equal quarterly payments beginning with the quarter ending September 30, 2020 through the quarter ending December 31, 2021, and up to an additional \$30.0 million upon the achievement of specified clinical development milestones with respect to the Company's clinical development of PB2452.

If the FDA approves a Biologics License Application for PB2452, the Company has agreed to pay to SFJ an initial payment of \$5.0 million and an additional \$325.0 million in the aggregate in seven additional annual payments (the "U.S. Approval Payments"). If the EMA or the national regulatory authorities in certain European countries provide marketing approval of PB2452, the Company will pay SFJ an initial payment of \$5.0 million and an additional \$205.0 million in the aggregate in seven additional annual payments (the "EU Approval Payments"). The majority of the U.S. Approval Payments and the EU Approval Payments will be made from the third anniversary to the seventh anniversary of marketing approval in the applicable jurisdiction. If either the Pharmaceuticals and Medical Devices Agency (the "PMDA") of Japan or the National Medical Products Administration (the "NMPA") of China provide marketing approval of PB2452, the Company will pay SFJ an initial payment of \$1.0 million and then an additional \$59.0 million in the aggregate in eight additional annual payments (the "Japan/China Approval Payments"), with the majority of the payments to be made from the fifth anniversary to the eighth anniversary of marketing approval. The Japan/China Approval Payments will only be paid once regardless of receipt of marketing approval in both Japan and China. The U.S. Approval Payments, EU Approval Payments and Japan/China Approval Payments will be proportionately adjusted in the event that the actual funding from SFJ is lower or greater than \$120.0 million. The Company will not be obligated to make the U.S. Approval Payments if it does not receive marketing approval for PB2452 from the FDA, the EU Approval Payments if it does not receive marketing approval for PB2452 from the EMA or the national regulatory authority in certain European countries or the Japan/China Approval Payments if it does not receive marketing approval for PB2452 from either the PMDA or the NMPA.

In connection with the SFJ Agreement, the Company issued to SFJ a ten-year warrant exercisable for 2,200,000 shares of the Company's common stock at an exercise price of \$6.50 per share. The warrant is exercisable as follows: (i) 1,100,000 shares may be exercised at any time after the effective date of the SFJ Agreement, provided that SFJ may not sell such exercised shares until one year after such effective date, and (ii) the remaining 1,100,000 shares may be exercised at any time at SFJ's election if the results of the Company's Phase 3 trial meet the interim primary endpoint as set forth in the Phase 3 trial protocol.

Under the SFJ Agreement, the Company granted SFJ a security interest in all of the Company's assets pertaining to PB2452. The SFJ Agreement also provides for certain default provisions and early payment provisions.

*Amendment to MedImmune License*

In January 2020, in connection with the Company entering the SFJ Agreement, the Company entered into an amendment to the MedImmune License pursuant to which MedImmune consented to a potential assignment of the MedImmune License and transfer of the Company's business related to PB2452 to SFJ in the event of the occurrence of certain program transfer events, should they ever occur.

*Viamet Asset Purchase Agreement*

In January 2020, the Company entered into an asset purchase agreement (the "PB6440 Agreement") with Viamet Pharmaceuticals Holdings, LLC ("Viamet") and its wholly-owned subsidiary, Selenity Therapeutics (Bermuda), Ltd. ("Selenity" and, together with Viamet, the "Sellers"), pursuant to which the Company acquired all of the assets and intellectual property rights related to the Sellers' proprietary CYP11B2 inhibitor compound, formerly known as SE-6440 or VT-6440, and certain other CYP11B2 inhibitor compounds that are covered by the patent rights acquired by the Company under the PB6440 Agreement (together, "Compounds"). The Company intends to designate SE-6440 as PB6440, which the Company intends to develop for treatment-resistant hypertension. Under the terms of the PB6440 Agreement, the Company is required to pay Viamet an upfront fee of \$100,000 upon the closing of the transaction, up to \$5.1 million upon the achievement of certain development and intellectual property milestones, up to \$142.5 million upon the achievement of certain commercial milestones and low- to mid-single digit royalty percentages on the net sales of approved products.

*Consent and Amendment to 2019 Loan*

In March 2020, in connection with the Company entering the SFJ Agreement, the Company entered into a Consent and First Amendment (the "First Amendment") to its 2019 Loan with SVB and WestRiver (together, the "Lenders"). Pursuant to the First Amendment, the Lenders consented to the Company's entry into the SFJ Agreement, which required that the Company obtain the consent of SVB to grant SFJ a security interest in all of the Company's assets owned or controlled by the Company that are necessary for the manufacture, use or sale of PB2452. The First Amendment also provides that in the event that the SFJ Agreement were terminated or the Company breached or was in default of the SFJ Agreement (after giving effect to applicable grace periods), the Company will grant to the Lenders a security interest in an amount of unrestricted cash

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equal to at least the aggregate outstanding balance of all of the obligations under the 2019 Loan as security for the prompt payment of such obligations.

In connection with the First Amendment, the Company and the Lenders concurrently entered into an intellectual property security agreement granting the Lenders a security interest in all of the Company's intellectual property. In addition, the Company, SVB, in its capacity as administrative agent and collateral agent, the Lenders and SFJ entered into a subordination agreement pursuant to which SFJ's liens and right to payment and performance under the SFJ Agreement are subordinated to the Lenders' liens and right to payment in full under the 2019 Loan.

**(a)(2) Financial Statement Schedules**

All financial statement schedules have been omitted as they are not required, not applicable, or the required information is included in the financial statements or notes to the financial statements.

**(a)(3) Exhibits****EXHIBIT INDEX**

Exhibit Number	Exhibit Title	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	<a href="#">Amended and Restated Certificate of Incorporation of PhaseBio Pharmaceuticals, Inc.</a>	8-K	001-38697	3.1	October 22, 2018
3.2	<a href="#">Amended and Restated Bylaws of PhaseBio Pharmaceuticals, Inc.</a>	S-1/A	333-227474	3.4	October 5, 2018
4.1	<a href="#">Form of Warrant to Purchase Shares of Series B Redeemable Convertible Preferred Stock, issued by PhaseBio Pharmaceuticals, Inc. on December 22, 2009.</a>	S-1	333-227474	4.2	September 21, 2018
4.2	<a href="#">Warrant to Purchase Shares of Series C-1 Redeemable Convertible Preferred Stock, issued by PhaseBio Pharmaceuticals, Inc. to Silicon Valley Bank on October 18, 2017.</a>	S-1	333-227474	4.3	September 21, 2018
4.3	<a href="#">Fourth Amended and Restated Investor Rights Agreement, by and among PhaseBio Pharmaceuticals, Inc. and certain of its stockholders, dated August 27, 2018.</a>	S-1	333-227474	4.4	September 21, 2018
4.4	<a href="#">Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to Silicon Valley Bank on March 25, 2019.</a>	10-K	001-38697	4.4	March 26, 2019
4.5	<a href="#">Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to WestRiver Innovation Lending Fund VIII, L.P. on March 25, 2019.</a>	10-K	001-38697	4.5	March 26, 2019
4.6	<a href="#">Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to WestRiver Innovation Lending Fund VIII, L.P. on July 26, 2019.</a>	10-Q	001-38697	4.6	August 14, 2019
4.7	<a href="#">Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to Silicon Valley Bank on July 26, 2019.</a>	10-Q	001-38697	4.7	August 14, 2019

Exhibit Number	Exhibit Title	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
4.8	<a href="#">Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to Silicon Valley Bank on October 2, 2019.</a>	10-Q	001-38697	4.8	November 14, 2019
4.9	<a href="#">Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to WestRiver Innovation Lending Fund VIII, L.P. on October 2, 2019.</a>	10-Q	001-38697	4.9	November 14, 2019
4.10#	<a href="#">Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to SFJ Pharmaceuticals X, Ltd. on January 9, 2020</a>				
4.11#	<a href="#">Description of PhaseBio Pharmaceuticals, Inc. Common Stock</a>				
10.1+	<a href="#">2018 Equity Incentive Plan and Forms of Stock Option Grant Notice and Agreement and Restricted Stock Unit Grant Notice and Agreement thereunder.</a>	S-8	333-227935	10.2	October 22, 2018
10.2+	<a href="#">2018 Employee Stock Purchase Plan.</a>	S-8	333-227935	10.3	October 22, 2018
10.3+	<a href="#">Non-Employee Director Compensation Policy, as amended.</a>	8-K	001-38697	10.1	February 13, 2020
10.4+	<a href="#">Form of Indemnification Agreement by and between PhaseBio Pharmaceuticals, Inc. and each of its directors and executive officers.</a>	S-1/A	333-227474	10.5	October 5, 2018
10.5+	<a href="#">Severance Benefit Plan and Form of Participation Agreement.</a>	S-1/A	333-227474	10.6.1	October 5, 2018
10.6+	<a href="#">Amended and Restated 2002 Stock Plan and Form of Option Agreement and Exercise Notice thereunder, as amended to date.</a>	S-1	333-227474	10.1	September 21, 2018
10.7+	<a href="#">Offer Letter, dated as of November 19, 2012, by and between PhaseBio Pharmaceuticals, Inc. and Jonathan P. Mow, as amended to date.</a>	S-1	333-227474	10.7	September 21, 2018
10.8+	<a href="#">Offer Letter, dated as of March 13, 2016, by and between PhaseBio Pharmaceuticals, Inc. and John Sharp.</a>	S-1	333-227474	10.8	September 21, 2018
10.9+	<a href="#">Offer Letter, dated as of November 19, 2012, by and between PhaseBio Pharmaceuticals, Inc. and John Lee, M.D., Ph.D.</a>	S-1	333-227474	10.9	September 21, 2018

Exhibit Number	Exhibit Title	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.10†	<a href="#">License Agreement, dated as of October 18, 2017 and as amended to date, by and between Phase Bioscience, Inc. (predecessor to PhaseBio Pharmaceuticals, Inc.) and Duke University</a>	S-1	333-227474	10.10	September 21, 2018
10.11††	<a href="#">Eighth Amendment to License Agreement, dated as of March 5, 2019, by and between PhaseBio Pharmaceuticals, Inc. and Duke University</a>	8-K	001-38697	10.1	April 9, 2019
10.12†	<a href="#">License Agreement, dated as of November 21, 2017, by and between PhaseBio Pharmaceuticals, Inc. and MedImmune Limited</a>	S-1	333-227474	10.11	September 21, 2018
10.13#	<a href="#">Amendment to License Agreement, dated January 9, 2020, by and between PhaseBio Pharmaceuticals, Inc. and MedImmune Limited</a>				
10.14	<a href="#">Loan and Security Agreement, dated as of October 18, 2017 and as amended to date, by and between PhaseBio Pharmaceuticals, Inc. and Silicon Valley Bank</a>	S-1	333-227474	10.12	September 21, 2018
10.15	<a href="#">Loan and Security Agreement, dated as of March 25, 2019, by and among PhaseBio Pharmaceuticals, Inc. and Silicon Valley Bank and WestRiver Innovation Lending Fund VIII, L.P.</a>	10-K	001-38697	10.13	March 26, 2019
10.16#	<a href="#">Consent and First Amendment to Loan and Security Agreement, dated as of March 19, 2020, by and among PhaseBio Pharmaceuticals, Inc. and Silicon Valley Bank and WestRiver Innovation Lending Fund VIII, L.P.</a>				
10.17#	<a href="#">Subordination Agreement, dated as of March 19, 2020, by and among Silicon Valley Bank, WestRiver Innovation Lending Fund VIII, L.P. and SFJ Pharmaceuticals X, Ltd.</a>				
10.18#††	<a href="#">Intellectual Property Security Agreement, dated as of March 19, 2020, by and among PhaseBio Pharmaceuticals, Inc. and Silicon Valley Bank and WestRiver Innovation Lending Fund VIII, L.P.</a>				
10.19††	<a href="#">Master Services Agreement, dated as of November 14, 2018, by and between PhaseBio Pharmaceuticals, Inc. and BioVectra Inc.</a>	10-K	001-38697	10.14	March 26, 2019

Exhibit Number	Exhibit Title	Incorporated by Reference		
		Form	File No.	Filing Date
10.20	<a href="#">Lease Agreement, dated as of January 15, 2010 and as amended to date, by and between PhaseBio Pharmaceuticals, Inc. and Liberty Property Limited Partnership.</a>	S-1	333-227474	10.13 September 21, 2018
10.21#††	<a href="#">Co-Development Agreement, dated January 9, 2020, by and between PhaseBio Pharmaceuticals, Inc. and SFJ Pharmaceuticals X, Ltd.</a>			
10.22#††	<a href="#">Form of Program Transfer Agreement by and between PhaseBio Pharmaceuticals Inc. and SFJ Pharmaceuticals X, Ltd.</a>			
10.23#††	<a href="#">Asset Purchase Agreement, dated January 13, 2020, by and between PhaseBio Pharmaceuticals, Inc., Viamet Pharmaceuticals Holdings, LLC and Selenity Therapeutics (Bermuda), Ltd.</a>			
23.1#	<a href="#">Consent of KPMG LLP</a>			
24.1#	<a href="#">Power of Attorney (included on signature page).</a>			
31.1#	<a href="#">Certification of Chief Executive Officer and President (Principal Executive Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>			
31.2#	<a href="#">Certification of Chief Financial Officer (Principal Financial Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>			
32.1#*	<a href="#">Certification of Chief Executive Officer (Principal Executive Officer), pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>			
32.2#*	<a href="#">Certification of Chief Financial Officer (Principal Financial Officer), pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>			
101.INS#	XBRL Instance Document.			
101.SCH#	XBRL Taxonomy Extension Schema Document.			
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document.			
101.DEF#	XBRL Taxonomy Extension Definition Linkbase Document.			
101.LAB#	XBRL Taxonomy Extension Label Linkbase Document.			

Exhibit Number	Exhibit Title	Incorporated by Reference		
		Form	File No.	Filing Date
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document.			
#	Filed herewith.			
+	Indicates management contract or compensatory plan.			
†	Confidential treatment has been granted for certain portions of this exhibit (indicated by asterisks). Such information has been omitted and was filed separately with the Securities and Exchange Commission.			
††	Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and would likely cause competitive harm to PhaseBio Pharmaceuticals, Inc. if publicly disclosed.			
*	These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.			

**Item 16. Form 10-K Summary**

Not applicable.



## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

### PHASEBIO PHARMACEUTICALS INC.

March 30, 2020

By: /s/ John P. Sharp

John P. Sharp  
Chief Financial Officer  
*(On behalf of the registrant and in his capacity as  
Principal Financial Officer and Principal Accounting Officer)*

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jonathan P. Mow and John P. Sharp, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of PhaseBio Pharmaceuticals, Inc., and any or all amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Jonathan P. Mow</u> Jonathan P. Mow	Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 30, 2020
<u>/s/ John P. Sharp</u> John P. Sharp	Chief Financial Officer <i>(Principal Financial Officer and Principal Accounting Officer)</i>	March 30, 2020
<u>/s/ Clay B. Thorp</u> Clay B. Thorp	Chairman of the Board of Directors	March 30, 2020
<u>/s/ Edmund P. Harrigan, M.D.</u> Edmund P. Harrigan, M.D.	Director	March 30, 2020
<u>/s/ Nancy J. Hutson, Ph.D.</u> Nancy J. Hutson, Ph.D.	Director	March 30, 2020
<u>/s/ Peter Justin Klein, M.D., J.D.</u> Peter Justin Klein, M.D., J.D.	Director	March 30, 2020
<u>/s/ Caroline M. Loewy</u> Caroline M. Loewy	Director	March 30, 2020
<u>/s/ Alex C. Sapir</u> Alex C. Sapir	Director	March 30, 2020
<u>/s/ Richard A. van den Broek</u> Richard A. van den Broek	Director	March 30, 2020

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTIONS 5.3 AND 5.4 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

### WARRANT TO PURCHASE COMMON STOCK

**Company:** PHASEBIO PHARMACEUTICALS, INC.

**Number of Shares of Common Stock:** 2,200,000

**Exercisability:** 1,100,000 shares (the "**Tranche A Shares**") are exercisable at any time after the Effective Date (as defined in the Agreement (as defined below)) and 1,100,000 shares (the "**Tranche B Shares**") are exercisable at any time at the election of the Holder (the "**Tranche B Exercise Date**") after the earlier of (i) the date of Successful Phase 3 Interim Analysis (as defined in the Agreement) and (ii) the consummation of an Acquisition (as defined below).

**Warrant Price:** \$6.5049 per share

**Issue Date:** January 9, 2020

**Expiration Date:** January 9, 2020 See also Section 5.1(b).

**Co-Development Agreement:** This Warrant to Purchase Common Stock ("**Warrant**") is issued in connection with the certain Co-Development Agreement dated as of January 9, 2020 by and between SFJ Pharmaceuticals X, Ltd. and the Company (as the same may from time to time be amended, modified, supplemented or restated) (the "**Agreement**").

THIS WARRANT CERTIFIES THAT, for good and valuable consideration, SFJ PHARMACEUTICALS X, LTD. (together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, "**Holder**") is entitled to purchase the number of fully paid and non-assessable shares (the "**Shares**") of the above-stated common stock (the "**Common Stock**") of PHASEBIO PHARMACEUTICALS, INC. (the "**Company**") at the above-stated Warrant Price, which for the avoidance of doubt, shall be calculated in accordance with Section 8.1 of the Agreement (i.e., the per-share Warrant Price shall be equal to the greater of \$5.00 or 120% of the volume weighted average closing price of the Company's common stock over the thirty (30) consecutive trading days preceding the Effective Date, all as set forth above and as adjusted pursuant to Section 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant.

#### SECTION 1. EXERCISE.

1.1 Method of Exercise. Holder may at any time and from time to time through 6:00 PM, Pacific time, on the Expiration Date, exercise this Warrant, subject to the limitations set forth in the recitals above, in whole or in part, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 1.2, a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.

1.2 Cashless Exercise. On any exercise of this Warrant, in lieu of payment of the aggregate Warrant Price in the manner as specified in Section 1.1 above, but otherwise in accordance with the requirements of Section 1.1, Holder may elect to receive Shares equal to the value of this Warrant, or portion hereof as to which this Warrant is being exercised. Thereupon, the Company shall issue to the Holder such number of fully paid and non-assessable Shares as are computed using the following formula:

$$X = Y(A-B)/A$$

where:

X = the number of Shares to be issued to the Holder;

Y = the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Warrant Price);

A = the Fair Market Value (as determined pursuant to Section 1.3 below) of one Share; and

B = the Warrant Price.

1.3 Fair Market Value. If the Company's Common Stock is then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market (a "**Trading Market**"), the fair market value of a Share shall be the closing price or last sale price of a share of Common Stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company. If the Company's Common Stock is not traded in a Trading Market, the Board of Directors of the Company shall determine the fair market value of a Share in its reasonable good faith judgment.

1.4 Delivery of Certificate and New Warrant. Within a reasonable time after Holder exercises this Warrant in the manner set forth in Section 1.1 or 1.2 above, the Company shall deliver to Holder a certificate representing the Shares issued to Holder upon such exercise (which certificate may be in the form of an electronic certificate or DTC entry, to the extent used by the Company at the time of such exercise) and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired.

1.5 Replacement of Warrant. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form, substance and amount to the Company or, in the case of mutilation, on surrender of this Warrant to the Company for cancellation, the Company shall, within a reasonable time, execute and deliver to Holder, in lieu of this Warrant, a new warrant of like tenor and amount.

#### 1.6 Treatment of Warrant Upon Acquisition of Company.

(a) Acquisition. For the purpose of this Warrant, "**Acquisition**" means any transaction or series of related transactions involving: (i) the sale, lease, exclusive license, or other disposition of all or substantially all of the assets of the Company (ii) any merger or consolidation of the Company into or with another person or entity (other than a merger or consolidation effected exclusively to change the Company's domicile), or any other corporate reorganization, in which the stockholders of the Company in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the Company's (or the surviving or successor entity's) outstanding voting power immediately after such merger, consolidation or reorganization; or (iii) any sale or other transfer by the stockholders of the Company of shares representing at least a majority of the Company's then-total outstanding combined voting power.

(b) Treatment of Warrant at Acquisition. In the event of an Acquisition in which the consideration to be received by the Company's stockholders consists solely of cash, solely of Marketable Securities or a combination

of cash and Marketable Securities (a “**Cash/Public Acquisition**”), and the fair market value of one Share as determined in accordance with Section 1.3 above would be greater than the Warrant Price in effect on such date immediately prior to the closing of such Cash/Public Acquisition, and Holder has not exercised this Warrant pursuant to Section 1.1 above as to all Shares, then this Warrant shall automatically be deemed to be Cashless Exercised pursuant to Section 1.2 above as to all Shares effective immediately prior to and contingent upon the consummation of a Cash/Public Acquisition. In connection with such Cashless Exercise, Holder shall be deemed to have restated each of the representations and warranties in Section 4 of the Warrant as the date thereof and the Company shall promptly notify the Holder of the number of Shares (or such other securities) issued upon exercise. In the event of a Cash/Public Acquisition where the fair market value of one Share as determined in accordance with Section 1.3 above would be less than the Warrant Price in effect immediately prior to such Cash/Public Acquisition, then this Warrant will expire immediately prior to the consummation of such Cash/Public Acquisition. Notwithstanding the foregoing, in the event of an Acquisition in which the consideration to be received by the Company’s stockholders consists solely of Marketable Securities or a combination of cash and Marketable Securities and the fair market value of one Share as determined in accordance with Section 1.3 above would be less than or equal to 150% of the Warrant Price in effect on such date immediately prior to the closing of such Acquisition, then such Acquisition will not be deemed to be a Cash/Public Acquisition and the provisions of Section 1.6(c) below shall apply with respect to such Acquisition.

(c) Upon the closing of any Acquisition other than a Cash/Public Acquisition, the acquiring, surviving or successor entity shall assume the obligations of this Warrant, and this Warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on and as of the closing of such Acquisition, subject to further adjustment from time to time in accordance with the provisions of this Warrant.

(d) As used in this Warrant, “**Marketable Securities**” means securities meeting all of the following requirements: (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by Holder in connection with the Acquisition were Holder to exercise this Warrant on or prior to the closing thereof is then traded in a Trading Market, and (iii) following the closing of such Acquisition, Holder would not be restricted from publicly re-selling all of the issuer’s shares and/or other securities that would be received by Holder in such Acquisition were Holder to exercise or convert this Warrant in full on or prior to the closing of such Acquisition, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Acquisition.

1.7 Agreement Not to Sell Tranche A Shares. Holder, and any affiliate of Holder, will not offer, sell, contract to sell, pledge or otherwise dispose of, or enter into any transaction that is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise), directly or indirectly, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Exchange Act and the rules and regulations of the Securities and Exchange Commission promulgated thereunder with respect to the Tranche A Shares for a period of one (1) year from the Effective Date. For the avoidance of doubt, this Section 1.7 does not apply to the Tranche B Shares.

## SECTION 2. ADJUSTMENTS TO THE SHARES AND WARRANT PRICE.

2.1 Stock Dividends, Splits, Etc. If the Company declares or pays a dividend or distribution on the outstanding shares of the Common Stock payable in securities or property (other than cash), then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without additional cost to Holder, the total number and kind of securities and property which Holder would have received had Holder owned the Shares of record as of the date the dividend or distribution occurred. If the Company subdivides the outstanding shares of the Common Stock by reclassification or otherwise into a greater number of shares, the number of Shares purchasable hereunder shall be proportionately increased and the Warrant Price shall be proportionately decreased. If the outstanding shares of the Common Stock are combined or consolidated, by reclassification or otherwise, into a lesser number of shares, the

Warrant Price shall be proportionately increased and the number of Shares shall be proportionately decreased.

2.2 Reclassification, Exchange, Combinations or Substitution. Upon any event whereby all of the outstanding shares of the Common Stock are reclassified, exchanged, combined, substituted, or replaced for, into, with or by Company securities of a different class and/or series, then from and after the consummation of such event, this Warrant will be exercisable for the number, class and series of Company securities that Holder would have received had the Shares been outstanding on and as of the consummation of such event, and subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant. The provisions of this Section 2.2 shall similarly apply to successive reclassifications, exchanges, combinations substitutions, replacements or other similar events.

2.3 No Fractional Share. No fractional Share shall be issuable upon exercise of this Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of the Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash the amount computed by multiplying the fractional interest by (i) the fair market value (as determined in accordance with Section 1.3 above) of a full Share, less (ii) the then-effective Warrant Price.

2.4 Notice/Certificate as to Adjustments. Upon each adjustment of the Warrant Price, Common Stock and/or number of Shares, the Company, at the Company's expense, shall notify Holder in writing within a reasonable time setting forth the adjustments to the Warrant Price, class and/or number of Shares and facts upon which such adjustment is based. The Company shall, upon written request from Holder, furnish Holder with a certificate of its Chief Financial Officer, including computations of such adjustment and the Warrant Price, class and number of Shares in effect upon the date of such adjustment.

### SECTION 3. REPRESENTATIONS AND COVENANTS OF THE COMPANY.

3.1 Representations and Warranties. The Company represents and warrants to, and agrees with, the Holder that all Shares which may be issued upon the exercise of this Warrant, shall, upon issuance, be duly authorized, validly issued, fully paid and non-assessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under applicable federal and state securities laws. The Company covenants that it shall at all times cause to be reserved and kept available out of its authorized and unissued capital stock such number of securities as will be sufficient to permit the exercise in full of this Warrant.

3.2 Notice of Certain Events. If the Company proposes at any time to:

- (a) declare any dividend or distribution upon the outstanding shares of the Company's stock, whether in cash, property, stock, or other securities and whether or not a regular cash dividend;
- (b) offer for subscription or sale pro rata to the holders of the outstanding shares any additional shares of any class or series of the Company's stock (other than pursuant to contractual pre-emptive rights);
- (c) effect any reclassification, exchange, combination, substitution, reorganization or recapitalization of the outstanding shares of the Common Stock; or
- (d) effect an Acquisition or to liquidate, dissolve or wind up;

then, in connection with each such event, the Company shall give Holder notice thereof at the same time and in the same manner as given to holders of the outstanding shares of the Common Stock.

### SECTION 4. REPRESENTATIONS, WARRANTIES OF THE HOLDER.

The Holder represents and warrants to the Company as follows:

4.1 Purchase for Own Account. This Warrant and the Shares to be acquired upon exercise of this Warrant by Holder are being acquired for investment for Holder's account, not as a nominee or agent, and not with a view to the public resale or distribution within the meaning of the Act. Holder also represents that it has not been formed for the specific purpose of acquiring this Warrant or the Shares.

4.2 Disclosure of Information. Holder is aware of the Company's business affairs and financial condition and has received or has had full access to all the information it considers necessary or appropriate to make an informed investment decision with respect to the acquisition of this Warrant and its underlying securities. Holder further has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of this Warrant and its underlying securities and to obtain additional information (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) necessary to verify any information furnished to Holder or to which Holder has access.

4.3 Investment Experience. Holder understands that the purchase of this Warrant and its underlying securities involves substantial risk. Holder has experience as an investor in securities of companies in the development stage and acknowledges that Holder can bear the economic risk of such Holder's investment in this Warrant and its underlying securities and has such knowledge and experience in financial or business matters that Holder is capable of evaluating the merits and risks of its investment in this Warrant and its underlying securities and/or has a preexisting personal or business relationship with the Company and certain of its officers, directors or controlling persons of a nature and duration that enables Holder to be aware of the character, business acumen and financial circumstances of such persons.

4.4 Accredited Investor Status. Holder is an "accredited investor" within the meaning of Regulation D promulgated under the Act.

4.5 The Act. Holder understands that this Warrant and the Shares issuable upon exercise hereof have not been registered under the Act in reliance upon a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of the Holder's investment intent and the accuracy of the Holder's representations and warranties as expressed herein. Holder understands that this Warrant and the Shares issued upon any exercise hereof must be held indefinitely unless subsequently registered under the Act and qualified under applicable state securities laws, or unless exemption from such registration and qualification are otherwise available. Holder is aware of the provisions of Rule 144 promulgated under the Act.

4.6 No Shareholder Rights. Without limiting any provision of this Warrant, Holder agrees that as a Holder of this Warrant it will not have any rights (including, but not limited to, voting rights) as a shareholder of the Company with respect to the Shares issuable hereunder unless and until the exercise of this Warrant and then only with respect to the Shares issued on such exercise.

## SECTION 5. MISCELLANEOUS.

### 5.1 Term and Automatic Cashless Exercise Upon Expiration.

(a) Term. Subject to the provisions of Section 1.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Pacific time, on the Expiration Date and shall be void thereafter.

(b) Automatic Cashless Exercise upon Expiration. In the event that, upon the Expiration Date, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above is greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall, within a reasonable time, cause its transfer agent and registrar to register in book-entry form, or to deliver to the Holder a certificate representing, the Shares (or such other securities) issued upon such exercise to Holder (which certificate may be in the form of an electronic certificate or DTC entry, to the extent used by the Company at the time of such exercise).

5.2 Legends. The Shares shall be imprinted with a legend in substantially the following form:

THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “**ACT**”), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE COMMON STOCK ISSUED BY THE ISSUER TO SILICON VALLEY BANK DATED MAY 30, 2019, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

5.3 Compliance with Securities Laws on Transfer. This Warrant and the Shares issuable upon exercise of this Warrant may not be transferred or assigned in whole or in part except in compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the Company). The Company shall not require Holder to provide an opinion of counsel if the transfer is to any affiliate of Holder, provided that any such transferee is an “accredited investor” as defined in Regulation D promulgated under the Act. Additionally, the Company shall also not require an opinion of counsel if there is no material question as to the availability of Rule 144 promulgated under the Act.

5.4 Transfer Procedure. The Holder shall not transfer any portion of this Warrant to a direct competitor of the Company or a vulture fund, in each case as reasonably determined by the Holder, without the Company’s consent, other than in connection with (x) assignments by the Holder due to a forced divestiture at the request of any regulatory agency, or (y) upon the occurrence of a default, event of default or similar occurrence with respect to the Holder’s own financing or securitization transactions.

5.5 Notices. All notices and other communications hereunder from the Company to the Holder, or vice versa, shall be deemed delivered and effective (i) when given personally, (ii) on the third (3rd) Business Day after being mailed by first-class registered or certified mail, postage prepaid, (iii) upon actual receipt if given by facsimile or electronic mail and such receipt is confirmed in writing by the recipient, or (iv) on the first Business Day following delivery to a reliable overnight courier service, courier fee prepaid, in any case at such address as may have been furnished to the Company or Holder, as the case may be, in writing by the Company or such Holder from time to time in accordance with the provisions of this Section 5.5. All notices to Holder shall be addressed as follows until the Company receives notice of a change of address in connection with a transfer or otherwise:

SFJ PHARMACEUTICALS X, LTD.  
SIX, 2nd Floor, Cricket Square  
PO Box 2681  
Grand Cayman, KY1-1111  
Cayman Islands  
Attn: Robert DeBenedetto  
Email: robert.debenedetto@sfj-pharma.com

With a copy (which shall not constitute notice) to:

Morrison & Foerster LLP  
Attn: Michael J. O'Donnell  
755 Page Mill Rd.  
Palo Alto, CA 94304  
Telephone: (650) 813-5977

Fax: (650) 251-3529  
Email: MichaelODonnell@mofo.com

Notice to the Company shall be addressed as follows until Holder receives notice of a change in address:

PHASEBIO PHARMACEUTICALS, INC.  
1 Great Valley Parkway, Suite 30  
Malvern, PA 19355  
Attn: Jonathan Mow, CEO  
Email: jonathan.mow@phasebio.com

With a copy (which shall not constitute notice) to:

COOLEY LLP  
Attn: Christian Plaza  
11951 Freedom Drive, 14<sup>th</sup> Floor Reston, VA 20190  
Telephone: (703) 456-8006  
Fax: (703) 456-8100  
Email: cplaza@cooley.com

5.6 Waiver. This Warrant and any term hereof may be changed, waived, discharged or terminated (either generally or in a particular instance and either retroactively or prospectively) only by an instrument in writing signed by the party against which enforcement of such change, waiver, discharge or termination is sought.

5.7 Attorney's Fees. In the event of any dispute between the parties concerning the terms and provisions of this Warrant, the party prevailing in such dispute shall be entitled to collect from the other party all costs incurred in such dispute, including reasonable attorneys' fees.

5.8 Counterparts; Facsimile/Electronic Signatures. This Warrant may be executed in counterparts, all of which together shall constitute one and the same agreement. Any signature page delivered electronically or by facsimile shall be binding to the same extent as an original signature page with regards to any agreement subject to the terms hereof or any amendment thereto.

5.9 Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of California, without giving effect to its principles regarding conflicts of law.

5.10 Headings. The headings in this Warrant are for purposes of reference only and shall not limit or otherwise affect the meaning of any provision of this Warrant.

5.11 Business Days. "**Business Day**" is any day that is not a Saturday, Sunday or a U.S. federal holiday.

***[Balance of Page Intentionally Left Blank]***



IN WITNESS WHEREOF, the parties have caused this Warrant to Purchase Common Stock to be executed by their duly authorized representatives effective as of the Issue Date written above.

"COMPANY"

**PHASEBIO PHARMACEUTICALS, INC.**

By: /s/ Jonathan Mow

Name: Jonathan Mow

Title: CEO

"HOLDER"

**SFJ PHARMACEUTICALS X, LTD.**

By: /s/ Robert DeBenedetto

Name: Robert DeBenedetto

Title: Director

*[Signature Page to Warrant to Purchase Common Stock]*

APPENDIX 1

NOTICE OF EXERCISE

1. The undersigned Holder hereby exercises its right to purchase \_\_\_\_\_ shares of the Common Stock of **PHASEBIO PHARMACEUTICALS, INC.** (the “**Company**”) in accordance with the attached Warrant To Purchase Common Stock, and tenders payment of the aggregate Warrant Price for such shares as follows:

check in the amount of \$\_\_\_\_\_ payable to order of the Company enclosed herewith

Wire transfer of immediately available funds to the Company’s account

Cashless Exercise pursuant to Section 1.2 of the Warrant

Other [Describe] \_\_\_\_\_

2. Please issue a certificate or certificates representing the Shares in the name specified below:

\_\_\_\_\_  
Holder’s Name  
\_\_\_\_\_  
\_\_\_\_\_  
(Address)

3. By its execution below and for the benefit of the Company, Holder hereby restates each of the representations and warranties in Section 4 of the Warrant to Purchase Common Stock as of the date hereof.

SFJ PHARMACEUTICALS X, LTD.

By:\_\_\_\_\_

Name:\_\_\_\_\_

Title:\_\_\_\_\_

(Date):\_\_\_\_\_

**DESCRIPTION OF PHASEBIO PHARMACEUTICALS, INC. COMMON STOCK**

The following description of the common stock of PhaseBio Pharmaceuticals, Inc., or the Company, is a summary and does not purport to be complete. This summary is qualified in its entirety by reference to the provisions of the Delaware General Corporation Law, or the DGCL, and the complete text of the Company's amended and restated certificate of incorporation, or certificate of incorporation, and amended and restated bylaws, or the bylaws, which are incorporated by reference as Exhibits 3.1 and 3.2, respectively, of the Company's Annual Report on Form 10-K to which this description is also an exhibit. The Company encourages you to read that law and those documents carefully.

**Common Stock*****Authorized Capital Stock***

The certificate of incorporation authorizes the issuance of up to 200,000,000 shares of common stock, \$0.001 par value per share, and 10,000,000 shares of preferred stock, \$0.001 par value per share. The Company's board of directors may establish the rights and preferences of the preferred stock from time to time.

***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. Under the certificate of incorporation and bylaws, common stockholders do not have cumulative voting rights. Because of this, the holders of a majority 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.

***Dividends***

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

***Liquidation***

In the event of the Company's liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of 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 common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the right of the holders of shares of any series of preferred stock that the Company may designate in the future.

**Anti-Takeover Provisions*****Section 203 of the Delaware General Corporation Law***

The Company is subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder

became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) 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
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66  $\frac{2}{3}$ % of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a business combination to include the following:

- any merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder (in one transaction or a series of transactions);
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or of such subsidiary to the interested stockholder;
- any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

#### ***Anti-Takeover Effects of Certain Provisions of the Certificate of Incorporation and Bylaws***

The certificate of incorporation provides for the Company's board of directors to 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. Because the Company's stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of common stock outstanding will be able to elect all of the Company's directors. The certificate of incorporation and bylaws also provide that directors may be removed by the stockholders only for cause upon the vote of 66  $\frac{2}{3}$ % or more of the Company's outstanding common stock. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

The certificate and incorporation and bylaws also provide that all stockholder actions must be effected at a duly called meeting of stockholders and will eliminate the right of stockholders to act by written consent without a meeting. The Company's bylaws also provide that only the Chairman of the board, Chief Executive Officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

The bylaws also provide that stockholders seeking to present proposals before the meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and specifies requirements as to the form and content of a stockholder's notice.

The certificate of incorporation and bylaws provide that the stockholders cannot amend many of the provisions described above except by a vote of 66 ⅔% or more of the Company's outstanding common stock.

The combination of these provisions could make it more difficult for the Company's existing stockholders to replace the board of directors as well as for another party to obtain control of the Company by replacing the board of directors. Since the board of directors has the power to retain and discharge the Company's officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for the board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change the Company's control.

These provisions are intended to enhance the likelihood of continued stability in the composition of the board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce the Company's vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for the Company's shares and may have the effect of delaying changes in control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of the Company's stock that could result from actual or rumored takeover attempts. The Company believes that the benefits of these provisions, including increased protection of its potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure the Company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

### **Choice of Forum**

The certificate of incorporation provides that the Court of Chancery of the state of Delaware will be the exclusive forum for:

- any derivative action or proceeding brought on the Company's behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising pursuant to the DGCL, the Company's certificate of incorporation or the bylaws; or
- any action asserting a claim against the Company that is governed by the internal affairs doctrine.

The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in the Company's certificate of incorporation to be inapplicable or unenforceable in such action.

The Company's certificate of incorporation provides 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 of 1933, as amended. Recently, the Court of Chancery of the State of Delaware issued an opinion invalidating the federal district court exclusive forum provision. In light of that recent decision, the Company will not attempt to enforce this provision of its certificate to the extent it is not permitted by applicable law. However, if the decision is reviewed on appeal and ultimately overturned by the Delaware Supreme Court, the Company would enforce the federal district court exclusive forum provision.

### **Transfer Agent and Registrar**

The transfer agent and registrar for the Company's common stock is Computershare Trust Company, N.A. The transfer agent's address is 250 Royall Street, Canton, Massachusetts 02021.

### **Stock Exchange Listing**

The common stock is listed on The Nasdaq Global Market under the trading symbol "PHAS."

**AMENDMENT TO LICENSE AGREEMENT  
BETWEEN MEDIMMUNE LIMITED AND PHASEBIO PHARMACEUTICALS, INC.**

This Amendment to License Agreement (“**Amendment**”) is made and entered into as of January 9, 2020 (the “**Amendment Date**”), by and between MedImmune Limited, a limited liability company formed under the laws of the United Kingdom (“**MedImmune**”), and PhaseBio Pharmaceuticals, Inc., a corporation formed under the laws of the State of Delaware (“**Licensee**”). SFJ (as defined below) shall be deemed to be a party to this Amendment for the purposes of paragraphs 3(a) and 6 hereof.

**Recitals**

**WHEREAS**, MedImmune and Licensee are parties to that certain License Agreement dated November 21, 2017 (the “**License Agreement**”), pursuant to which MedImmune granted to Licensee a license under certain intellectual property rights owned or controlled by MedImmune to develop and commercialize Licensed Products in the Field in the Territory in accordance with the terms and conditions set forth in the License Agreement;

**WHEREAS**, Licensee and SFJ Pharmaceuticals X, Ltd., an SFJ Pharmaceuticals® company and corporation organized and existing under the laws of the Cayman Islands (“**SFJ**”), propose to enter into a Co-Development Agreement in substantially the form provided by Licensee to MedImmune on December 12, 2019 (the “**Co-Development Agreement**”), pursuant to which, among other things, SFJ would provide operational support to Licensee for the conduct of clinical trials of Licensed Products in Europe, would conduct clinical trials of Licensed Products in China, Japan and Hong Kong, and would provide global financing to Licensee for the continued development of Licensed Products; and

**WHEREAS**, as a condition to entering into the Co-Development Agreement, SFJ requires certain assurances from MedImmune regarding the License Agreement, including, among other things:

- (i) MedImmune’s consent to Licensee’s assignment of the License Agreement to SFJ under certain circumstances specified in the Co-Development Agreement; and
- (ii) MedImmune’s agreement to certain amendments to the License Agreement;

in each case, on the terms and subject to the conditions set forth in this Amendment.

**NOW, THEREFORE**, in consideration of the premises and the mutual promises and conditions set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

**1. Defined Terms.** Capitalized terms used but not otherwise defined in this Amendment have the meanings ascribed to such terms in the License Agreement.

**2. Ownership of Trial Data Package.** Notwithstanding the provisions of Sections 5.1.6(a)(ii) and 5.1.6(b) of the License Agreement, MedImmune hereby consents to SFJ's ownership of the "Trial Data Package" (as such term is defined in the Co-Development Agreement) during the applicable period specified in Section 11.1.1.4 of the Co-Development Agreement, subject to SFJ's acknowledgment and agreement (as evidenced by its signature of this Amendment).

**3. Consent to Assignment of License Agreement to SFJ.**

(a) MedImmune hereby consents, pursuant to Section 10.3 of the License Agreement, to the assignment by Licensee to SFJ of the License Agreement and all of Licensee's rights and obligations thereunder under the circumstances set forth in, and subject to the terms and conditions of, Section 3.20 of the Co-Development Agreement and in the form of Program Transfer Agreement attached to the Co-Development Agreement as Exhibit O (the "**Form of Program Transfer Agreement**").

(b) Notwithstanding the provisions of Sections 9.2.1(a), 9.2.1(b) and 9.2.2 of the License Agreement, if MedImmune becomes, or believes in good faith that it is, entitled to terminate the License Agreement pursuant to Section 9.2.1(a), 9.2.1(b) or Section 9.2.2 thereof, MedImmune shall, prior to delivering any notice of termination of the License Agreement to Licensee, deliver written notice of such entitlement to SFJ (with a copy to Licensee), specifying the applicable Section of the License Agreement under which MedImmune is, or believes it is, entitled to terminate the License Agreement (a "**Termination Entitlement Notice**"). In such event, SFJ shall have the right, exercisable by written notice to MedImmune and Licensee within thirty (30) days after delivery of such Termination Entitlement Notice, to cause the "Program Transfer" (as such term is defined in the Form of Program Transfer Agreement) to become immediately effective, and upon delivery of such notice to MedImmune, MedImmune shall not have the right to so terminate the License Agreement and MedImmune shall be deemed to have consented to the assignment by Licensee to SFJ of the License Agreement and all of Licensee's rights and obligations thereunder as part of such Program Transfer, *provided* that:

(i) in the case of MedImmune's entitlement, or claimed entitlement, to terminate the License Agreement pursuant to Section 9.2.1(a) thereof, SFJ cures the applicable material breach of the License Agreement by Licensee within ninety (90) days (or thirty (30) days in the case of a payment default) after delivery of such Termination Entitlement Notice, subject to Section 9.2.1(c) of the License Agreement;

(ii) in the case of MedImmune's entitlement, or claimed entitlement, to terminate the License Agreement pursuant to Section 9.2.1(b) thereof, SFJ and MedImmune shall meet within thirty (30) days after delivery of such Termination Entitlement Notice, and the provisions of Section 9.2.1(b) shall apply, *mutatis mutandis* (with SFJ having the right to cure the breach specified in the Section 9.2.1(b) Termination Notice during the Section 9.2.1(b) Notice Period, *mutatis mutandis*), subject to Section 9.2.1(c) of the License Agreement; and

(iii) in the case of MedImmune's entitlement, or claimed entitlement, to terminate the License Agreement pursuant to Section 9.2.2 thereof, such assignment to SFJ shall not become effective if MedImmune would have been entitled to terminate the License Agreement pursuant to



Section 9.2.2 thereof had SFJ, rather than Licensee, been a Party to the License Agreement as of the date of the Termination Entitlement Notice.

(c) In the event of assignment of the License Agreement to SFJ in accordance with paragraph 3(a) or 3(b) of this Amendment, Section 10.3.1(a) of the License Agreement shall not apply to any information, materials and intellectual property rights owned by SFJ or its Affiliates that arose out of the development, manufacture or commercialization of Licensed Compounds or Licensed Products by or on behalf of SFJ or its Affiliates pursuant to the Co-Development Agreement prior to such assignment.

**4. Affiliate.** MedImmune acknowledges that SFJ is supported by Blackstone Life Sciences, a division of private-equity and financial-services firm The Blackstone Group Inc. (“**Blackstone**”). MedImmune hereby agrees that, notwithstanding Blackstone Life Sciences’ support of SFJ, neither Blackstone nor any of its divisions, including Blackstone Life Sciences, shall be considered an Affiliate of SFJ for purposes of:

(a) the Co-Development Agreement, including Section 3.19 of the Co-Development Agreement; or

(b) in the event that the License Agreement and Licensee’s rights and obligations thereunder are assigned to SFJ in accordance with paragraph 3(a) or paragraph 3(b) of this Amendment, the License Agreement, including Section 2.5.2 of the License Agreement.

**5. Notice.** Any notice permitted or required under this Amendment shall be made in accordance with Section 10.9 of the License Agreement, for which purpose notices to SFJ shall be addressed as follows:

SFJ Pharmaceuticals X, Ltd  
SIX, 2nd Floor, Cricket Square  
PO Box 2681  
Grand Cayman, KY1-1111  
Cayman Islands  
Attention: Robert DeBenedetto

with a copy (which shall not constitute notice) to:

Morrison & Foerster LLP  
755 Page Mill Road  
Palo Alto, CA 94304-1018  
United States  
Attention: Michael O’Donnell

**6. Intended Third Party Beneficiary.** The Parties agree that SFJ (including, for purposes of this Amendment, SFJ’s permitted successor to or assignee of the Co-Development Agreement) is an intended third party beneficiary of this Amendment, and this Amendment may not be modified, amended, waived or terminated without the consent of SFJ in its sole discretion.

**7. Effectiveness of Amendment.** In the event that Licensee and SFJ have not entered into the Co-Development Agreement by January 31, 2020, this Amendment shall be deemed null and void *ab initio*. In the event that Licensee and SFJ have entered into the Co-Development Agreement by January 31, 2020, then, at such time as Licensee has fulfilled all payment obligations to SFJ under the Co-Development Agreement, and provided the License Agreement was not previously assigned to SFJ, this Amendment shall terminate and be of no further force or effect. Licensee agrees to provide MedImmune with prompt written notice of the fulfillment of all payment obligations of Licensee to SFJ under the Co-Development Agreement if the License Agreement has not been assigned to SFJ prior to such time.

**8. Effectiveness of License Agreement.** Except as expressly amended by this Amendment, the License Agreement shall remain in full force and effect in accordance with its terms.

**9. Counterparts.** This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Amendment may be executed by facsimile, PDF format via email, or other electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were original signatures.

[SIGNATURE PAGE FOLLOWS.]

THIS AMENDMENT IS EXECUTED by the authorized representatives of the Parties as of the Amendment Date.

**MEDIMMUNE LIMITED**

**PHASEBIO PHARMACEUTICALS, INC.**

By: /s/ Greg Mueller

By: /s/ Jonathan Mow

Name: Greg Mueller

Name: Jonathan Mow

Title: Authorized Signatory

Title: CEO

*Acknowledged and agreed:*

**SFJ PHARMACEUTICALS X, LTD.**

By: /s/ Robert DeBenedetto

Robert DeBenedetto  
Director

[SIGNATURE PAGE TO AMENDMENT TO LICENSE AGREEMENT]

**CONSENT AND FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT**

THIS **CONSENT AND FIRST AMENDMENT** to Loan and Security Agreement (this “**Amendment**”) is entered into as of March 19, 2020, by and among (a) **SILICON VALLEY BANK**, a California corporation (“**SVB**” or “**Bank**”), in its capacity as administrative agent and collateral agent (“**Agent**”), (b) **SVB** as a lender, (c) **WESTRIVER INNOVATION LENDING FUND VIII, L.P.**, a Delaware limited partnership (“**WestRiver**”), as a lender (SVB and WestRiver and each of the other “**Lenders**” from time to time a party hereto are referred to herein collectively as the “**Lenders**” and each individually as a “**Lender**”), and (d) **PHASEBIO PHARMACEUTICALS, INC.**, a Delaware corporation (“**Borrower**”), whose address is 1 Great Valley Parkway, Suite 30, Malvern, PA 19355.

**Recitals**

**A.** Lenders and Borrower have entered into that certain Loan and Security Agreement dated as of March 25, 2019 (as the same may from time to time be amended, modified, supplemented, or restated, including, without limitation, by that certain Consent to Loan and Security Agreement dated as of April 10, 2019, collectively, the “**Loan Agreement**”). Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

**B.** Borrower has requested that Lenders amend the Loan Agreement to (i) modify the Collateral description and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein.

**C.** Lenders have agreed to so amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

**D.** In addition, Borrower has agreed (i) to transfer to SFJ, pursuant to the terms of the Co-Development Agreement, certain business related to Borrower’s product containing PB2452 that is described in Exhibit A to the Co-Development Agreement, and (ii) to grant to SFJ a security interest in certain assets of the Borrower, pursuant to the Co-Development Agreement.

**E.** Section 7.1 of the Loan Agreement provides that Borrower shall not convey, sell, lease, transfer, assign, or otherwise dispose of all or any part of its business or property without the prior written consent of the Lenders.

**F.** Section 7.5 of the Loan Agreement provides that Borrower shall not create, incur, allow, or suffer any Lien on any of its property, except as is otherwise permitted in Section 7.1 of the Loan Agreement and the definition of “Permitted Liens” therein, without the prior written consent of the Lenders.

**G.** Borrower has requested that Lenders agree to waive the provisions of Sections 7.1 and 7.5 of the Loan Agreement with respect to Borrower’s entry into and performance of the Co-Development Agreement.

**H.** Lenders have agreed to so consent to Borrower’s entry into the Co-Development Agreement and the consummation of the transactions contemplated thereby, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

**Agreement**

**Now, Therefore**, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

**1. Definitions.** Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. **Consent.** Subject to the terms of Section 9 below, Lenders hereby consent to Borrower's entry into the Co-Development Agreement and the consummation of the transactions contemplated thereby, notwithstanding anything to the contrary contained in the Financing Agreement or any other Loan Document.

3. **Amendments to Loan Agreement.**

3.1 **Section 4.4 (Pledge of Account).** New Section 4.4 hereby is added to the Loan Agreement to read as follows:

**"4.4 Pledge of Account.** At all times following the date that (a) the Co-Development Agreement is terminated for any reason or (b) Borrower breaches or is in default of the Co-Development Agreement for any reason (after giving effect to any applicable grace periods provided in the Co-Development Agreement), Borrower hereby pledges and grants to Agent, for the ratable benefit of the Lenders, a security interest in the Pledged Account and agrees to take such actions as Agent shall reasonably request in connection with the Pledge Agreement, including, but not limited to, establishment of the Pledged Account containing at all times an amount of unrestricted cash equal to at least the aggregate outstanding balance of all of the Obligations as security for the prompt payment of such Obligations."

3.2 **Section 6.7 (Protection of Intellectual Property Rights).** Section 6.7 of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

**"6.7 Protection and Registration of Intellectual Property Rights.**

(a) (i) Protect, defend and maintain the validity and enforceability of its Intellectual Property; (ii) promptly advise Agent in writing of material infringements or any other event that could reasonably be expected to materially and adversely affect the value of its Intellectual Property; and (iii) not allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without Agent's written consent.

(b) If Borrower (i) obtains any Patent, registered Trademark, registered Copyright, registered mask work, or any pending application for any of the foregoing, whether as owner, licensee or otherwise, or (ii) applies for any Patent or the registration of any Trademark, then Borrower shall immediately provide written notice thereof to Agent and shall execute such intellectual property security agreements and other documents and take such other actions as Agent may request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Lenders in such property. If Borrower decides to register any Copyrights or mask works in the United States Copyright Office, Borrower shall: (x) provide Agent with at least fifteen (15) days prior written notice of Borrower's intent to register such Copyrights or mask works together with a copy of the application it intends to file with the United States Copyright Office (excluding exhibits thereto); (y) execute an intellectual property security agreement and such other documents and take such other actions as Agent may request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Lenders in the Copyrights or mask works intended to be registered with the United States Copyright Office; and (z) record such intellectual property security agreement with the United States Copyright Office contemporaneously with filing the Copyright or mask work application(s) with the United States Copyright Office. Borrower shall promptly provide to Agent copies of all applications that it files for Patents or for the registration of Trademarks, Copyrights or mask works, together with evidence of the recording of the intellectual property security agreement required for Lenders to perfect and maintain a first priority perfected security interest in such property.

(c) Provide written notice to Agent within ten (10) days of entering or becoming bound by any Restricted License (other than over-the-counter software that is commercially available to the public). Borrower shall take such steps as Agent requests to obtain the consent of, or waiver by, any person whose consent or waiver is necessary for (i) any Restricted License to be deemed

“Collateral” and for Agent to have a security interest in it that might otherwise be restricted or prohibited by law or by the terms of any such Restricted License, whether now existing or entered into in the future, and (ii) Agent to have the ability in the event of a liquidation of any Collateral to dispose of such Collateral in accordance with Agent’s and Lenders’ rights and remedies under this Agreement and the other Loan Documents.”

**3.3 Section 14 (Definitions).** The following terms and their respective definitions hereby are added or amended and restated in their entirety in Section 14.1 of the Loan Agreement, as appropriate, to read as follows:

“**Co-Development Agreement**” means that certain Co-Development Agreement dated as of January 9, 2020, by and between Borrower and SFJ, as amended, modified, supplemented, and/or restated from time to time.

“**First Amendment Effective Date**” is March 19, 2020.

“**IP Agreement**” is that certain Intellectual Property Security Agreement by and among Borrower, SVB as administrative agent and collateral agent, SVB as a lender, and WestRiver as a lender dated as of the First Amendment Effective Date, as may be amended, modified or restated from time to time.

“**Loan Documents**” are, collectively, this Agreement and any schedules, exhibits, certificates, notices, and any other documents related to this Agreement, the Warrants, the IP Agreement, the Perfection Certificate, each Disbursement Letter, the Lender Intercreditor Agreement, any Bank Services Agreement, any Control Agreement, any subordination agreement, any note, or notes or guaranties executed by Borrower, and any other present or future agreement by Borrower with or for the benefit of Agent and the Lenders in connection with this Agreement or Bank Services, all as amended, restated, or otherwise modified.

“**Pledge Agreement**” means that certain Bank Services Cash Pledge Agreement together with Annex I attached thereto executed by Borrower in favor of Bank on or about the First Amendment Effective Date.

“**Pledged Account**” means Borrower’s restricted account number xxx-xxxx-179 held at Bank.

“**SFJ**” means SFJ Pharmaceuticals X, Ltd., an SFJ Pharmaceuticals Group company and corporation organized and existing under the laws of the Cayman Islands, having its principal place of business at SIX, 2nd Floor, Cricket Square PO Box 2681, Grand Cayman, KY1-1111 Cayman Islands.

**3.4 Exhibit A (Collateral Description).** Exhibit A to the Loan Agreement hereby is replaced with Exhibit A attached hereto.

#### **4. Limitation of Consent and Amendment.**

**4.1** This Amendment is effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Lenders may now have or may have in the future under or in connection with any Loan Document.

**4.2** This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

5. **Representations and Warranties.** To induce Lenders to enter into this Amendment, Borrower hereby represents and warrants to Lenders as follows:

5.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

5.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

5.3 The organizational documents of Borrower delivered to Agent on the Effective Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

5.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

5.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

5.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and

5.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

6. **Ratification of Intellectual Property Security Agreement.** Borrower hereby ratifies, confirms, and reaffirms, all and singular, the terms and conditions of the IP Security Agreement and acknowledges, confirms, and agrees that said IP Security Agreement (a) contains an accurate and complete listing of all Intellectual Property Collateral (as defined therein) and (b) shall remain in full force and effect.

7. **Ratification of Perfection Certificate.** Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and disclosures contained in a certain Perfection Certificate dated on or prior to the Effective Date and acknowledges, confirms and agrees that the disclosures and information Borrower provided to Agent in such Perfection Certificate have not changed, as of the date hereof.

8. **Counterparts.** This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

9. **Effectiveness.** This Amendment shall be deemed effective upon (a) the due execution and delivery to Agent of (i) this Amendment by each party hereto, (ii) an updated Corporate Borrowing Certificate from Borrower in the form satisfactory to Agent, (iii) the IP Security Agreement, and (iv) a subordination agreement, in form satisfactory to Agent, duly executed by SFJ, (b) filing of a UCC-3 financing statement amendment, prepared in connection with

the amended Collateral description, and (c) Borrower's payment to Lenders of all Lenders' Expenses due and owing as of the date hereof, which may be debited from any of Borrower's accounts at SVB.

**10. Post-Closing Condition.** As soon as possible, but no later than April 19, 2020, Borrower shall deliver to Bank the Pledge Agreement, duly executed by Borrower.

***[Balance of Page Intentionally Left Blank]***



**In Witness Whereof**, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

BORROWER:

**PHASEBIO PHARMACEUTICALS, INC.**

By: /s/ Jonathan Mow

Name: Jonathan Mow

Title: Chief Executive Officer

***[Signature Page to Consent and First Amendment to Loan and Security Agreement]***

**In Witness Whereof**, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

AGENT:

**SILICON VALLEY BANK**, as Agent

By: /s/ Thomas F. Gordon

Name: Thomas F. Gordon

Title: Managing Director

LENDER:

**SILICON VALLEY BANK**, as Lender

By: /s/ Thomas F. Gordon

Name: Thomas F. Gordon

Title: Managing Director

***[Signature Page to Consent and First Amendment to Loan and Security Agreement]***

**In Witness Whereof**, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

LENDER:

**WESTRIVER INNOVATION LENDING FUND VIII, L.P.**

By: /s/ Trent Dawson

Name: Trent Dawson

Title: Chief Financial Officer

*[Signature Page to Consent and First Amendment to Loan and Security Agreement]*

## **EXHIBIT A**

### **COLLATERAL DESCRIPTION**

The Collateral consists of all of Borrower's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles, Intellectual Property, commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts, certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

all Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

**CORPORATE BORROWING CERTIFICATE**

**Borrower:** PHASEBIO PHARMACEUTICALS, INC.  
**Lenders:** SILICON VALLEY BANK ("Bank") and  
 WESTRIVER INNOVATION LENDING FUND VIII, L.P.

**Date:** March \_\_, 2020

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.
2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.
3. Attached hereto are true, correct and complete copies of Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth above. Such Certificate of Incorporation have not been amended, annulled, rescinded, revoked or supplemented, and remain in full force and effect as of the date hereof.
4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until the Lenders receive written notice of revocation from Borrower.

**Resolved**, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

<u>Name</u>	<u>Title</u>	<u>Signature</u>	Authorized to Add or Remove <u>Signatories</u>
			0
			0
			0
			0

**Resolved Further**, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

**Resolved Further**, that such individuals may, on behalf of Borrower:

- Borrow Money.** Borrow money from Lenders.
- Execute Loan Documents.** Execute any loan documents the Lenders require.
- Grant Security.** Grant the Lenders a security interest in any of Borrower's assets.
- Negotiate Items.** Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.
- Apply for Letters of Credit.** Apply for letters of credit from Bank.
- Enter Derivative Transactions.** Execute spot or forward foreign exchange contracts, interest rate swap

agreements, or other derivative transactions with Bank.

**Issue Warrants.** Issue warrants for Borrower's capital stock.

**Further Acts.** Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effect these resolutions.

**Resolved Further,** that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

**PHASEBIO PHARMACEUTICALS, INC.**

By:

Name:

Title:

*\*\*\* If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the \_\_\_\_\_ of Borrower, hereby certify as to paragraphs 1 through 5 above, as of the date set forth above.

By:

Name:

Title:

## SUBORDINATION AGREEMENT

**THIS SUBORDINATION AGREEMENT** (as may be amended, modified, restated, amended and restated, replaced or supplemented from time to time, this “**Agreement**”), is entered into as of March 19, 2020 (the “**Effective Date**”), by and between **SILICON VALLEY BANK**, a California corporation, in its capacity as administrative agent and collateral agent (“**Senior Agent**”) under the Senior Creditor Agreement (as defined below), **SILICON VALLEY BANK**, a California corporation (“**SVB**”) in its capacity as a lender under the Senior Creditor Agreement (as defined below), **WESTRIVER INNOVATION LENDING FUND VIII, L.P.**, a Delaware limited partnership (“**WestRiver**”), in its capacity as a lender under the Senior Creditor Agreement (as defined below) (SVB and WestRiver in such capacities and each of the other “**Lenders**” from time to time a party to the Senior Creditor Agreement (as defined below) are referred to herein collectively as the “**Senior Creditors**” and each individually as a “**Senior Creditor**”), and **SFJ PHARMACEUTICALS X, LTD.**, an exempted company incorporated with limited liability under the laws of the Cayman Islands (“**Subordinated Creditor**”). Capitalized terms used but not otherwise defined herein shall have the meanings given them in Section 1(a) below.

### RECITALS

A. **PHASEBIO PHARMACEUTICALS, INC.**, a Delaware corporation (“**Borrower**”), is indebted to Senior Creditors pursuant to that certain Loan and Security Agreement dated March 25, 2019 (as may be amended, modified, restated, amended and restated, replaced or supplemented from time to time, the “**Senior Creditor Agreement**”), by and between Borrower, Senior Agent and Senior Creditors. The funds advanced to or owed by Borrower under the Senior Creditor Agreement shall be referred to collectively herein as the “**Senior Loans**.” To secure the Senior Debt (as defined below), Borrower granted to Senior Agent, for the benefit of Senior Creditors, a security interest in the Senior Collateral (as defined below).

B. Borrower has entered into certain Subordinated Loan Documents with Subordinated Creditor which are secured by the Subordinated Collateral (described below).

C. Subordinated Creditor and Borrower desire to obtain Senior Creditors’ consent to Borrower’s execution and performance of the Subordinated Loan Documents and the Borrower’s granting of Liens in the Subordinated Collateral, and Subordinated Creditor and each Senior Creditor desire to agree to, and to set forth, their respective rights, priorities and interests governing their respective relationships with Borrower and the collateral for the obligations owing pursuant to the Subordinated Loan Documents and the Senior Loan Documents, respectively, at all times on and after the Effective Date.

### AGREEMENT

NOW, THEREFORE, in consideration of the mutual agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Subordinated Creditor, Senior Agent and each Senior Creditor hereby agree as follows:

#### 1. DEFINITIONS; EFFECTIVENESS

(a) **DEFINITIONS.** As used herein, the following terms shall have the following meanings:

“**Bank Services**” is defined in the Senior Creditor Agreement.

“**Collateral**” means the Senior Collateral and the Subordinated Collateral.

**“Discharge”** means indefeasible payment in full of the Senior Debt (other than contingent indemnity obligations in connection therewith) and termination of the Senior Loan Documents.

**“Lien”** means, with respect to any asset, any mortgage, lien (statutory or otherwise), pledge, hypothecation, charge, security interest, preference, priority or encumbrance of any kind in respect of such asset, whether or not filed, recorded or otherwise perfected under applicable law, including any conditional sale or other title retention agreement, any lease in the nature thereof, any option or other agreement to sell or give a security interest in and any filing of or agreement to give any financing statement under the Uniform Commercial Code (or equivalent statutes) of any jurisdiction; provided, that in no event shall an operating lease be deemed to constitute a Lien.

**“Senior Collateral”** means (a) any “Collateral” as defined in any Senior Loan Document and (b) any other assets of Borrower with respect to which a Lien is granted or purported to be granted pursuant to a Senior Loan Document as security for any Senior Debt.

**“Senior Debt”** means any and all indebtedness and obligations for borrowed money (including, without limitation, principal, premium (if any), interest, fees, charges, expenses, costs, professional fees and expenses, and reimbursement obligations) at any time owing by Borrower to each Senior Creditor under the Senior Loan Documents (including, without limitation, the Obligations (as defined in the Senior Creditor Agreement) and all other credit relationships with each Senior Creditor including but not limited to such amounts as may accrue or be incurred before or after default or workout or the commencement of any liquidation, dissolution, bankruptcy, receivership, or reorganization case by or against Borrower, and any other credit extensions or agreements between Borrower and either Senior Creditor, including, but not limited to, letters of credit, interest rate swap arrangements, foreign exchange services, cash management services, credit cards, overdrafts, etc. and other Bank Services, subject in all respects to an aggregate cap equal to Sixteen Million Five Hundred Thousand Dollars (\$16,500,000).

**“Senior Debt Event of Default”** means any “Event of Default” as defined in the Senior Loan Documents.

**“Senior Loan Documents”** means the Senior Creditor Agreement and any other agreement, security agreement, document, promissory note, UCC financing statement, or instrument executed by Borrower in favor of Senior Agent or any Senior Creditor, as the same may from time to time be amended, modified, supplemented, extended, renewed, restated, amended and restated or replaced in accordance with Section 11.

**“Subordinated Agreement”** means that certain Co-Development Agreement dated January 9, 2020, between Borrower and Subordinated Creditor, as the same may from time to time be amended, modified, supplemented, extended, renewed, restated, amended and restated, or replaced.

**“Subordinated Collateral”** means (a) any “SFJ Collateral” as defined in the Subordinated Agreement or (b) any other assets of Borrower with respect to which a Lien is granted or purported to be granted pursuant to a Subordinated Loan Document as security for any Subordinated Obligations; provided, however, that at no time shall the Subordinated Collateral include any assets that do not also constitute Senior Collateral.

**“Subordinated Debt”** means the Subordinated Obligations, including without limitation any and all indebtedness and payment obligations (including, without limitation, principal, premium (if any), interest, fees, charges, expenses, costs, professional fees and expenses, and reimbursement obligations) at any time owing by Borrower to Subordinated Creditor under the Subordinated Loan Documents, including but not



limited to such amounts as may accrue or be incurred before or after default or workout or the commencement of any liquidation, dissolution, bankruptcy, receivership, or reorganization case by or against Borrower.

**“Subordinated Debt Event of Default”** means any “Event of Default” as defined in the Subordinated Loan Documents.

**“Subordinated Loan Documents”** means the Subordinated Agreement and any other agreement, document, promissory note, financing statement, or instrument executed by Borrower in favor of Subordinated Creditor pursuant to or in connection with the Subordinated Debt, as the same may from time to time be amended, modified, supplemented, extended, renewed, restated, amended and restated, or replaced.

**“Subordinated Obligations”** means the “PB Obligations” as defined in the Subordinated Agreement and any other payment obligations arising pursuant to the Subordinated Loan Documents.

Unless otherwise specified, all references in this Agreement to a “Section” shall refer to the corresponding Section in or to this Agreement. Other capitalized terms used herein and not otherwise defined herein shall have the meaning given such terms in the Uniform Commercial Code as in effect in the State of California, as in effect from time to time (“UCC”).

## 2. SUBORDINATION

(a) On the terms and conditions set forth below, Subordinated Creditor’s right to payment and performance of the Subordinated Debt and all Liens securing the Subordinated Debt are hereby subordinated to each Senior Creditor’s right to payment in full (other than contingent indemnity obligations) of the Senior Debt and all Liens securing the Senior Debt. Subject to and except as set forth in Section 3, Subordinated Creditor shall not ask, demand, sue for, take or receive from Borrower, by setoff or in any other manner, the whole or any part of any monies which may now or hereafter be owing by Borrower to Subordinated Creditor, or be owing by any other person to Subordinated Creditor under a guaranty or similar instrument, on account of the Subordinated Debt, nor any collateral security for any of the foregoing, including, without limitation, any Subordinated Collateral granted to Subordinated Creditor pursuant to the Subordinated Loan Documents, unless and until the Senior Debt shall have been fully paid in cash (other than contingent indemnity obligations) and all commitments to extend credit under the Senior Creditor Agreement shall have been terminated (the temporary reduction of outstanding obligations, liabilities and indebtedness of Borrower to each Senior Creditor not being deemed to constitute full payment or satisfaction thereof).

(b) Subordinated Creditor shall not create, maintain or perfect any Lien on any property of Borrower, other than the Liens granted in favor of Subordinated Creditor in the Subordinated Collateral under and as described in the Subordinated Loan Documents, which Liens in the Subordinated Collateral are junior and subordinated to the Lien securing the Senior Debt. If, notwithstanding the foregoing, any Lien shall be created or shall arise (including, without limitation, the Liens granted in favor of Subordinated Creditor pursuant to the Subordinated Loan Documents), whether by operation of law or otherwise, and may from time to time exist in favor of Subordinated Creditor in or on any property of Borrower to secure all or any portion of the Subordinated Debt, then any Lien granted by Borrower in favor of Senior Agent for the benefit of Senior Creditors to secure the Senior Debt shall in all respects be first and senior liens, superior to any Lien in favor of Subordinated Creditor securing the Subordinated Debt, including, without limitation, the Lien granted in favor of Subordinated Creditor pursuant to the Subordinated Loan Documents notwithstanding (i) the date, manner or order of perfection of the Lien granted in favor of Senior Agent, (ii) the provisions of the UCC or any other applicable laws or decisions, (iii) the provisions of any contract in effect between Senior Agent or any Senior Creditor, on the one hand, and Borrower or any affiliate thereof,

on the other, and (iv) whether Senior Agent, any Senior Creditor or any agent or bailee thereof holds possession of any part or all of the Collateral. In the event Subordinated Creditor has or obtains possession of any such property or forecloses upon or enforces its Lien upon any such property, whether by judicial action or otherwise, then all such property shall be immediately delivered in kind to Senior Agent or any Senior Creditor or, if not deliverable in kind, all cash or non-cash proceeds and profits of such property shall be held in trust for the benefit of Senior Agent for the benefit of Senior Creditors and paid over to Senior Agent for the benefit of Senior Creditors, without any deduction or offset, unless and until all of the Senior Debt shall have been paid in cash in full (other than contingent indemnity obligations) and all commitments to extend credit under the Senior Creditor Agreement shall have been terminated.

(c) Without limiting the generality of any other covenant or agreement made by Subordinated Creditor in this Agreement, Subordinated Creditor hereby covenants and agrees that (i) Senior Creditor has not made any warranties or representations with respect to the due execution, legality, validity, completeness or enforceability of the Senior Creditor Agreement or any of the other Senior Loan Documents, or the collectibility of the Senior Debt; (ii) Subordinated Creditor will not interfere with or in any manner oppose a disposition of any Senior Collateral by Senior Creditor; (iii) Subordinated Creditor shall not contest, challenge or dispute the validity, attachment, perfection, priority or enforceability of Senior Creditor's security interest in the Collateral, or the validity, priority or enforceability of the Senior Debt; and (iv) Subordinated Creditor shall use commercially reasonable efforts to give Senior Creditor prompt written notice of the occurrence of any Subordinated Debt Event of Default under the Subordinated Loan Documents.

(d) Without limiting the generality of any other covenant or agreement made by Senior Creditor in this Agreement, Senior Creditor hereby covenants and agrees that (i) Subordinated Creditor has not made any warranties or representations with respect to the due execution, legality, validity, completeness or enforceability of the Subordinated Agreement or any of the other Subordinated Loan Documents, or the collectability of the Subordinated Debt; (ii) Senior Creditor will not interfere with or in any manner oppose a disposition of any Subordinated Collateral by Subordinated Creditor to the extent otherwise permitted hereunder; provided, that any proceeds received from such disposition shall be applied in accordance with Section 6, (iii) Senior Creditor shall not contest, challenge or dispute the validity, attachment, perfection, priority or enforceability of Subordinated Creditor's Lien on the Subordinated Collateral, or the validity, priority or enforceability of the Subordinated Debt; and (iii) Senior Creditor shall use commercially reasonable efforts to give Subordinated Creditor prompt written notice of the occurrence of any Senior Debt Event of Default under the Senior Loan Documents.

(e) The subordination contained in this Agreement is intended to define the rights and duties of Subordinated Creditor Senior Agent and Senior Creditors; it is not intended that any third party (including any bankruptcy trustee, receiver, or debtor in possession) shall benefit from it. If the effect of the subordination contained in this Agreement would be to give any third party a priority status to which that party would not otherwise be entitled, then that provision shall, to the extent necessary to avoid that priority, be given no effect and the rights and priorities of Senior Agent, each Senior Creditor and Subordinated Creditor shall be determined in accordance with applicable law and this Agreement.

(f) Notwithstanding anything in this Agreement to the contrary, nothing herein shall be deemed to subordinate, waive or restrict the contractual rights of Subordinated Creditor under any warrants or capital stock that the Borrower may issue to Subordinated Creditor from time to time, nor shall anything herein restrict the performance of Borrower's obligations under such warrants or with respect to such capital stock.

(g) In the event of the occurrence of an Insolvency Event (as hereinafter defined), (i) this Agreement shall remain in full force and effect in accordance with Section 510(a) of the United States

Bankruptcy Code, and (ii) the Collateral shall include, without limitation, all Collateral arising during or after any such Insolvency Event.

### 3. PERMITTED PAYMENTS; PAYMENT BLOCKAGE

(a) Notwithstanding anything to the contrary contained in Section 2, but subject expressly to Section 3(b), Borrower shall be permitted to make, and Subordinated Creditor shall be permitted to ask, demand, sue for, take or receive from Borrower, by setoff or in any other manner, the following payments (collectively, “**Permitted Payments**”): (i) scheduled payments when due under the Subordinated Loan Documents, (ii) all reimbursable expenses, costs and professional fees and expenses as and when due under the Subordinated Loan Documents (provided that such reimbursements shall be limited to up to Two Hundred Fifty Thousand Dollars (\$250,000) per calendar year during a Blockage Period), and (iii) other payments consented to in writing by Senior Creditor.

(b) Notwithstanding anything to the contrary contained in this Section 3 or elsewhere in this Agreement, if Senior Agent or any Senior Creditor delivers to Subordinated Creditor written notice (a “**Blockage Notice**”) of the occurrence and continuation of a Senior Debt Event of Default, during any Blockage Period (as defined below), Subordinated Creditor shall not accept or receive any payment of any kind of or on account of the Subordinated Debt (other than any Permitted Payment), unless and until the earlier of (A) the time Senior Agent or any Senior Creditor notifies Subordinated Creditor in writing that such Senior Debt Event of Default has been cured by the Borrower or waived by Senior Agent and each Senior Creditor, or (B) the expiration of the Blockage Period for such Blockage Notice. Additionally, Subordinated Creditor shall disgorge any payments (other than any Permitted Payments) received during the time commencing upon the occurrence of a Senior Debt Event of Default until the date of receipt by Subordinated Creditor of the related Blockage Notice; provided, that Subordinated Creditor may accept and retain any distribution to Borrower’s unsecured creditors constituting the proceeds of Borrower’s assets that are not otherwise subject to Senior Agent’s or any Senior Creditor’s Lien.

As used herein, “**Blockage Period**” means a period of time beginning on the date a Blockage Notice is delivered to Subordinated Creditor and terminating on the earliest to occur of:

(1) 120 days following such date; provided that if, prior to the expiration of such 120 day period, Senior Creditor has accelerated the maturity of the Senior Debt, commenced a judicial proceeding or non-judicial actions to collect or enforce the Senior Debt or foreclose on any collateral for the Senior Debt, or a case or proceeding by or against Borrower is commenced under the United States Bankruptcy Code or any other insolvency law, then such period shall be extended during the continuation of such proceedings and actions until the payment in cash in full (other than contingent indemnity obligations) of the Senior Debt;

- (1) the Discharge of the Senior Debt;
- (2) the maturity of the Senior Debt in accordance with the Senior Loan Documents; or
- (3) the written consent of each Senior Creditor to such termination.

provided that if during the Blockage Period, Senior Creditor has commenced actions to diligently enforce the Senior Debt then the Blockage Period shall be extended until Discharge of the Senior Debt.

Senior Creditors shall not issue more than (i) two (2) Blockage Notices for defaults which do not involve a failure to make a payment of Senior Debt in any period of 365 consecutive days or (ii) six (6) Blockage Notices for any defaults during the term of the Senior Loan Documents.

#### **4. ENFORCEMENT RIGHTS**

Notwithstanding anything to the contrary contained in Section 2, Subordinated Creditor shall not accelerate the maturity of the Subordinated Debt, enforce any claim (including any default remedy) with respect to the Subordinated Debt or the Subordinated Collateral, or otherwise take any action against Borrower or Borrower's property with respect to the Subordinated Debt so long as any Blockage Period is in effect; provided, however, that Subordinated Creditor may (i) file claims or proofs of claims upon the occurrence of an Insolvency Event (as defined in Section 6 below) pursuant to the terms of Section 6(b), (ii) take action for nonpayment of the Subordinated Debt including demanding and accelerating Subordinated Debt, for the purposes of obtaining a monetary judgment in respect thereof provided that no measure is taken to enforce any such judgment, or (iii) take action as required to preserve the validity, efficacy or priority of the Subordinated Debt and the Subordinated Loan Documents provided such action is not otherwise prohibited hereunder.

#### **5. ASSIGNMENT OF SUBORDINATED DEBT**

Subordinated Creditor hereby covenants to each Senior Creditor that prior to the termination of this Agreement in accordance with Section 10, the entire Subordinated Debt created in favor of Subordinated Creditor shall continue to be owing only to Subordinated Creditor, and any collateral security therefor (including, without limitation, the Subordinated Collateral) shall continue to be held solely for the benefit of Subordinated Creditor, unless assigned pursuant to an assignment made expressly subject to this Agreement (which, for the avoidance of doubt, does not create any consent or other similar type of right in favor of Senior Creditor).

#### **6. SENIOR CREDITOR'S PRIORITY**

In the event of any distribution, division, or application, partial or complete, voluntary or involuntary, by operation of law or otherwise, of all or any part of the property of Borrower or the proceeds thereof to the creditors of Borrower, or the readjustment of the Senior Debt and the Subordinated Debt of Borrower, whether by reason of liquidation, bankruptcy, arrangement, receivership, assignment for the benefit of creditors or any other action or proceeding involving the readjustment of all or any part of the Senior Debt or the Subordinated Debt, or the application of the property of Borrower to the payment or liquidation thereof, or upon the dissolution, liquidation, reorganization, or other winding up of Borrower's business, or upon the sale of all or any substantial part of Borrower's property (any of the foregoing being hereinafter referred to as an "Insolvency Event"), then, and in any such event, each Senior Creditor shall be entitled to receive the payment in cash in full (other than contingent indemnity obligations) of the Senior Debt before Subordinated Creditor shall be entitled to receive any payment on account of the Subordinated Debt, and to that end and in furtherance thereof:

(a) All payments and distributions of any kind or character, whether in cash, property, or securities, in respect of the Subordinated Debt to which Subordinated Creditor would be entitled if the Subordinated Debt were not subordinated pursuant to this Agreement, shall be paid to Senior Creditors and applied in payment of the Senior Debt;

(b) Subordinated Creditor shall file a claim or claims, on the form required in such proceedings, on or before five (5) Business Days prior to the last date such claims or proofs of

claim may be filed pursuant to law or the order of any court exercising jurisdiction over such proceeding; and

(c) Notwithstanding the foregoing, if any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by Subordinated Creditor on account of the Subordinated Debt before all of the Senior Debt has been paid, then such payment or distribution shall be received by Subordinated Creditor in trust for and shall be promptly paid over to Senior Creditors for application to the payments of amounts due on the Senior Debt until the Senior Debt shall have been paid in cash in full (other than contingent indemnity obligations).

## **7. GRANT OF AUTHORITY; AGREEMENTS OF SUBORDINATED CREDITOR**

In the event of the occurrence of an Insolvency Event, and in order to enable each Senior Creditor to enforce its rights hereunder in any of the aforesaid actions or proceedings, each Senior Creditor is hereby irrevocably authorized and empowered, in such Senior Creditor's discretion, as follows:

(a) Such Senior Creditor is hereby irrevocably authorized and empowered (in its own name or in the name of Subordinated Creditor or otherwise), but shall have no obligation, ((i) to demand, sue for, collect and receive every payment or distribution referred to in Section 6, and give acquittance therefor and, (ii) (if Subordinated Creditor has failed to file claims or proofs of claim on or before five (5) Business Days prior to the last date such claims or proofs of claim may be filed pursuant to law or the order of any court exercising jurisdiction over such proceeding) to file claims and proofs of claim, and (iii) to take such other action (including, without limitation, enforcing any Lien securing payment of the Subordinated Debt) as it may deem necessary or advisable for the exercise or enforcement of any of the rights or interests of either Senior Creditor hereunder. Subordinated Creditor shall duly and promptly take such action as each Senior Creditor may reasonably request to execute and deliver to each Senior Creditor such authorizations, endorsements, assignments, or other instruments as each Senior Creditor may reasonably request in order to enable each Senior Creditor to enforce any and all claims with respect to, and any Lien securing payment of, the Subordinated Debt as such enforcement is contemplated herein.

(b) To the extent that payments or distributions on account of the Subordinated Debt are made in property or securities other than cash, Subordinated Creditor authorizes each Senior Creditor, to sell or dispose of such property or securities on such terms as are commercially reasonable in the situation in question. Following full payment in cash of the Senior Debt, each Senior Creditor shall remit to Subordinated Creditor (with all necessary endorsements), to the extent of Subordinated Creditor's interest therein, all payments and distributions of cash, property, or securities paid to and held by any Senior Creditor in excess of the allowed amount of the Senior Debt.

In addition to and without limiting the foregoing: (a) so long as the Discharge of Senior Debt has not occurred, Subordinated Creditor shall not commence or join in any involuntary bankruptcy petition or similar judicial proceeding against Borrower except upon written consent of Senior Creditor, and (b) if an Insolvency Event occurs: (i) Subordinated Creditor shall not assert, without the prior written consent of each Senior Creditor, any claim, motion, objection or argument in respect of the Collateral in connection with any Insolvency Event which could otherwise be asserted or raised in connection with such Insolvency Event, including, without limitation, any claim, motion, objection or argument seeking adequate protection (except, however, that Subordinated Creditor may do so to the same extent Senior Creditor has sought adequate protection) or relief from the automatic stay in respect of the Collateral, (ii) Senior Creditors may consent to the use of cash collateral on such terms and conditions and in such amounts as it shall in good faith determine without

seeking or obtaining the consent of Subordinated Creditor as (if applicable) holder of an interest in the Collateral, (iii) if use of cash collateral by Borrower is consented to by Senior Creditors, Subordinated Creditor shall not oppose such use of cash collateral on the basis that Subordinated Creditor's interest in the Collateral (if any) is impaired by such use or inadequately protected by such use, or on any other ground, and (iv) Subordinated Creditor shall not object to, or oppose, any sale or other disposition of any assets comprising all or part of the Collateral, free and clear of Liens and claims of any party, including Subordinated Creditor, under Section 363 of the United States Bankruptcy Code or otherwise, on the basis that the interest of Subordinated Creditor in the Collateral (if any) is impaired by such sale or inadequately protected as a result of such sale, or on any other ground (and, if requested by either Senior Creditor, Subordinated Creditor shall affirmatively and promptly consent to such sale or disposition of such assets), if Senior Creditors have consented to, or supports, such sale or disposition of such assets.

#### **8. PAYMENTS RECEIVED BY SUBORDINATED CREDITOR**

Should any payment, distribution, or security be received by Subordinated Creditor upon or with respect to the Subordinated Debt (other than any payment of Subordinated Debt permitted pursuant to Section 3) prior to termination of this Agreement in accordance with Section 10, Subordinated Creditor shall receive and hold the same in trust for the benefit of each Senior Creditor and shall forthwith deliver the same to Senior Creditors in precisely the form received (except for the endorsement or assignment of Subordinated Creditor where necessary) for application to the Senior Debt, and, until so delivered, the same shall be held in trust by Subordinated Creditor as the property of Senior Creditors.

#### **9. FURTHER ASSURANCES.**

Subject to Section 16(b), each of Senior Creditor and Subordinated Creditor agrees to take all further actions and execute and deliver such additional documents and instruments (in recordable form, if requested) as the other parties hereto may reasonably request to effectuate the terms of, and the lien priorities contemplated by, this Agreement.

#### **10. TERMINATION OR AMENDMENT OF AGREEMENT**

This Agreement shall be effective upon its execution by each of Senior Agent, Senior Creditors and Subordinated Creditor. After the Effective Date, this Agreement may be amended or waived in writing signed by Senior Creditor and Subordinated Creditor. Senior Creditors and Subordinated Creditor agree that no amendment hereto shall be binding upon Borrower unless Borrower shall have received notice of such amendment. Subject to Section 14, this Agreement shall automatically and without further action terminate upon the Discharge of Senior Debt.

#### **11. ADDITIONAL AGREEMENTS FOR SENIOR AGENT AND SENIOR CREDITORS**

Senior Agent and Senior Creditors may administer and manage their credit and other relationships with Borrower in its own best interest, without notice to or consent of Subordinated Creditor. At any time and from time to time, Senior Agent and Senior Creditors may enter into any amendment or agreement with Borrower as Senior Creditors may deem proper, extending the time of payment of or renewing or otherwise altering the terms of all or any of the obligations constituting Senior Debt or affecting the collateral security for, supporting or underlying any or all of the Senior Debt, and may exchange, sell, release, surrender or otherwise deal with any such collateral without in any way thereby impairing or affecting this Agreement, and all such additional agreements and amendments shall be Senior Loan Documents evidencing the Senior Debt; provided, that neither this Section 11 nor any provision of such agreements shall affect the limitations contained in the definition of Senior Debt.

## **12. SUBROGATION**

If cash or other property otherwise payable or deliverable to Subordinated Creditor or on account of the Subordinated Debt shall have been applied pursuant to this Agreement to the payment of the Senior Debt, and if the Discharge of Senior Debt has occurred, then Subordinated Creditor shall be subrogated to any rights of Senior Creditors to receive further payments or distributions applicable to the Senior Debt until the Subordinated Debt shall have been fully paid. No such payments or distributions received by Subordinated Creditor by reason of such subrogation shall, as between Borrower and its creditor other than Senior Creditors, on the one hand, and Subordinated Creditor, on the other hand, be deemed to be a payment by Borrower on account of the Subordinated Debt owed to Subordinated Creditor.

## **13. AMENDMENTS**

(a) Subordinated Creditor shall have the right to amend the Subordinated Loan Documents at any time, provided that without Senior Agent's consent such amendment shall not (i) restrict the Borrower's ability to repay the Senior Debt in any respect, (ii) accelerate or otherwise shorten the payment schedule under the Subordinated Loan Documents or (iii) increase the amount of any scheduled payment under the Subordinated Loan Documents.

## **14. REINSTATEMENT OF SENIOR DEBT**

To the extent that Senior Agent or Senior Creditors receives payments on or proceeds of any collateral security for the Senior Debt, which payments or proceeds are subsequently invalidated, declared to be fraudulent or preferential, set aside or required to be repaid to a trustee, receiver or any other party under any bankruptcy law, state or federal law, common law, or equitable cause, then, to the extent of such payments or proceeds invalidated, declared to be fraudulent or preferential, set aside or required to be repaid, the Senior Debt, or part thereof, intended to be satisfied shall be revived and continue in full force and effect as if such payments or proceeds had not been received by Senior Agent or Senior Creditors.

## **15. NO WAIVERS**

None of Senior Agent, Senior Creditors or Subordinated Creditor shall be prejudiced in their rights under this Agreement by any act or failure to act of any party hereto or any noncompliance of any other party hereto with any agreement or obligation, regardless of any knowledge thereof which Senior Agent, Senior Creditors or Subordinated Creditor, as applicable, may have, or with which Senior Agent or Senior Creditors may be charged; no action permitted hereunder that has been taken by any party hereto shall in any way affect or impair the rights or remedies of such party in the exercise of any other right or remedy or shall operate as a waiver thereof; no single or partial exercise by any party hereto of any right or remedy shall preclude any other or further exercise thereof; and no modification or waiver of any of the provisions of this Agreement shall be binding upon any party hereto, in each case except as expressly set forth in a writing duly signed and delivered by such party.

## **16. INFORMATION CONCERNING BORROWER; CREDIT ADMINISTRATION**

(a) Subordinated Creditor hereby assumes responsibility for keeping itself informed of the financial condition of Borrower, any and all endorsers and any and all guarantors of the Senior Debt and of all other circumstances bearing upon the risk of nonpayment of the Senior Debt or the Subordinated Debt that diligent inquiry would reveal, and Subordinated Creditor hereby agrees that Senior Agent or Senior Creditors shall not have any duty to advise Subordinated Creditor of information known to Senior Agent or Senior Creditors regarding such condition.

(b) Subject to Sections 2(b), 3, 4, 7 and 8, Subordinated Creditor may (i) administer and manage its credit and other relationships with Borrower in its own best interest, and (ii) amend or extend its agreements with Borrower or enter into additional agreements with Borrower, all without the consent of or notice to Senior Agent or Senior Creditors; provided that neither this Section 16(b) nor any amendments or additional agreements referred to therein shall impair or affect the subordination of Subordinated Debt or change the definition of Permitted Payments, Subordinated Debt, Subordinated Creditor, Senior Debt or Senior Creditor.

## 17. NOTICES

Except as otherwise provided herein, all notices and service of process required, contemplated, or permitted hereunder or with respect to the subject matter hereof shall be in writing, and shall be deemed to have been validly served, given or delivered upon the earlier of: (a) the first business day after transmission by facsimile or hand delivery or deposit with an overnight express service or overnight mail delivery service; or (b) the third calendar day after deposit in the United States mails, with proper first class postage prepaid, and shall be addressed to the party to be notified as follows:

If to Borrower:	Phasebio Pharmaceuticals, Inc. 1 Great Valley Parkway, Suite 30 Malvern, PA 19355 Attn: Jonathan Mow, CEO Email: jonathan.mow@phasebio.com
If to Agent or SVB:	Silicon Valley Bank 3475 Piedmont Road, Suite 560 Atlanta, GA 30305 Attn: Myron Jensen Email: MJensen@svb.com
If to WestRiver:	WestRiver Innovation Lending Fund VIII, L.P. c/o WestRiver Management, LLC 3720 Carillon Point Kirkland, Washington 98033-7455 Attn: Harper Ellison Email: Harper@wrg.vc
If to Subordinated Creditor:	SFJ Pharmaceuticals X, Ltd SIX, 2nd Floor, Cricket Square PO Box 2681 Grand Cayman, KY1-1111 Cayman Islands

## 18. SEVERABILITY

Wherever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.



## **19. GOVERNING LAW**

This Agreement shall be governed by and interpreted in accordance with the laws of the State of California without regard to principles of conflict of laws that would cause the application of laws of any other jurisdiction.

## **20. ASSIGNMENT**

This Agreement shall be binding upon Senior Creditor, Subordinated Creditor, the Borrower and their respective successors and assigns, and shall inure to the benefit of and be enforceable by Senior Agent or Senior Creditors and their successors and assigns.

## **21. CONSENT**

Senior Agent and each Senior Creditor hereby consents to the Liens in the Subordinated Collateral and the indebtedness and other obligations created or to be created under Subordinated Agreement and agrees that the grant or existence of such Lien does not and shall not constitute a default or an event of default under or a breach of the Senior Loan Documents or this Agreement. Subordinated Creditor hereby consents to the Lien on the Senior Collateral and the indebtedness created or to be created under the Senior Creditor Agreement and agrees that the grant or existence of such Liens does not and shall not constitute a default or an event of default under the Subordinated Loan Documents.

## **22. WAIVER AND JUDICIAL REFERENCE**

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, SUBORDINATED CREDITOR AND SENIOR CREDITOR EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE SENIOR LOAN DOCUMENTS, THE SUBORDINATED LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY, AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR THE PARTIES HERETO TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES' AGREEMENT TO WAIVE THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY, if the above waiver of the right to a trial by jury is not enforceable, the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties hereto (or, if they cannot agree, by the Presiding Judge of the Santa Clara County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a jury, in Santa Clara County, California; and the parties hereto hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure §§ 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and permanent injunctions and appointing receivers. All such proceedings shall be closed to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the Santa Clara County, California Superior Court for such relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings.

The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The private judge shall oversee discovery and may enforce all discovery rules and order applicable to judicial proceedings in the same manner as a trial court judge. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to the California Code of Civil Procedure § 644(a). Nothing in this paragraph shall limit the right of any party at any time to exercise self-help remedies, foreclose against collateral, or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this paragraph.

### 23. COUNTERPARTS

This Agreement and any amendments, waivers, consents or supplements hereto may be executed in any number of counterparts, and by different parties hereto in separate counterparts, each of which when so executed and delivered shall be deemed an original, but all of which counterparts together shall constitute but one and the same instrument.

### 24. PURCHASE OPTION

(a) In the event that (i) a Blockage Notice has been issued, or (ii) the Senior Debt is accelerated by Senior Creditors (each a “**Purchase Trigger Event**”), Subordinated Creditor shall have the option (but not the obligation) to purchase all (but not less than all) of the then-outstanding Senior Debt; provided that such option shall expire if Subordinated Creditor fails to deliver a written notice (the “**Purchase Notice**”) to Senior Creditors within thirty (30) business days following the occurrence of a Purchase Trigger Event, which Purchase Notice shall (i) be signed by Subordinated Creditor and (ii) state that (A) it is a Purchase Notice delivered pursuant to Section 24 of this Agreement, and (B) Subordinated Creditor is thereby offering to purchase all of the Senior Debt at the Purchase Price set forth in Section 24(d) hereof. The Purchase Notice shall be irrevocable by Subordinated Creditor once received by Senior Creditors. After the expiration of the thirty (30) business day period above, Subordinated Creditor shall not be entitled to send a Purchase Notice until the occurrence of a subsequent Purchase Trigger Event.

(b) Notwithstanding the delivery of a Purchase Notice in accordance with the terms hereunder, Senior Agent and Senior Creditors may continue to exercise all of their rights and remedies under the Senior Debt until the close of the Purchase on the Purchase Date (as such terms are defined below), and until the close of the Purchase on the Purchase Date Senior Agent and each Senior Creditor shall not be precluded from taking any action, including commencing judicial proceeding or non-judicial actions to collect or enforce the Senior Debt or foreclose on any collateral for the Senior Debt. For the avoidance of doubt, upon the close of the Purchase, such rights and remedies of Senior Agent and Senior Creditors shall cease.

(c) On the date (the “**Purchase Date**”) specified by Subordinated Creditor in the Purchase Notice (which date shall be not less than thirty (30) days, after the receipt by Senior Creditors of the Purchase Notice), subject to any required approval of any court or other governmental authority then in effect, Senior Creditors shall sell to Subordinated Creditor, and Subordinated Creditor shall purchase from Senior Creditors (the “**Purchase**”), the aggregate amount of Senior Debt outstanding at the time of purchase at par, on a non-recourse basis; provided that the Senior Debt purchased shall not include any rights of Senior Creditors with respect to indemnification obligations of Borrower arising under the Senior Loan Documents prior to the Purchase Date (the “**Surviving Obligations**”).

(d) Without limiting the obligations of Borrower under the Senior Loan Documents to Senior Creditors with respect to the Surviving Obligations (which shall not be transferred in connection with the

Purchase), upon the Purchase Date, Subordinated Creditor shall: (i) as the purchase price (the “**Purchase Price**”) for all of the Senior Debt, pay to Senior Creditors in cash an amount equal to all outstanding Senior Debt as of the Purchase Date, and (ii) furnish cash collateral to SVB (X) in an amount equal to one hundred five percent (105.0%) of the face amount of all letters of credit issued by Senior Creditor that are denominated in United States Dollars, plus all interest, reasonable and documented fees, and costs due in connection therewith (as determined by Senior Creditor in its good faith business judgment), (Y) in an amount equal to one hundred five percent (105.0%) of the face amount of all letters of credit issued by SVB that are denominated in a currency other than United States Dollars, plus all interest, reasonable and documented fees, and costs due in connection therewith (as estimated by SVB in its good faith business judgment) and (Z) in an amount equal to all Bank Services and any other contingent obligations (all of the foregoing in clause (X), clause (Y) and clause (Z) being “**Reimbursement Obligations**”), to cash collateralize such Reimbursement Obligations (or make such other arrangements as are acceptable to SVB in its sole discretion to assume any reimbursement obligations relating to such Reimbursement Obligations), and (iii) agree to reimburse Senior Creditors for any loss, cost, damage or reasonable and documented out-of-pocket cost or expense (including reasonable and documented out-of-pocket attorneys’ fees and legal expenses) in connection with any commissions, fees, costs or expenses related to any issued and outstanding letters of credit as described above and any checks or other payments provisionally credited to Senior Creditors and/or as to which Senior Creditors have not yet received final payment. The Purchase Price and cash collateral above shall be remitted by wire transfer in immediately available federal funds to such bank account of Senior Creditors as Senior Creditors may designate in writing to Subordinated Creditor for such purpose. Interest shall be calculated to and including the business day on which the Purchase shall occur if the amounts so paid by Subordinated Creditor to the bank account designated by Senior Creditors are received in such bank account prior to 12:00 p.m., New York City time, and interest shall be calculated to and including the following business day if the amounts so paid by Subordinated Creditor to the bank account designated by Senior Creditors are received in such bank account later than 12:00 p.m., New York City time. Until the Purchase is final and the Senior Debt (other than contingent indemnity obligations) is paid in full, Senior Agent and each Senior Creditor may continue to exercise all of its rights and remedies under the Senior Debt.

(e) Such purchase of the Senior Debt shall be made on a non-recourse basis, pursuant to SVB’s standard non-recourse sale and assignment agreement, without representation or warranty by any Senior Creditor as to the Senior Debt, any property serving as the Senior Collateral, or otherwise, except that each Senior Creditor shall represent and warrant: (i) the amount of the Senior Debt being purchased from Senior Creditors; (ii) that such Senior Creditor owns the Senior Debt free and clear of any Lien or encumbrances; and (iii) such Senior Creditor has the right to sell and assign the Senior Debt.

## 25. ATTORNEYS’ FEES

In the event of any legal action to enforce the rights of a party under this Agreement, the party prevailing in such action shall be entitled, in addition to such other relief as may be granted, all reasonable and documented out-of-pocket costs and expenses, including reasonable attorneys’ fees, incurred in such action.

[Signature page follows.]

IN WITNESS WHEREOF, this Agreement has been executed as of the date first above written.

BORROWER:

**PHASEBIO PHARMACEUTICALS, INC.**

By: /s/ Jonathan Mow

Name: Jonathan Mow

Title: Chief Financial Officer

AGENT:

**SILICON VALLEY BANK**, as Agent

By: /s/ Thomas F. Gordon

Name: Thomas F. Gordon

Title: Managing Director

LENDERS:

**SILICON VALLEY BANK**, as Lender

By: /s/ Thomas F. Gordon

Name: Thomas F. Gordon

Title: Managing Director

**WESTRIVER INNOVATION LENDING FUND VIII, L.P.**, as  
Lender

By: /s/ Trent Dawson

Name: Trent Dawson

Title: Chief Financial Officer

***[Signature Page to Subordination Agreement]***

**EXECUTED** as a **DEED** for and on behalf of **SFJ Pharmaceuticals X, Ltd.** in )  
the presence of: )

)

By: /s/ Jonathan Roney  
Name: Jonathan Roney  
Position: Director

/s/ Neil Gray

Witness signature

Name: Neil Gray

Address: 190 Elign Ave., George Town,  
Grand Cayman

Occupation: Director, Fiduciary Services

***[Signature Page to Subordination Agreement]***

Certain information has been excluded from this agreement (indicated by “[\*\*\*]”) because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

## INTELLECTUAL PROPERTY SECURITY AGREEMENT

This Intellectual Property Security Agreement (“**Agreement**”) is entered into as of March 19, 2020, by and among (a) **SILICON VALLEY BANK**, a California corporation (“**SVB**”), in its capacity as administrative agent and collateral agent (“**Agent**”), (b) SVB as a lender, (c) **WESTRIVER INNOVATION LENDING FUND VIII, L.P.**, a Delaware limited partnership (“**WestRiver**”), as a lender (SVB and WestRiver and each of the other “**Lenders**” from time to time a party hereto are referred to herein collectively as the “**Lenders**” and each individually as a “**Lender**”), and (d) **PHASEBIO PHARMACEUTICALS, INC.**, a Delaware corporation (“**Grantor**”).

### RECITALS

A. Lenders have agreed to make certain advances of money and to extend certain financial accommodation to Grantor (the “**Loans**”) in the amounts and manner set forth in that certain Loan and Security Agreement by and among Lenders and Grantor dated as of March 25, 2019 (as the same may be amended, modified or supplemented from time to time, including, without limitation, by that certain Consent to Loan and Security Agreement dated as of April 10, 2019, and that certain First Amendment to Loan and Security Agreement dated as of the same date hereof, collectively, the “**Loan Agreement**”; capitalized terms used herein are used as defined in the Loan Agreement). Lenders are willing to make the Loans to Grantor, but only upon the condition, among others, that Grantor shall grant to Agent, for the ratable benefit of Lenders, a security interest in certain Copyrights, Trademarks, Patents, and Mask Works (as each term is described below) to secure the obligations of Grantor under the Loan Agreement.

B. Pursuant to the terms of the Loan Agreement, Grantor has granted to Agent, for the benefit of the Lenders, a security interest in all of Grantor’s right, title and interest, whether presently existing or hereafter acquired, in, to and under all of the Collateral.

NOW, THEREFORE, for good and valuable consideration, receipt of which is hereby acknowledged, and intending to be legally bound, as collateral security for the prompt and complete payment when due of its obligations under the Loan Agreement, Grantor hereby represents, warrants, covenants and agrees as follows:

### AGREEMENT

1. Grant of Security Interest. To secure its obligations under the Loan Agreement, Grantor grants and pledges to Agent, for the ratable benefit of Lenders, a security interest in all of Grantor’s right, title and interest in, to and under its intellectual property (all of which shall collectively be called the “**Intellectual Property Collateral**”), including, without limitation, the following:

(a) Any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret, now or hereafter existing, created, acquired or held, including without limitation those set forth on Exhibit A attached hereto (collectively, the “**Copyrights**”);

(b) Any and all trade secrets, and any and all intellectual property rights in computer software and computer software products now or hereafter existing, created, acquired or held;

(c) Any and all design rights that may be available to Grantor now or hereafter existing, created, acquired or held;

(d) All patents, patent applications and like protections including, without limitation, improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same, including without limitation the patents and patent applications set forth on Exhibit B attached hereto (collectively, the “**Patents**”);

(e) Any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Grantor connected with and symbolized by such trademarks, including without limitation those set forth on Exhibit C attached hereto (collectively, the “**Trademarks**”);

(f) All mask works or similar rights available for the protection of semiconductor chips, now owned or hereafter acquired, including, without limitation those set forth on Exhibit D attached hereto (collectively, the “**Mask Works**”);

(g) Any and all claims for damages by way of past, present and future infringements of any of the rights included above, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the intellectual property rights identified above;

(h) All licenses or other rights to use any of the Copyrights, Patents, Trademarks, or Mask Works and all license fees and royalties arising from such use to the extent permitted by such license or rights;

(i) All amendments, extensions, renewals and extensions of any of the Copyrights, Trademarks, Patents, or Mask Works; and

(j) All proceeds and products of the foregoing, including without limitation all payments under insurance or any indemnity or warranty payable in respect of any of the foregoing.

2. Recordation. Grantor authorizes the Commissioner for Patents, the Commissioner for Trademarks and the Register of Copyrights and any other government officials to record and register this Agreement upon request by Agent.

3. Authorization. Grantor hereby authorizes Agent, on behalf of the Lenders, to (a) modify this Agreement unilaterally by amending the exhibits to this Agreement to include any Intellectual Property Collateral which Grantor obtains subsequent to the date of this Agreement, and (b) file a duplicate original of this Agreement containing amended exhibits reflecting such new Intellectual Property Collateral.

4. Loan Documents. This Agreement has been entered into pursuant to and in conjunction with the Loan Agreement, which is hereby incorporated by reference. The provisions of the Loan Agreement shall supersede and control over any conflicting or inconsistent provision herein. The rights and remedies of Agent, on behalf of the Lenders, with respect to the Intellectual Property Collateral are as provided by the Loan Agreement and related documents, and nothing in this Agreement shall be deemed to limit such rights and remedies.

5. Execution in Counterparts. This Agreement may be executed in counterparts (and by different parties hereto in different counterparts), each of which shall constitute an original, but all of which when taken together shall constitute a single contract. Delivery of an executed counterpart of a signature page to this Agreement by facsimile or in electronic (i.e., “pdf” or “tif” format) shall be effective as delivery of a manually executed counterpart of this Agreement.

6. Successors and Assigns. This Agreement will be binding on and shall inure to the benefit of the parties hereto and their respective successors and assigns.

7. Governing Law. This Agreement and any claim, controversy, dispute or cause of action (whether in contract or tort or otherwise) based upon, arising out of or relating to this Agreement and the transactions contemplated hereby and thereby shall be governed by, and construed in accordance with, the laws of the United States and the State

of California, without giving effect to any choice or conflict of law provision or rule (whether of the State of California or any other jurisdiction).

***[Balance of Page Intentionally Left Blank]***



IN WITNESS WHEREOF, the parties have caused this Intellectual Property Security Agreement to be duly executed by its officers thereunto duly authorized as of the first date written above.

Address:

1 Great Valley Parkway, Suite 30  
Malvern, PA 19355  
Attn: CEO

GRANTOR:

**PHASEBIO PHARMACEUTICALS, INC.**

By: /s/ Jonathan Mow

Name: Jonathan Mow

Title: Chief Executive Officer

***[Signature Page to Intellectual Property Security Agreement]***

IN WITNESS WHEREOF, the parties have caused this Intellectual Property Security Agreement to be duly executed by its officers thereunto duly authorized as of the first date written above.

Address:

3475 Piedmont Road, Suite 560  
Atlanta, GA 30305  
Attn: Myron Jensen

AGENT:

**SILICON VALLEY BANK**

By: /s/ Thomas F. Gordon  
Name: Thomas F. Gordon  
Title: Managing Director

Address:

3475 Piedmont Road, Suite 560  
Atlanta, GA 30305  
Attn: Myron Jensen

LENDER:

**SILICON VALLEY BANK**

By: /s/ Thomas F. Gordon  
Name: Thomas F. Gordon  
Title: Managing Director

***[Signature Page to Intellectual Property Security Agreement]***

IN WITNESS WHEREOF, the parties have caused this Intellectual Property Security Agreement to be duly executed by its officers thereunto duly authorized as of the first date written above.

Address:

c/o WestRiver Management, LLC  
920 5th Avenue, Floor 34, Suite 3450  
Seattle, WA 98104  
Attn: Doug Hollenbeck or Harper Ellison

LENDER:

**WESTRIVER INNOVATION LENDING FUND VIII, L.P.**

By: /s/ Trent Dawson

Name: Trent Dawson

Title: Chief Financial Officer

***[Signature Page to Intellectual Property Security Agreement]***

EXHIBIT A

Copyrights

<u>Description</u>	Registration/ Application <u>Number</u>	Registration/ Application <u>Date</u>
None		

EXHIBIT B

Patents

<u>Description</u>	Registration/ Application <u>Number</u>	Registration/ Application <u>Date</u>
[***]	[***]	[***]

EXHIBIT C

Trademarks

<u>Description</u>	<u>Registration/ Application Number</u>	<u>Registration/ Application Date</u>
PHASEBIO	88107576	9/6/2018

EXHIBIT D

Mask Works

<u>Description</u>	Registration/ Application <u>Number</u>	Registration/ Application <u>Date</u>
None		

Certain information has been excluded from this agreement (indicated by “[\*\*\*]”) because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

EXECUTION VERSION

**CO-DEVELOPMENT AGREEMENT**

This Co-Development Agreement (“Agreement”), made effective as of January 9, 2020 (the “Effective Date”), is by and between PhaseBio Pharmaceuticals Inc., a Delaware corporation, with a principal place of business at 1 Great Valley Parkway, Suite 30, Malvern, Pennsylvania 19355, USA (“PB”), and SFJ Pharmaceuticals X, Ltd. (“SFJ”), an SFJ Pharmaceuticals Group company and corporation organized and existing under the laws of the Cayman Islands, having its principal place of business at SIX, 2nd Floor, Cricket Square PO Box 2681, Grand Cayman, KY1-1111 Cayman Islands (each, a “Party” and collectively, the “Parties”).

WHEREAS, SFJ is in the business of facilitating, among other things, the development and approval of pharmaceutical products and desires to provide financing and participate in conducting the Clinical Trials for the development of the Product as a treatment of patients for the reversal of the effects of the Ticagrelor Compound; and

WHEREAS, PB has rights to the Product, is conducting clinical trials of the Product in the United States and the European Clinical Trial Countries, and would like to enter into an agreement with SFJ to provide operational support for the conduct of clinical trials of the Product in the European Clinical Trial Countries, to conduct clinical trials of the Product in the Designated Asian Countries, and to provide global financing for the continued development of the Product.

NOW THEREFORE, in consideration of the mutual agreements contained herein and other good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties agree as follows:

**ARTICLE 1**

**DEFINITIONS**

1.1 **Defined Terms.** Initially capitalized terms will have the meaning ascribed to such terms in this Agreement, including the following terms which will have the following respective meanings:

1.1.1 “Account” is any “account” as defined in the UCC with such additions as such term may hereafter be made and includes, without limitation, all accounts receivable and other sums owing to PB.

1.1.2 “Affiliate” means, with respect to a party, a business entity under common control with, or controlling or controlled by, such party, with “control” meaning direct or indirect ownership of 50% or more of the voting interest in such other entity, and in the case



of a partnership, control of the general partner. Notwithstanding the foregoing, neither The Blackstone Group Inc. nor any of its divisions, including Blackstone Life Sciences, shall be deemed to be an “Affiliate” of SFJ.

1.1.3 “Alliance Manager” has the meaning ascribed to such term in Section 5.1.5.

1.1.4 “Anti-Corruption Laws” means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.

1.1.5 “Applicable Law” means the applicable laws, rules and regulations, including any rules, regulations, guidelines, or other requirements of any Governmental Authorities (including any Regulatory Authorities), to the extent legally binding, that may be in effect from time to time in any country or regulatory jurisdiction of the Territory. For clarity, Applicable Laws will include the FFDCAs, the PHSA, the Anti-Corruption Laws, and all laws, regulations and legally binding guidelines applicable to the Clinical Trials, including GCP, GLP, GMP and ICH guidelines.

1.1.6 “Approval Buy-Out Payment” has the meaning ascribed to such term in Section 6.7.1.

1.1.7 “Approval Payments” has the meaning ascribed to such term in Section 6.1.

1.1.8 “Approved CRO” has the meaning ascribed to such term in Section 2.4.1.

1.1.9 “Approved Third Party Vendor Costs” has the meaning ascribed to such term in Section 5.2.2.2(g).

1.1.10 “Approved Vendor” has the meaning ascribed to such term in Section 2.4.2.

1.1.11 “AstraZeneca Product” has the meaning ascribed to such term in the AZ License.

1.1.12 “AstraZeneca Product Improvements” has the meaning ascribed to such term in the AZ License.

1.1.13 “AstraZeneca Product Know-How” has the meaning ascribed to such term in the AZ License.

1.1.14 “AstraZeneca Product Patents” has the meaning ascribed to such term in the AZ License.

1.1.15 “AstraZeneca Product References” has the meaning ascribed to such term in the AZ License.

1.1.16 “AZ License” means the License Agreement between MedImmune and PB dated November 21, 2017, a copy of which is attached hereto as Exhibit L, as amended by that certain First Amendment to License Agreement dated January 9, 2020, a copy of which is attached hereto as Exhibit M.

1.1.17 “BLA” means: (a) a biologics license application submitted to the FDA pursuant to Section 351(a) of the PHSA and the regulations promulgated thereunder, or its successor application; or (b) an application for authorization to market and/or sell a biological product in any country or regulatory jurisdiction other than the US submitted to the applicable Regulatory Authority in such country or regulatory jurisdiction, including, with respect to the EU, a marketing authorization application submitted either (i) to the EMA pursuant to the centralized EU filing procedure or (ii) to the applicable national Regulatory Authority in an individual EU member state if the centralized EU filing procedure is not used.

1.1.18 “Brilinta Competing Product” means any P2Y12 receptor antagonist, other than the AstraZeneca Product or Generic Ticagrelor Product.

1.1.19 “Business Day” means a day that is not a Saturday, Sunday or a US federal holiday.

1.1.20 “Buy-Out Payment” means an Approval Buy-Out Payment or a Change of Control Buy-Out Payment.

1.1.21 “Calendar Quarter” means each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, that, (a) the first Calendar Quarter shall begin on the Effective Date and end on the last day of the Calendar Quarter in which the Effective Date falls, and (b) the final Calendar Quarter shall end on the last day of the Term.

1.1.22 “Calendar Year” means each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided, that, (a) the first Calendar Year shall begin on the Effective Date and end on December 31 of the Calendar Year in which the Effective Date falls, and (b) the final Calendar Year shall end on the last day of the Term.

1.1.23 “Case Report Form” or “CRF” means the collection of documents designed specifically for recording data pursuant to the Protocol. A CRF is completed for each Subject and will be in electronic form, validated and in compliance with all Applicable Laws.

1.1.24 “CFC” means a “controlled foreign corporation” as defined in the IRC.

1.1.25 “Change of Control” means, with respect to PB, at any time prior to the date of the payment by PB of the final Approval Payment hereunder, (a) a merger, reorganization or consolidation with a Third Party which results in the voting securities of PB outstanding

immediately prior thereto ceasing to represent, or being converted into or exchanged for voting securities that do not represent, at least fifty percent (50%) of the combined voting power of the voting securities of the surviving entity or the parent corporation of the surviving entity immediately after such merger, reorganization or consolidation, (b) a transaction in which a Third Party becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of PB, other than through the issuance of voting securities for the purpose of raising financing to one or more financial or institutional investors that are not then controlled by an entity engaged in the development or commercialization of pharmaceutical or biotechnology products, or (c) the sale or other transfer of all or substantially all of PB's business or assets relating to the Product for use in the Indication. A Licensing Transaction shall not constitute a Change of Control, unless such Licensing Transaction includes the grant of US Commercialization Rights in which event such Licensing Transaction shall be deemed to be a Change in Control.

1.1.26 "Change of Control Buy-Out Payment" has the meaning ascribed to such term in Section 6.7.2.

1.1.27 "Claim" means any Third Party claim, demand, suit and/or cause of action.

1.1.28 "Clinical Investigator" means the principal investigator at each Site.

1.1.29 "Clinical Investigator Meeting" has the meaning ascribed to such term in Section 3.2.2.1.

1.1.30 "Clinical Supply Agreement" has the meaning ascribed to such term in Section 3.14.1.2.

1.1.31 "Clinical Supply Agreement" has the meaning ascribed to such term in Section 3.14.1.1.

1.1.32 "Clinical Trials" means the Phase 3 Trial, any required supplemental clinical trial of the Product in China contemplated by the Development Plan, and the pharmacokinetic study of the Product in Japanese Subjects contemplated by the Development Plan.

1.1.33 "Clinical Trial Activity" has the meaning ascribed to such term in Section 2.3.1.

1.1.34 "Clinical Trial Agreement" has the meaning ascribed to such term in Section 3.2.1.3.

1.1.35 "Clinical Trials Database" has the meaning ascribed to such term in Section 3.5.3.1.

1.1.36 "Clinical Trials Master File" has the meaning ascribed to such term in Section 3.5.4.

1.1.37 “CMC” means chemistry, manufacturing and controls.

1.1.38 “CMC Information” means the CMC information intended or required for the submission of an IND or BLA.

1.1.39 “CMO” means contract manufacturing organization or contract development and manufacturing organization.

1.1.40 “Commercial Launch” means, with respect to the Product and a country in the Territory, the first sale to a Third Party of such Product in such country after (a) Regulatory Approval and (b) in any country in which price approval is necessary or relevant for a majority of the population to obtain access to pharmaceutical products, price approval for such Product in such country.

1.1.41 “Commercialization” or “Commercialize” means the commercial manufacture, marketing, promotion, sale and/or distribution of the Product. For clarity, Commercialization excludes all activities associated with development and seeking Regulatory Approval for the Product.

1.1.42 “Commercially Reasonable Efforts” means with respect to the performance of activities under this Agreement by a Party (as pertains to its role in conducting the Clinical Trials): reasonable, diligent, good-faith efforts to accomplish such objective which are consistent with industry standards for companies of comparable size as that of such Party. “Commercially Reasonable Efforts” requires, with respect to a particular task or activity in making, using, selling, offering for sale, importing, exporting, developing (including seeking regulatory approvals or applicable pricing or reimbursement approvals) or otherwise commercializing the Product, that a Party: (i) promptly assign responsibility for such task or activity to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis; (ii) set and consistently seek to achieve specific and meaningful objectives for carrying out such task or activity; and (iii) make and implement decisions and allocate resources designed to advance progress with respect to such objectives in accordance with established timelines; provided, however, that, to the extent that the performance of a Party’s obligations hereunder is adversely affected by the other Party’s breach in performing its obligations hereunder, the impact on the first Party of such performance failure by the other Party will be taken into account in determining whether the first Party has used its Commercially Reasonable Efforts to perform any such affected obligations.

1.1.43 “Competing Product” means any agent intended to neutralize, abrogate or reverse the antiplatelet activity of the Ticagrelor Compound.

1.1.44 “Completion Date” means, as to a particular Clinical Trial, the earlier of (a) the date of final database lock for such Clinical Trial and (b) the date such Clinical Trial or this Agreement is terminated.

1.1.45 “Confidential Information” of a Party means all information and materials provided and/or disclosed (including in written form, electronic form or otherwise) by,

or on behalf of, such Party or its Affiliates, agents or representatives to the other Party, its Affiliates, agents or representatives in connection with this Agreement, including, technical, scientific, regulatory and other information, results, knowledge, techniques, data, analyses, inventions, invention disclosures, plans, processes, methods, know-how, ideas, concepts, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, formulae, specifications, marketing, pricing, distribution, cost, sales, and manufacturing data and descriptions. In addition, the terms and conditions of this Agreement shall be deemed to be Confidential Information of both SFJ and PB. For further clarity, the terms of the AZ License shall be considered the Confidential Information of PB, and SFJ acknowledges that the terms of the AZ License are also considered “Confidential Information” (as defined in the AZ License) of MedImmune, and that each of PB and MedImmune is deemed to be the “receiving Party” and the “disclosing Party” with respect thereto for purposes of the AZ License. Notwithstanding the foregoing, any AstraZeneca Product Know-How and any AstraZeneca Product Improvement shall be deemed to be the Confidential Information of PB for purposes of this Agreement and of MedImmune for purposes of the AZ License, and SFJ shall be deemed to be the receiving Party and PB shall be deemed to be the disclosing Party with respect thereto for purposes of this Agreement (it being understood that MedImmune is deemed to be the “receiving Party” and MedImmune is deemed to be the “disclosing Party” with respect thereto for purposes of the AZ License). In addition, notwithstanding SFJ’s ownership of the Research Results prior to assignment thereof in accordance with Section 11.1.1.4, the Research Results shall at all times be deemed to be Confidential Information of PB, and PB and SFJ shall be deemed the disclosing Party and the receiving Party, respectively, with respect thereto.

1.1.46 “Contingent Liabilities” means, for any Person, (i) Indebtedness (as defined in Section 7.7.3) of that Person, and (ii) any direct or indirect liability, contingent or not, of that Person for (a) warranty obligations, (b) potential claims for damages, (c) assessments, and (d) any other condition, situation or set of circumstances involving various degrees of uncertainty that may result in a loss or liability.

1.1.47 “Control” or “Controlled” means (a) for Intellectual Property, a Party’s ability to grant applicable licenses, sublicenses and/or other rights thereunder and (b) for materials and documents, a Party’s ability to provide, or provide access to, such materials and/or documents, each without violating any contractual obligations to a Third Party. For clarity, if a Party only can grant a license or sublicense and/or provide rights and/or access of limited scope, for a specific purpose or under certain conditions due to an encumbrance, “Control” or “Controlled” will be construed to so limit such license, sublicense, provision of rights and/or access.

1.1.48 “Copyrights” means, collectively, all works of authorship, mask works and any and all other registered and unregistered copyrights and copyrightable works, and all applications, registrations, extensions, and renewals thereof.

1.1.49 “Cover”, “Covered” or “Covering” means, with respect to the applicable Intellectual Property, in the absence of the applicable rights and licenses granted, would be infringed, misappropriated, or otherwise violated by.

1.1.50 “CRO” means contract research organization.

1.1.51 “CRO Agreement” has the meaning ascribed to such term in Section 2.4.1.

1.1.52 “CSR” means, for with respect to a Clinical Trial, a clinical study report, or other equivalent document or series of materials, constituting a summary report of the clinical and medical data resulting from such Clinical Trial and prepared for incorporation into submissions seeking Regulatory Approval for the Product, and includes all statistical analyses of such data per the statistical analysis plan.

1.1.53 “Data Room” means that certain electronic data room established by PB and to which SFJ and/or its advisors were granted access.

1.1.54 “Designated Asian Countries” means China, Japan, and Hong Kong.

1.1.55 “Designated European Countries” means [\*\*\*].

1.1.56 “Development” has the meaning ascribed to such term in the AZ License.

1.1.57 “Development Costs” means all internal and external costs incurred or paid by SFJ or PB associated with completing the Clinical Trials, including but not limited to all Approved Third Party Vendor Costs, Product Supply Costs, the Initial Development Cost Payment, PB Costs, the SFJ Interim Management Fee and, if applicable, the SFJ Final Management Fee.

1.1.58 “Development Plan” means a written plan for the Development Program, the initial version of which is attached hereto as Exhibit D, and which will be subject to amendment by the JDC from time to time during the Development Term.

1.1.59 “Development Program” means a CMC, clinical and regulatory development program to be undertaken by the Parties to develop the Product for the Indication, carry out the Clinical Trials, and seek Regulatory Approval for the Product.

1.1.60 “Development Term” means the period commencing on the Effective Date and ending on the later of (a) the latest of the Completion Dates of the Clinical Trials, and (b) the date on which all efforts in pursuit of Regulatory Approval of the Product for Indication have been concluded or terminated.

1.1.61 “Disclosing Party” has the meaning ascribed to such term in Section 10.1.

1.1.62 “Dispute” has the meaning ascribed to such term in Section 15.10.

1.1.63 “Effective Date” has the meaning ascribed to such term in the Preamble.

1.1.64 “EMA” means the European Medicines Agency and any successor agency thereto in the EU having substantially the same function.

1.1.65 “EU” means the European Union or any successor union of European states thereto having a substantially similar function.

1.1.66 “European Clinical Trial Countries” means [\*\*\*].

1.1.67 “Excluded Licensing Transaction” means (a) a license or sublicense granted to an academic collaborator, service provider, contract research organization, contract manufacturer or similar Third Party that does not grant to such Third Party any right to Commercialize the Product (other than, in the case of a CMO, the right to commercially manufacture PB2452 or the Product on behalf of PB or its Affiliates, without any other right to Commercialize the Product), or (b) a license or sublicense not involving a grant of rights to the Product (by way of example and not of limitation, a license or sublicense to develop and commercialize any product based on PB’s proprietary ELP technology, including PB1046 and PB1023).

1.1.68 “Exclusive Period” means, subject to the earlier termination of the AZ License, (a) in the case of the conduct of human clinical trials with respect to a Competing Product, the period beginning on the Effective Date and ending on November 21, 2022, and (b) in the case of the sale or offer for sale of a Competing Product, the period beginning on the Effective Date and ending on November 21, 2024.

1.1.69 “Exercise Price” has the meaning set forth in Section 8.1.

1.1.70 “Executive Officers” means the executive officers of each of PB and SFJ identified on Exhibit E.

1.1.71 “Existing Licenses” means: (a) the License, Development and Commercialization Agreement dated March 28, 2019, between PB and ImmunoForge Co., Ltd., including the ancillary agreements between such parties entered into in connection therewith; and (b) the License Agreement dated April 13, 2018, between PB and [\*\*\*], as amended.

1.1.72 “Existing PB Intellectual Property” has the meaning ascribed to such term in Section 11.1.1.1.

1.1.73 “Exploit” has the meaning ascribed to such term in the AZ License.

1.1.74 “FDA” means the US Food and Drug Administration and any successor agency thereto in the US having substantially the same function.

1.1.75 “FFDCA” means the US Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.1.76 “Financial Disclosure Form” has the meaning ascribed to such term in Section 3.2.1.4.

1.1.77 “GAAP” means generally accepted accounting principles in the US, as consistently applied by the applicable Party.

1.1.78 “Generic Ticagrelor Product” means an oral formulation of the Ticagrelor Compound that is (a) sold, offered for sale or distributed under: (i) in the U.S., an ANDA (as defined in the FFDCA) that refers to the AstraZeneca Product as the reference listed drug, (ii) in the EU, a marketing authorization for a generic medicinal product granted in accordance with Article 10 of Directive 2001/83/EC or (iii) in any other country or jurisdiction, an equivalent of provisions set forth in clause (i) or clause (ii) and (b) approved in the applicable country or jurisdiction for at least one of the indications for which the AstraZeneca Product is approved in such country or jurisdiction. For purposes of this definition, references to AstraZeneca Product exclude Generic Ticagrelor Products.

1.1.79 “GMP Manufacturer” means the Party that is responsible for ensuring that the Product is manufactured in accordance with GMP.

1.1.80 “Going Concern Cure Period” has the meaning ascribed to such term in Section 3.18.3.

1.1.81 “Going Concern Funding” has the meaning ascribed to such term in Section 4.2.4.

1.1.82 “Going Concern Notice” has the meaning ascribed to such term in Section 3.18.3.

1.1.83 “Good Clinical Practices” or “GCP” means all applicable good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (a) the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (“ICH”) Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for clinical trials on medicinal products; (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto; and (c) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of clinical trial Subjects.



1.1.84 “Good Manufacturing Practices” or “GMP” means all applicable good manufacturing practices including, as applicable, (a) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principals and guidelines of good manufacturing practice; (b) the principles detailed in the US Current Good Manufacturing Practices, 21 CFR Sections 210, 211, 601 and 610; (c) the Rules Governing Medicinal Product in the European Community, Volume IV Good Manufacturing Practice for Medicinal Product; (d) the principles detailed in the ICH Q7A guidelines; and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.1.85 “Government Official” is broadly defined as and includes: (a) any elected or appointed government official (e.g., a member of a ministry of health); (b) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function; (c) any non-US political party officer, employee, or person acting for or on behalf of a non-US political party or candidate for public office; (d) any employee or person acting for or on behalf of a public international organization; (e) all government employees and employees of state-owned enterprises; or (f) any person otherwise categorized as a government official under local law; where “government” is meant to include all levels and subdivisions of non-US governments (i.e., local, regional, or national and administrative, legislative, or executive).

1.1.86 “Governmental Authority” means any supranational, federal, national, state or local court, agency, authority, department, regulatory body or other governmental instrumentality.

1.1.87 “ICH” has the meaning ascribed to such term in Section 1.1.78.

1.1.88 “IDMC” means the independent data monitoring committee, which will be established pursuant to Section 3.9.1.

1.1.89 “IDMC Charter” has the meaning ascribed to such term in Section 3.9.1.

1.1.90 “IND” means an investigational new drug application, clinical trial application, clinical trial exemption, or similar application or submission filed with or submitted to a Regulatory Authority in a jurisdiction that is necessary to initiate human clinical testing of a pharmaceutical product in such jurisdiction, including any such application filed with the FDA pursuant to 21 C.F.R. Part 312.

1.1.91 “Indemnification Claim Notice” has the meaning ascribed to such term in Section 12.2.1.

1.1.92 “Indemnified Party” has the meaning ascribed to such term in Section 12.2.1.

1.1.93 “Indemnifying Party” has the meaning ascribed to such term in Section 12.2.1.

1.1.94 “Indication” means the reversal of the effects of the Ticagrelor Compound in Ticagrelor Compound-treated in at least one of (i) patients with major bleeding or (ii) patients requiring urgent surgery / invasive procedure.

1.1.95 “Information” means technical or scientific know-how, trade secrets, methods, processes, formulae, designs, specifications and data, including biological, chemical, pharmacological, toxicological, pre-clinical, clinical, safety, manufacturing and quality control data and assays; in each case, whether or not confidential, proprietary, patented or patentable.

1.1.96 “Informed Consent” has the meaning ascribed to such term in Section 3.3.2.1.

1.1.97 “Initial Development Cost Payment” has the meaning ascribed to such term in Section 4.2.2(i).

1.1.98 “Initial EU Payment” has the meaning ascribed to such term in Section 6.1.

1.1.99 “Initial Funding Date” has the meaning ascribed to such term in Section 4.2.2(i).

1.1.100 “Initial US Payment” has the meaning ascribed to such term in Section 6.1.

1.1.101 “Intellectual Property” means all intellectual property and industrial property rights of any kind or nature throughout the world, including all US and foreign, (a) Patents; (b) Trademarks; (c) Copyrights; (d) rights in computer programs (whether in source code, object code, or other form), algorithms, databases, compilations and data, technology supporting the foregoing, and all documentation, including user manuals and training materials, related to any of the foregoing; (e) trade secrets and all other confidential information, know-how, inventions, proprietary processes, formulae, models, and methodologies; (f) rights of publicity, privacy, and rights to personal information; (g) all rights in the foregoing and in other similar intangible assets; and (h) all applications and registrations for the foregoing.

1.1.102 “Interim Period” has the meaning ascribed to such term in Section 4.2.2.

1.1.103 “Investigator’s Brochure” means the written document containing a brief description of the drug substance and formulation of the Product, a summary of the pharmacological and toxicological effects of the Product in animals and human nonclinical models, a summary of the pharmacokinetics and biological disposition of the Product in animals and humans, a summary of information relating to safety and effectiveness of the Product in humans obtained from prior clinical studies, and a description of possible risks and side effects to

be anticipated on the basis of prior experience with the Product under investigation or with related drugs.

1.1.104 “IRB” means institutional review board, or its equivalent.

1.1.105 “IRC” means the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder.

1.1.106 “JCC” has the meaning ascribed to such term in Section 5.5.1.

1.1.107 “JDC” has the meaning ascribed to such term in Section 5.4.1.

1.1.108 “JDC Chairperson” has the meaning ascribed to such term in Section 5.4.2.

1.1.109 “JDC Representative(s)” has the meaning ascribed to such term in Section 5.4.1.

1.1.110 “JSC” has the meaning ascribed to such term in Section 5.1.1

1.1.111 “JSC Chairperson” has the meaning ascribed to such term in Section 5.1.2.

1.1.112 “JSC Representative(s)” has the meaning ascribed to such term in Section 5.1.1.

1.1.113 “Licensed Compound” has the meaning ascribed to such term in the AZ License.

1.1.114 “Licensed Know-How” has the meaning ascribed to such term in the AZ License.

1.1.115 “Licensed Patents” has the meaning ascribed to such term in the AZ License.

1.1.116 “Licensed Product” has the meaning ascribed to such term in the AZ License.

1.1.117 “Licensing Transaction” means: (a) a license or sublicense to a Third Party under any of the PB Intellectual Property to Commercialize the Product in the US, Designated European Countries, or Designated Asian Countries (other than, in the case of a Third Party CMO, a license or sublicense to commercially manufacture PB2452 or the Product on behalf of PB or its Affiliates, without any license or sublicense to engage in any other Commercialization activities with respect to the Product); or (b) a sale or transfer to a Third Party of any of the PB Intellectual Property, in each case, other than in conjunction with a permitted assignment of this Agreement pursuant to Section 15.6 in connection with the sale or other transfer of all or substantially all of its business or assets to which this Agreement relates.

For clarity, an assignment of the AZ License to a Third Party in conjunction with a permitted assignment by PB of this Agreement pursuant to Section 15.6 in connection with the sale or other transfer of all or substantially all of its business or assets to which this Agreement relates shall not be deemed a Licensing Transaction.

1.1.118 “Licensing Transaction Agreement” means a definitive agreement for a Licensing Transaction between PB and a Third Party.

1.1.119 “Losses” means liabilities, losses, costs, damages, fees and/or expenses (including reasonable legal expenses and attorneys’ fees) payable to a Third Party.

1.1.120 “Manufacturer” means the company set forth on Exhibit J.

1.1.121 “Material Adverse Event” means (i) an event occurring after the Effective Date that has a material adverse effect on (a) the business, operations, prospects or financial condition of PB, (b) prospect of payment of the Approval Payments by PB, or (c) the development of the Product for the Indication or prospects for Regulatory Approval of the Product for the Indication (it being understood that if the interim results of the Phase 3 Trial do not demonstrate Successful Phase 3 Interim Analysis, it shall be deemed to be a Material Adverse Event), or (ii) if PB has not obtained the SVB Consent within [\*\*\*] of the Effective Date, or (iii) if PB is in default of its obligations under the AZ License (excluding any such default that would not entitle AZ to terminate the AZ License); *provided however*, that none of the following shall constitute, or shall be considered in determining whether there has occurred, a Material Adverse Event: (A) changes in laws or regulations or in the interpretations or methods of enforcement thereof; (B) changes in the pharmaceutical or biotechnology industries in general; or (C) any earthquakes, hurricanes, tsunamis, tornadoes, floods, mudslides, wildfires or other natural disasters, weather conditions, sabotage, terrorism, military action or war (whether or not declared) or other force majeure events in the US or any other country or region in the world.

1.1.122 “Material Anti-Corruption Law Violation” means a violation by a Party or its Affiliate of an Anti-Corruption Law relating to the subject matter of this Agreement that would, if it were publicly known, have a material adverse effect on the other Party or its Affiliate because of its relationship with such Party.

1.1.123 “Maximum Development Costs” has the meaning ascribed to such term in Section 4.1.

1.1.124 “MedImmune” means MedImmune Limited, a limited liability company formed under the laws of the United Kingdom.

1.1.125 “MedImmune Confidential Information” means (a) the terms of the AZ License; and (b) any AstraZeneca Product Know-How and any AstraZeneca Product Improvement.

1.1.126 “MedImmune Pharmacovigilance Agreement” has the meaning ascribed to the term “Pharmacovigilance Agreement” in the AZ License.

1.1.127 “NMPA” means China’s National Medical Products Administration or any successor agency thereto in China having substantially the same function.

1.1.128 “Participation Rights” means with respect to a Party, such Party’s Chief Executive Officer and Chief Medical Officer (or their respective designees) shall be entitled to participate on a silent basis in all meetings with Regulatory Authorities during the Development Term and to the extent practicable such Party shall be entitled to review pre-meeting briefing materials. The other Party shall provide such Party with copies of the minutes of all of the aforementioned meetings within [\*\*\*] after receipt of the final minutes from the applicable Regulatory Authority.

1.1.129 “Party” or “Parties” has the meaning ascribed to such term in the Preamble.

1.1.130 “Patent” will mean patents, patent applications, patent disclosures, and all related continuations, continuations-in-part, divisionals, reissues, re-examinations, substitutions, and extensions thereof.

1.1.131 “PB” has the meaning ascribed to such term in the Preamble.

1.1.132 “PB2452” means the anti-ticagrelor antibody fragment product known as PB2452 (and referred to in the AZ License as “MEDI2452”), as further defined by the protein sequence set forth in Schedule 1.96 to the AZ License.

1.1.133 “PB Confidential Information” means all Confidential Information provided and/or disclosed by or on behalf of PB or its Affiliates, agents or representatives to SFJ or its Affiliates, agents or representatives hereunder. For clarity, PB Confidential Information will include any and all CMC Information.

1.1.134 “PB Costs” has the meaning ascribed to such term in Section 4.2.2(ii)(3).

1.1.135 “PB Financial Statements” has the meaning ascribed to such term in Section 3.18.2.

1.1.136 “PB Indemnified Parties” has the meaning ascribed to such term in Section 12.1.1.

1.1.137 “PB Intellectual Property” means all Intellectual Property owned or Controlled by PB that is necessary or useful for the manufacture, use, sale or import of the Product, including Trial Inventions.

1.1.138 “PB Services” means performing or managing all CMC related activities (including supply of Product for use in the Clinical Trials) and oversight of the Phase 3 Trial in the US and the European Clinical Trial Countries.

1.1.139 “PB SOPs” has the meaning ascribed to such term in Section 3.1.6.

1.1.140 “PB Territory” means the US and the European Clinical Trial Countries.

1.1.141 “Permitted Third Party” means any CRO, Site, Clinical Investigator and/or Vendor to whom PB or SFJ has delegated responsibility or whom PB or SFJ has engaged in connection with the Clinical Trials or any CMO whom PB has engaged to perform CMC related activities (including supply of Product for use in the Clinical Trials). For clarity, Third Parties that have been delegated responsibility by or engaged by a Permitted Third Party will be considered Permitted Third Parties.

1.1.142 “Person” means any individual, corporation, general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, labor union, or other entity or Governmental Authority.

1.1.143 “Personally Identifiable Information” means any information relating to an identified or, in combination with other information, identifiable person or persons captured in an electronic or hardcopy format, including such information as it relates to clinical trials subjects (including key-coded patient data), physicians, clinicians, healthcare professionals, consultants, or other persons participating in the Clinical Trials, and any equivalent definition in the Applicable Laws to the extent that such definition is broader than that provided here.

1.1.144 “Phase 3 Interim Data” means the data collected from the Phase 3 Trial as of database lock for the interim analysis of the Phase 3 Trial expressly contemplated by the Phase 3 Trial Protocol.

1.1.145 “Phase 3 Success Criteria” shall mean that the results of the Phase 3 Trial meet at least one of the two primary endpoints set forth in the Phase 3 Trial Protocol.

1.1.146 “Phase 3 Trial” means the clinical trial of the Product described in PhaseBio Protocol Number PB-CL-004, entitled “A Phase 3, multicenter, open-label, single arm study of PB2452 in Ticagrelor-treated patients with major bleeding or requiring urgent surgery / invasive procedure,” as such protocol may be amended from time to time in accordance with this Agreement.

1.1.147 “Phase 3 Trial Protocol” has the meaning ascribed to such term in Section 2.1.1.

1.1.148 “PHSA” means the Public Health Service Act as set forth at 42 U.S.C. Chapter 6A, as may be amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.1.149 “PK Studies” means the pharmacokinetic study of the Product in Japanese Subjects contemplated by the Development Plan, any pharmacokinetic study of the Product in Chinese Subjects contemplated by the Development Plan, and any other pharmacokinetic study of the Product in Japanese Subjects or Chinese Subjects that may be

required by the PMDA or NMPA, as applicable. PK Studies shall not include any clinical trial of the Product with any efficacy endpoint.

1.1.150 “PMDA” means the Pharmaceuticals and Medical Devices Agency of Japan or any successor agency thereto in Japan having substantially the same function.

1.1.151 “Pre-Approval Commercialization Activities” has the meaning ascribed to such term in Section 4.3.

1.1.152 “Product” means the product containing PB2452 described on Exhibit A.

1.1.153 “Product Filings” has the meaning ascribed to such term in Section 3.1.2.

1.1.154 “Product Supply Costs” has the meaning ascribed to such term in Section 3.14.1.2.

1.1.155 “Program Transfer” has the meaning ascribed to such term in the form of Program Transfer Agreement attached hereto as Exhibit O.

1.1.156 “Program Transfer Agreement” has the meaning ascribed to such term in Section 3.20.

1.1.157 “Protocol” means the Phase 3 Trial Protocol or an SFJ Territory Clinical Trial Protocol.

1.1.158 “Receiving Party” has the meaning ascribed to such term in Section 10.1.

1.1.159 “Regulatory Approval” means conditional or unconditional approval of a BLA for the Product for the Indication: (a) by the FDA in the US; (b) by EMA in the EU or by the applicable national Regulatory Authority in any individual Designated European Country; (c) by the PMDA in Japan; or (d) by the NMPA in China. For clarity, “Regulatory Approval” excludes any pricing or reimbursement approval that may be necessary or useful for marketing or sale of the Product in any country or regulatory jurisdiction. For further clarity, the Parties acknowledge that, as of the Effective Date, PB intends to file a BLA with EMA using the centralized EU filing procedure to seek Regulatory Approval in the EU, and PB neither intends, nor has any obligation under this Agreement, to submit any BLA to, or seek Regulatory Approval from, the applicable national Regulatory Authority in any individual Designated European Country.

1.1.160 “Regulatory Authority” means in a particular country or regulatory jurisdiction in the Territory, any applicable Governmental Authority involved in granting approval to initiate or conduct clinical testing in humans, for Regulatory Approval, including FDA, EMA, PMDA, and NMPA.

1.1.161 “Regulatory Documentation” has the meaning ascribed to such term in the AZ License.

1.1.162 “Research Results” means all Information arising out of, or resulting from, the Clinical Trials and/or the CMC activities contemplated by the Development Program, including the Clinical Trials Database; but excluding AstraZeneca Product Improvements, AstraZeneca Product Know-How, AstraZeneca Product Patents, and Trial Inventions (including Intellectual Property in or to Trial Inventions).

1.1.163 “Serious Safety Issue” means any SUSAR or series of SUSARs directly related to or caused by the administration of the Product in the conduct of the Clinical Trials where such SUSAR or series of SUSARs substantially diminishes the probability of receiving Regulatory Approval for the Product, or results in a Regulatory Authority imposing a clinical hold on further development of the Product which clinical hold is not lifted or removed within [\*\*\*].

1.1.164 “SFJ” has the meaning ascribed to such term in the Preamble.

1.1.165 “SFJ Confidential Information” means all Confidential Information provided and/or disclosed by, or on behalf of, SFJ or its Affiliates, agents or representatives to PB or its Affiliates, agents or representatives hereunder.

1.1.166 “SFJ Final Management Fee” has the meaning ascribed to such term in Section 4.2.3(i).

1.1.167 “SFJ Indemnified Parties” has the meaning ascribed to such term in Section 12.1.2.

1.1.168 “SFJ Interim Management Fee” has the meaning ascribed to such term in Section 4.2.2(ii)(2).

1.1.169 “SFJ Services” means providing global oversight of the CRO and other Third Party Vendors and execution of the Clinical Trials in European Clinical Trial Countries, Japan, and China.

1.1.170 “SFJ SOPs” has the meaning ascribed to such term in Section 3.1.5.

1.1.171 “SFJ Territory” means the Designated Asian Countries.

1.1.172 “SFJ Territory Clinical Trial Protocol” has the meaning ascribed to such term in Section 2.1.1.

1.1.173 “Site” has the meaning ascribed to such term in Section 3.2.1.3.

1.1.174 “SOPs” means the PB SOPs or SFJ SOPs.



1.1.175 “Statistical Analysis Plan” has the meaning ascribed to such term in Section 3.5.6.

1.1.176 “Subject” has the meaning ascribed to such term in Section 3.3.2.1.

1.1.177 “Subject Recruitment Plan” has the meaning ascribed to such term in Section 3.3.1.

1.1.178 “Successful Phase 3 Interim Analysis” means that the interim results of the Phase 3 Trial meet the interim primary endpoint set forth in the Phase 3 Trial Protocol.

1.1.179 “SUSAR” means a suspected unexpected serious adverse reaction, without regard to causality, that is life-threatening (i.e., causes an immediate risk of death) or that results in any of the following outcomes: death; in-patient hospitalization or prolongation of existing hospitalization; persistent or significant disability or incapacity (i.e., substantial disruption of the ability to conduct normal life functions); or a congenital anomaly or birth defect. For clarity, a planned medical or surgical procedure is not, in itself, a SUSAR.

1.1.180 “SVB” means, subject to Section 7.4, Silicon Valley Bank, a California corporation.

1.1.181 “SVB Consent” has the meaning ascribed to such term in Section 7.6.1.2.

1.1.182 “SVB Collateral” means, subject to Section 7.4, “Collateral” as defined in the SVB Loan Agreement.

1.1.183 “SVB Loan” means, subject to Section 7.4, the \$15,000,000 term loan evidenced by the SVB Loan Agreement.

1.1.184 “SVB Loan Agreement” means, subject to Section 7.4, that certain Loan and Security Agreement dated as of March 25, 2019 among SVB, WestRiver Innovation Lending Fund VIII, L.P., and PB, as amended, restated, or otherwise modified from time to time.

1.1.185 “Term” has the meaning ascribed to such term in Section 14.1.

1.1.186 “Territory” of a Party means: (a) in the case of PB, the PB Territory; or (b) in the case of SFJ, the SFJ Territory.

1.1.187 “Third Party” means any Person other than PB, SFJ and their Affiliates.

1.1.188 “Third Party Infringement” means any actual or threatened infringement, misappropriation, or other violation by a Third Party of any Intellectual Property Controlled by PB that relates to this Agreement and/or the Product, including the Trial Inventions.

1.1.189 “Ticagrelor Compound” means (1S,2S,3R,5S)-3-[7-(((1R,2S)-2-(3,4-difluorophenyl)cyclopropyl)amino)-5-(propylthio)-3H-[1,2,3]-triazolo[4,5-d]pyrimidin-3-yl]-5-(2-hydroxyethoxy)cyclopentane-1,2-diol.

1.1.190 “Timeline” has the meaning ascribed to such term in Section 2.3.1.

1.1.191 “Timeline Remediation Plan” has the meaning ascribed to such term in Section 2.3.2.

1.1.192 “Trademarks” means, collectively, all registered and unregistered marks, trade dress rights, logos, taglines, slogans, Internet domain names, web addresses, and other indicia of origin, together with the goodwill associated with any of the foregoing, and all applications, registrations, extensions and renewals thereof, selected for use on the Product.

1.1.193 “Trial Data Package” means all Information, in any form, generated or developed by or on behalf of a Party or any of its Affiliates (including by any of their respective Permitted Third Parties) in the conduct of the Clinical Trials during the Development Term, including the Clinical Trial Database and other data and reports arising out of the Clinical Trials, any Clinical Trial Agreements or any Vendor Agreements or CRO Agreements related to the conduct of the Clinical Trials, including the Research Results; but, in each case, excluding Trial Inventions.

1.1.194 “Trial Invention” means: (a) any invention or discovery, whether or not patentable, made, developed, generated, conceived, or reduced to practice by or on behalf of a Party or any of its Affiliates or Permitted Third Parties, or jointly by or on behalf of the Parties or any of their respective Affiliates or Permitted Third Parties, in the course or as a result of the conduct of any Clinical Trial or any other activity conducted pursuant to this Agreement, including, without limitation, any improvement to any Existing PB Intellectual Property; and (b) all Intellectual Property in any of the items described in the preceding clause (a); but excluding, in each case, AstraZeneca Product Improvements, AstraZeneca Product Know-How and AstraZeneca Product Patents.

1.1.195 “UCC” means the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of Delaware; provided, that, to the extent that the UCC is used to define any term herein and such term is defined differently in different Articles or Divisions of the UCC, the definition of such term contained in Article or Division 9 shall govern; and provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection or priority of, or remedies with respect to, the SFJ Security Interest on any SFJ Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of Delaware, the term “UCC” shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority or remedies and for purposes of definitions relating to such provisions.

1.1.196 “US”, “U.S.” or “USA” means the United States of America, its territories and possessions, including Puerto Rico.

1.1.197 “US Approval Payments” has the meaning ascribed to such term in Section 6.1.

1.1.198 “US Commercialization Rights” shall mean any license or grant of other rights exclusive or non-exclusive to Commercialize the Product for the Indication in the US (other than a license or grant of other rights to a CMO to commercially manufacture PB2452 or the Product on behalf of PB or its Affiliates, without any license or grant of other rights to engage in any other Commercialization activities with respect to the Product).

1.1.199 “VAD” means the value added data set, including the data in the format as described in the Statistical Analysis Plan.

1.1.200 “Vendor(s)” has the meaning ascribed to such term in Section 2.4.2.

1.1.201 “Vendor Agreement” has the meaning ascribed to such term in Section 2.4.2.

1.2 Construction. For purposes of this Agreement: (1) words in the singular will be held to include the plural and vice versa as the context requires; (2) the words “including” and “include” will mean “including, without limitation,” unless otherwise specified; (3) the terms “hereof,” “herein,” “herewith,” and “hereunder,” and words of similar import will, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement; and (4) all references to “Section” and “Exhibit,” unless otherwise specified, are intended to refer to a Section or Exhibit of or to this Agreement.

1.3 Conflicts. In the event of any conflict between the terms of this Agreement, the Protocol and/or any other Exhibit, the Protocol will control (as applicable), followed by the terms of this Agreement, and followed by any applicable other Exhibit.

## ARTICLE 2

### THE CLINICAL TRIALS

#### 2.1 The Protocols.

2.1.1 The Protocols. The protocol for the Phase 3 Trial (the “Phase 3 Trial Protocol”) as it exists on the Effective Date has separately been mutually agreed upon by the Parties in writing. The protocol for each Clinical Trial (other than the Phase 3 Trial) of the Product to be conducted in the SFJ Territory (each, an “SFJ Territory Clinical Trial Protocol”) will be prepared by SFJ in consultation with PhaseBio and approved by the JDC within [\*\*\*].

#### 2.1.2 Changes to the Protocols.

2.1.2.1 Any changes to the Phase 3 Trial Protocol, including any country-specific appendices required by Applicable Law and changes made in response to any communications with any Regulatory Authorities, that require a submission to a Regulatory Authority, an IRB or other ethics committee, will be prepared by PB, with support from SFJ, and

will require the JDC's approval, which will not be unreasonably withheld or delayed and which will be communicated to the Parties as soon as reasonably practicable following the JDC's receipt of the draft amendment from PB. Any changes to an SFJ Territory Clinical Trial Protocol, including changes made in response to any communications with a Regulatory Authority, an IRB or other ethics committee in the SFJ Territory, will be prepared by SFJ, with support from PB, and will require the JDC's approval, which will not be unreasonably withheld or delayed and which will be communicated to the Parties as soon as reasonably practicable following the JDC's receipt of the draft amendment from SFJ.

2.1.2.2 If either Party believes that a Protocol requires amendment to comply with any Applicable Laws or based on any communications from any Regulatory Authorities, such Party will inform the JDC. If the JDC agrees that such an amendment is required by any Applicable Laws the JDC will provide the applicable Party (PB in the case of the Phase 3 Trial or SFJ in the case of any other Clinical Trial) with written notice thereof as soon as reasonably practicable, and such Party, with support from the other Party, will prepare a draft amendment to such Protocol, which will only be effective and part of such Protocol upon approval by the JDC pursuant to Section 5.2.2, which approval will not be unreasonably withheld and which will be communicated to the Parties as soon as reasonably practicable following the JDC's receipt of the draft amendment from such Party.

2.1.3 Protocol Approval. SFJ will be responsible for obtaining all necessary approvals of each Protocol (including as required by Applicable Laws) within the SFJ Territory, and PB will be responsible for obtaining all necessary approvals of the Phase 3 Trial Protocol (including as required by Applicable Laws) within the PB Territory, in each case prior to commencing the applicable Clinical Trial in such Party's Territory. Each Party will reasonably co-operate with the other in such regard.

## 2.2 Sponsor.

2.2.1 Sponsorship and Responsibilities. PB will be the sponsor of the Clinical Trials in the PB Territory. SFJ will be the sponsor of the Clinical Trials in the SFJ Territory. SFJ in the SFJ Territory, and PB in the PB Territory, will have all responsibilities of a sponsor as specified in Applicable Laws, except, in the case of the Phase 3 Trial in the European Clinical Trial Countries, that SFJ shall perform certain activities that are PB's responsibilities as sponsor as set forth in Exhibit G.

2.2.2 Compliance with the Protocol and Applicable Laws. Each Party will conduct the Phase 3 Trial within its Territory, and SFJ will conduct each other Clinical Trial in the SFJ Territory, and perform all other responsibilities assigned to it hereunder in connection with any such Clinical Trial in compliance with the applicable Protocol, all Applicable Laws and the terms hereof.

2.2.3 Diligence. Each Party will conduct due diligence with respect to each Permitted Third Party used by such Party to ensure that such Permitted Third Party can comply with all applicable terms and obligations of this Agreement and Applicable Laws.

## 2.3 Compliance with the Timeline.

2.3.1 The Timeline. The timeline for conducting the Clinical Trials is attached as Exhibit I hereto (the "Timeline"). In conducting the Clinical Trials, the Parties will use Commercially Reasonable Efforts to complete each activity specified on the Timeline (each, a "Clinical Trial Activity") by the date specified for such Clinical Trial Activity on the Timeline. The Parties will notify the JDC in writing upon completion or achievement of each of their designated Clinical Trial Activities.

2.3.2 Failure to Complete a Clinical Trial Activity. If a Party fails to, or knows that it will not, complete a Clinical Trial Activity in accordance with the timeline specified for such Clinical Trial Activity on the Timeline, that Party will promptly notify the JDC. Within [\*\*\*] of such written notice, if the Party has failed to, or knows that it will not, complete (a) any Clinical Trial Activity within [\*\*\*] of the date for the Clinical Trial Activity on the Timeline or (b) the final Clinical Trial Activity within [\*\*\*] of the date for the final Clinical Trial Activity on the Timeline, the Party will provide the JDC with a written remediation plan detailing the means by which, and the date on which, that Party expects to be able to complete the relevant Clinical Trial Activities (each, a "Timeline Remediation Plan"). Following receipt thereof, the JDC Representatives will discuss and consider in good faith such Timeline Remediation Plan. If the JDC approves such Timeline Remediation Plan (such approval not to be unreasonably withheld or delayed), the JDC will provide the appropriate Party with written notice thereof, specifying the dates on which the Party will be required to update the JDC of its progress with respect thereto. If the JDC is unable to approve such Timeline Remediation Plan, the matter will be decided by the JSC in accordance with Section 5.2. After approval of a Party's Timeline Remediation Plan, if such Party believes in good faith that any modification to such Timeline Remediation Plan is necessary or appropriate, such Party may propose such modification to the JDC and shall disclose to the JDC any additional information or circumstances that have become known to such Party that form the basis for its request for modification. The JDC will discuss and consider such in good faith such modification, which shall be subject to JDC approval (such approval not to be unreasonably withheld or delayed) as described above.

2.3.3 Failure to Complete a Timeline Remediation Plan. If PB fails to complete a Clinical Trial Activity it is responsible for as outlined in an approved Timeline Remediation Plan, then SFJ has the right to withhold any quarterly fixed payments due to PB pursuant to Section 4.2 until the Clinical Trial Activity is completed, in which event SFJ will not be considered in breach of this Agreement for withholding any such amounts any amounts due to PB pursuant to this Section 2.3.3. If either Party fails to complete a Clinical Trial Activity it is responsible for as outlined in an approved Timeline Remediation Plan, then the other Party, at its sole discretion, may assume responsibility for completing such Clinical Trial Activity, in which event:

2.3.3.1 in the case of SFJ's assumption of responsibility for completing a Clinical Trial Activity that was to have been performed by PB, (a) the costs incurred by SFJ in completing such Clinical Trial Activity shall be included as Development Costs hereunder and

(b) in no event shall any failure or delay by SFJ in performing any of its obligations hereunder that are dependent upon the completion of such Clinical Trial Activity constitute a breach of this Agreement or entitle PB to terminate this Agreement or exercise any remedy available to it under this Agreement; and

2.3.3.2 in the case of PB's assumption of responsibility for completing a Clinical Trial Activity that was to have been performed by SFJ, (a) an amount equal to the costs incurred by PB in completing such Clinical Activity shall be deducted (i) first from the SFJ Interim Management Fee until the SFJ Interim Management Fee is reduced to zero, and (ii) thereafter from the SFJ Final Management Fee, and (b) in no event will any such costs incurred by PB be included in actual Development Costs for purposes of Section 14.2, and (c) in no event shall any failure or delay by PB in performing any of its obligations hereunder that are dependent upon the completion of such Clinical Trial Activity constitute a breach of this Agreement or a Material Adverse Event, or entitle SFJ (i) to withhold any quarterly fixed payments due to PB or other amounts SFJ is obligated to pay or incur pursuant to Section 4.2, (ii) to terminate this Agreement or (iii) to exercise any other remedy available to it under this Agreement, including the remedy set forth in Section 3.20.

## 2.4 Approved CROs and Approved Vendors.

2.4.1 Approved CROs. Except as otherwise provided herein, a Party may delegate any of its responsibilities described in Section 2.2 to its Affiliates (subject to Section 15.1) and/or any CRO that is either listed on Exhibit B or is approved in advance by the JDC (in either case, an "Approved CRO"). Each Party will be required to enter into a written agreement with each Approved CRO utilized by such Party (each, a "CRO Agreement") on commercially reasonable and customary terms, consistent with industry standards for similar agreements and sufficient to enable such Party to comply with its obligations hereunder with respect to the delegated responsibilities, including, but not limited to, Section 2.2.2, and the terms pertaining to ownership of Intellectual Property and publications, and treatment of Confidential Information.

2.4.2 Approved Vendors. Each Party will be permitted to contract for services, equipment, tools, materials and/or supplies required for the Clinical Trials or Regulatory Approval with any Person that is either listed on Exhibit C or is approved in advance by the JDC (each, an "Approved Vendor"). Such Party will be required to enter into a written agreement with each such Person (each, a "Vendor Agreement") on commercially reasonable and customary terms, consistent with industry standards for similar agreements and sufficient to enable such Party to comply with its obligations hereunder with respect to the contracted activities, including, but not limited to, the terms pertaining to publications and ownership of Intellectual Property, and treatment of Confidential Information.

2.4.3 Responsibility. For clarity, each Party will remain responsible for all of its obligations under this Agreement, notwithstanding any delegation to an Affiliate or an Approved CRO or any contracting to an Approved Vendor. Each Party shall use Commercially Reasonable Efforts to oversee the services of its Affiliates and any Approved CRO or Approved Vendor utilized by such Party to provide services hereunder.

## 2.5 Background Materials and Reasonable Assistance.

### 2.5.1 Background Materials.

2.5.1.1 Promptly following the Effective Date, PB will provide SFJ with all copies of documents and information Controlled by PB that SFJ, acting in good faith, identifies as reasonably necessary for SFJ to perform its Development Program responsibilities hereunder (the “Background Materials”), except to the extent the provision of any such documents is otherwise provided for in this Agreement. For clarity, PB will remain the sole owner of, and will retain all right, title and interest in, to and under all Background Materials, including all Intellectual Property thereto, and the Background Materials will be PB Confidential Information.

2.5.1.2 If, during the Development Term, any additional documents and/or information that PB Controls are reasonably necessary for the performance of SFJ’s Development Program responsibilities, SFJ may request such documents and/or information (with reasonable specificity) from PB, and PB will provide such documents and/or information as reasonably necessary to SFJ (and such documents will be deemed Background Materials).

2.5.2 Questions Pertaining to the Phase 3 Trial Protocol. Promptly following the Effective Date during the Development Term, PB will identify one (1) individual with knowledge of the Phase 3 Trial Protocol and the Product who will be made available at reasonable times during normal business hours in such employee’s country of residence upon reasonable advance notice to answer SFJ’s questions directly pertaining to such Protocol.

## **ARTICLE 3**

### **CLINICAL TRIALS ACTIVITIES, REGULATORY APPROVAL AND RESPONSIBILITIES**

#### 3.1 Parties’ Roles and Responsibilities.

3.1.1 PB Responsibilities. PB will have primary responsibility for conducting the Phase 3 Trial in the US and the European Clinical Trial Countries, provided that SFJ will provide operational support for and assist with the conduct of the Phase 3 Trial in the European Clinical Trial Countries as specified on Exhibit G and will enter into Clinical Trial Agreements with Sites in the European Clinical Trial Countries and CRO Agreements for the Phase 3 Trial in the European Clinical Trial Countries. Except as expressly set forth in Section 3.1.2 with respect to the PK Studies, PB will have sole responsibility for interactions with Regulatory Authorities in the US and the European Clinical Trial Countries during the Development Term with SFJ to have Participation Rights. Thereafter, if the Phase 3 Trial meets the Phase 3 Trial Success Criteria, PB will use Commercially Reasonable Efforts to perform all activities associated with submitting BLAs and seeking Regulatory Approval for the Indications in the US and the Designated European Countries.

3.1.2 SFJ Responsibilities. SFJ will have primary responsibility for conducting the Phase 3 Trial in the Designated Asian Countries and sole responsibility for conducting the other Clinical Trials in the Designated Asian Countries (provided that SFJ may elect not to conduct Clinical Trials in Hong Kong). If SFJ elects to conduct any PK Study in Japanese Subjects in the US or Chinese Subjects in the US, PB shall, with SFJ's assistance and cooperation, file an appropriate amendment to the US IND for the Product with the protocol for such PK Study, and SFJ may conduct such PK Study in the applicable Subjects in the US in accordance with such protocol. In connection with any Japanese or Chinese PK Study during the Development Term, (i) SFJ will have sole responsibility for interactions with Regulatory Authorities in Japan and China, with PB to have Participation Rights, and (ii) PB, as the sponsor of the US IND for the Product, will have primary formal responsibility for interactions with the FDA regarding any PK Study conducted in Japanese Subjects or Chinese Subjects (as applicable) in the US, with SFJ to have Participation Rights, but, as between PB and SFJ (but not vis-à-vis the FDA), SFJ shall, in consultation with PB, determine the strategy for such interactions, and, except to the extent contrary to Applicable Law or in violation of PB's duties as the sponsor of such US IND, PB's interactions with the FDA shall at all times be consistent with SFJ's strategy. Thereafter, if the Phase 3 Trial meets the Phase 3 Trial Success Criteria and the necessary endpoints are met in the other Clinical Trials in the SFJ Territory, SFJ will use Commercially Reasonable Efforts to perform all activities associated with submitting BLAs and seeking Regulatory Approval for the Indication in Japan and China, and PB will use Commercially Reasonable Efforts to perform all activities associated with seeking Approval for the Indication in the Designated European Countries. Upon approval of a BLA for the Product for the Indication by NMPA in China or PMDA in Japan, SFJ, on behalf of itself and its Affiliates, shall, and hereby does, assign to PB all of SFJ's and its Affiliates' right, title and interest in and to all INDs, BLAs and Regulatory Approvals (including all amendments and supplements to any of the foregoing) and other filings with, and formal submissions to, NMPA or PMDA, respectively, and other applicable Regulatory Authorities in such country, in each case, with respect to the Product in such country (collectively, "Product Filings"). Within [\*\*\*] after assignment of such Product Filings in the applicable country, SFJ shall deliver to PB: (a) true, correct and complete copies of all Product Filings in such country (in each case, whether held in the name of SFJ or any of its Affiliates), and disclose to PB in writing all previously-undisclosed Research Results within the Trial Data Package; (b) formally transfer or assign, or cause to be formally transferred or assigned, into the name of PB or its designee all Product Filings in such country (in each case, whether held in the name of SFJ or any of its Affiliates); and (c) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect, evidence, register and record the transfer, assignment or other conveyance of such rights to PB or its designee.

3.1.3 Regulatory Interactions. Without limitation to Section 3.12.5, SFJ shall, except to the extent a need for exigent action prevents it from doing so, cooperate with PB to provide MedImmune with copies of SFJ's initial BLA relating to the Product to PMDA or NMPA, as applicable, a reasonable amount of time (but no less than [\*\*\*]) prior to the anticipated date for the applicable submission to allow MedImmune to review and comment on such BLA, and SFJ shall consider all comments and proposed revisions from MedImmune in good faith in connection with effecting such submission. SFJ shall cooperate with PB in PB's



consultation with MedImmune regarding, and in keeping MedImmune informed of, the status of the preparation of the dossier rationale and proposed labeling with respect to the Product in the SFJ Territory. Upon MedImmune's request (as communicated by PB to SFJ), SFJ shall promptly (and in any event, within [\*\*\*]) provide to MedImmune access to and copies of any Regulatory Documentation necessary or reasonably useful for MedImmune to Exploit the AstraZeneca Product or update the label with respect thereto.

3.1.4 Compliance. Each Party will conduct its portion of the Development Program and perform all other of its duties and responsibilities hereunder in accordance with the Development Plan and in material compliance with all Applicable Laws. PB will use Commercially Reasonable Efforts to oversee the Manufacture of the Product, and PB will materially comply, and PB will require that all Permitted Third Parties of PB materially comply, with all Applicable Laws with respect to the analysis, storage, handling, disposal and transfer of the Product. SFJ will materially comply, and SFJ will require that all Permitted Third Parties of SFJ materially comply, with all Applicable Laws with respect to the storage, handling, disposal and transfer of all quantities of Product supplied by or on behalf of PB for use in the conduct of Clinical Trials in the European Clinical Trial Countries and the Designated Asian Countries.

3.1.5 SFJ SOPs. Subject to the terms hereof, SFJ will, within the SFJ Territory, use Commercially Reasonable Efforts to conduct, or ensure that the Approved CRO conducts, the Clinical Trials in accordance with the standard operating procedures (the "SFJ SOPs") that will be provided to PB within [\*\*\*] following the later of (i) the Effective Date or (ii) the selection of such Approved CRO for PB's review and comment. Following the Effective Date, SFJ may amend any SOPs; provided that with respect to material amendments to SOPs that pertain to Clinical Trials activities and/or other obligations that are, or will be, performed by SFJ or any Permitted Third Party utilized by SFJ during the remainder of the Term or any time thereafter as set forth in this Agreement, SFJ will provide the JDC with a copy of each such amendment to permit the JDC Representatives to review and comment on such amendments and SFJ will reasonably consider incorporating such comments.

3.1.6 PB SOPs. Subject to the terms hereof, PB will, within the PB Territory, use Commercially Reasonable Efforts to conduct, or ensure that the Approved CRO conducts, the Clinical Trials in accordance with the standard operating procedures (the "PS SOPs") that will be provided to SFJ within [\*\*\*] following the later of (i) the Effective Date or (ii) the selection of such Approved CRO for SFJ's review and comment. Following the Effective Date, PB may amend any SOPs; provided that with respect to material amendments to SOPs that pertain to Clinical Trials activities and/or other obligations that are, or will be, performed by PB or any Permitted Third Party utilized by PB during the remainder of the Term or any time thereafter as set forth in this Agreement, PB will provide the JDC with a copy of each such amendment to permit the JDC Representatives to review and comment on such amendments and PB will reasonably consider incorporating such comments.

## 3.2 Sites and Clinical Investigators.

### 3.2.1 Selection of Sites and Investigators.

3.2.1.1 SFJ will select the study sites within the SFJ Territory and the European Clinical Trial Countries to conduct the Clinical Trials and will inform the JDC in advance of SFJ's choice of each study site; the JDC will have the right to reject any such site(s) which the JDC will determine in its reasonable judgment are not appropriate.

3.2.1.2 PB will select the study sites within the US to conduct the Clinical Trials and will inform the JDC in advance of PB's choice of each study site; the JDC will have the right to reject any such site(s) which the JDC will determine in its reasonable judgment are not appropriate.

3.2.1.3 Each Party will enter, and will ensure that its Affiliates enter, and each Approved CRO will enter, into an agreement with each study site; such an agreement will be substantially in the form to be provided by PB and agreed upon by the Parties within [\*\*\*] following the Effective Date (the "Clinical Trial Agreement") (upon execution of such Clinical Trial Agreement, such study site will be deemed a "Site"). If a study site requires any material changes to such form Clinical Trial Agreement, SFJ with regard to the European Clinical Trial Countries and the SFJ Territory and PB with regard to the US, will inform the JDC and seek JDC approval of such change, and the JDC will not unreasonably withhold such approval. For clarity, each Clinical Trial Agreement will be on commercially reasonable and customary terms, consistent with industry standards for similar agreements and sufficient to enable such Party to comply with its obligations hereunder with respect to such Clinical Trial, including, but not limited to, Section 2.2.2, the terms pertaining to ownership of Intellectual Property and publications, and treatment of Confidential Information.

3.2.1.4 The Clinical Trials Agreements will also require that the Clinical Investigators, any sub-investigators (e.g., research fellows, residents and associates) and any others required by Applicable Law at each Site complete a financial disclosure document substantially in the form to be agreed upon by the Parties (the "Financial Disclosure Form"). For clarity, if any of the foregoing individuals do not complete such Financial Disclosure Form, such individuals may not participate in, or do any work in connection with, the Clinical Trials.

### 3.2.2 Obligations During the Clinical Trials Conduct.

3.2.2.1 During the Development Term, SFJ will conduct meetings with the Clinical Investigators within the SFJ Territory and the European Clinical Trial Countries, and PB will conduct meetings with the Clinical Investigators in the US (each, a "Clinical Investigator Meeting"), of which the JDC will be provided with reasonable advance notice and in which the other Party will have the right (but not the obligation) to attend and participate. Minutes of Clinical Investigator Meetings will be made available to the JDC upon request.

3.2.2.2 Each Party will provide the JDC with copies of all communications relevant to the Clinical Trials and provided to all Sites, and upon request of the

JDC, provide the JDC with copies of any other communications between such Party and any individual Sites and/or any Affiliate or Approved CRO and any individual Sites.

3.2.2.3 If a Party terminates a Site, such Party will inform the JDC with the reason for such termination and if reasonably practicable, such notice will be provided reasonably in advance of such termination.

3.2.2.4 PB in the PB Territory and SFJ in the SFJ Territory will be responsible for preparing and submitting any INDs and amendments thereto to Regulatory Authorities as required by Applicable Laws in the countries for which Sites have been selected. PB will prepare the CMC Information and any updates to this information and submit it to the applicable Regulatory Authority as required by Applicable Laws.

### 3.3 Subjects and Informed Consent.

3.3.1 Subject Recruitment Plan. The Parties will comply with the subject recruitment plan for the Clinical Trials, which will be established by each Party for their respective Territory, except in the case of the European Clinical Trial Countries which SFJ will be responsible for, and communicated to the JDC, for approval by the JDC not to be unreasonably withheld, within a reasonable period of time after the Effective Date not to exceed [\*\*\*] of the Effective Date (the “Subject Recruitment Plan”) in recruiting subjects to participate in the Clinical Trials. For clarity, prior to engaging in any recruiting activities, the Parties, within their respective Territory, will ensure that the applicable IRBs and/or other ethics committees approve any related materials and activities as required by the JDC and all Applicable Laws.

#### 3.3.2 Informed Consent.

3.3.2.1 PB, with support from SFJ, will prepare the informed consent document(s) for use in the Clinical Trials. Each Party will ensure that the informed consent of each subject participating in a Clinical Trial in such Party’s respective Territory, except in the case of the European Clinical Trial Countries which SFJ will be responsible for, be obtained in accordance with all Applicable Laws, including completion of the informed consent document. Such informed consent document for a Clinical Trial will be substantially in the form to be approved by the JDC within [\*\*\*] following approval by the JDC of the final Protocol for such Clinical Trial (collectively, “Informed Consent”) (upon obtaining such Informed Consent, a prospective subject will be deemed a “Subject”). For clarity, the Informed Consent document that each Subject signs will expressly state that each Subject understands that such Party is providing support for the Clinical Trials and will authorize disclosure of data and results related to the Clinical Trials to PB or SFJ, as applicable, for any purpose, subject to all Applicable Laws.

3.3.2.2 PB will ensure that the Informed Consent has been obtained by a Permitted Third Party from each Subject in the US prior to administration of the Product to such Subject in accordance with the Protocol. SFJ will ensure that the Informed Consent has been obtained by a Permitted Third Party from each Subject in the European Clinical Trial Countries and the SFJ Territory prior to administration of the Product to such Subject in accordance with the Protocol.

3.3.3 Inclusion and Exclusion Criteria. Neither Party will waive, and each Party will require that its Permitted Third Parties do not waive, any exclusion or inclusion criteria specified in the Protocol.

#### 3.4 Investigator's Brochure.

3.4.1 Investigator's Brochure. PB will maintain the Investigator's Brochure for the Product. SFJ will, promptly following receipt of written notice from PB of the need for an Investigator's Brochure update, provide PB with all information regarding the Clinical Trials that is necessary to enable PB to update the Investigator's Brochure.

3.4.2 Parties' Responsibilities. Promptly following the Effective Date, PB will provide SFJ with the most recent version of the Investigator's Brochure. PB will also promptly provide SFJ with any updated versions of the Investigator's Brochure. Each Party will ensure that each Site in such Party's respective Territory, except in the case of the European Clinical Trial Countries which SFJ will be responsible for, and all applicable IRBs and other ethics committees receive a copy of, and promptly receive any updates to, the Investigator's Brochure.

#### 3.5 Data Collection and Data Management.

3.5.1 CRF. PB, with support from SFJ, will be responsible for preparing the form of CRF for the Clinical Trials in accordance with the Protocol.

##### 3.5.2 Data Management Plan.

3.5.2.1 Each Party will use Commercially Reasonable Efforts to comply with the data management plan to be agreed upon by the Parties within [\*\*\*] following approval by the JDC of the final Protocol (the "Data Management Plan"). For clarity, the Data Management Plan will be agreed upon by the Parties prior to recruitment of subjects for the Clinical Trials.

3.5.2.2 With respect to any data collected in connection with the Clinical Trials, each Party will ensure that such data is held in one or more appropriate facilities with information security protections in accordance with all Applicable Laws including [\*\*\*].

##### 3.5.3 Clinical Trials Database.

3.5.3.1 PB, with support from SFJ, will use Commercially Reasonable Efforts to establish a Clinical Trials database for the data collected from each Site for the Clinical Trials (the "Clinical Trials Database") within [\*\*\*] following approval by the JSC of the Final Protocol. SFJ with regard to European Clinical Trial Countries and the SFJ Territory and PB with regard to the US will promptly update the Clinical Trials Database upon receiving data for the Clinical Trials from any Site and any other applicable Permitted Third Party, and each Party will ensure that the Sites and such other Permitted Third Parties promptly following collection thereof, provide data in connection with the Clinical Trials to such Party.

3.5.3.2 Each Party will provide the JDC with electronic copies of such data requested by the JDC at JDC meetings and in accordance with Applicable Laws.

3.5.3.3 If, at any time during the Development Term, PB decides to change the format of the database for the Clinical Trials, PB will so notify SFJ and the Parties will cooperate to ensure that the format that PB selects permits SFJ to incorporate the data from the Clinical Trials into its relevant systems and is in compliance with all Applicable Laws.

3.5.3.4 The Vendor responsible for the database will provide SAS datasets to the Parties in accordance with specifications as defined by PB (i) when the data in the Clinical Trials Database are equivalent to [\*\*\*] of total data expected to be recorded in the Clinical Trials Database; (ii) if a safety signal is identified; and/or (iii) if a request is received from the Regulatory Authorities.

3.5.3.5 PB and SFJ will jointly maintain the Clinical Trials Database including ensuring that information included in the Clinical Trials Database is accurate and up-to-date. PB will be responsible for registering, maintaining and updating any registries pertaining to the Clinical Trials to the extent required by any Applicable Laws, including [www.clinicaltrials.gov](http://www.clinicaltrials.gov), [www.clinicalstudyresults.org](http://www.clinicalstudyresults.org), and the PHRMA Website Synopsis.

3.5.4 Clinical Trials Master File. Promptly following the Effective Date, PB and SFJ will jointly establish and maintain a Clinical Trials master file for each Clinical Trial in the format as agreed upon by the JDC (each a "Clinical Trials Master File"). Notwithstanding anything to the contrary herein, neither PB nor SFJ will be permitted to delegate its rights and obligations pursuant to this Section 3.5.4 to any Permitted Third Parties without the prior approval of the JDC, except either Party may delegate its rights and obligations pursuant to this Section 3.5.4 to any of its Affiliates.

3.5.5 Source Data Verification. PB will be responsible for source verification of data records in the US, and SFJ will be responsible for source data verification of data records in European Clinical Trial Countries and the SFJ Territory. At either Party's request, a Party will provide the other Party with copies of any reports relating to source data verification and other types of Clinical Trials audits.

3.5.6 Statistical Analysis. PB will perform any statistical analysis required in accordance with the statistical analysis plan for the Clinical Trials to be agreed upon by the Parties within [\*\*\*] of the Effective Date (the "Statistical Analysis Plan").

### 3.6 Audits.

3.6.1 Each Party will conduct quality oversight inspections and audits of the facilities and services of the Permitted Third Parties utilized by such Party in accordance with its standard operating procedures and will provide the other Party with copies of such audit reports upon request.

3.6.2 During the Development Term, PB will conduct quality oversight inspections and audits of the manufacturing facilities for the Product in accordance with its internal policies and PB will provide SFJ with copies of such audit reports.

3.7 Monitoring. PB in the US, and SFJ in European Clinical Trial Countries and the SFJ Territory, will monitor the Clinical Trials, and share information with the JDC pertaining to monitoring the Clinical Trials, in accordance with the monitoring plan for the Clinical Trials to be agreed upon by the Parties within [\*\*\*] following the Effective Date.

### 3.8 IRBs and Other Ethics Committees.

3.8.1 Each Party will be responsible for obtaining the approval of the IRBs and other ethics committees required prior to commencing, and during, the Clinical Trials at every Site in such Party's Territory, except in the case of the European Clinical Trial Countries which SFJ will be responsible for.

3.8.2 Each Party will ensure that IRBs and such other relevant ethics committees have current registrations and accreditations as required by Applicable Law and will provide all ethics committees, including all IRBs, and Regulatory Authorities, with all necessary documentation prior to, and during the course of, the Clinical Trials as required by Applicable Law.

3.8.3 PB in the US, and SFJ in the SFJ Territory and in the European Clinical Trial Countries, will be responsible for responding to all queries from the IRBs and other ethics committees; provided that (a) the other Party will make itself reasonably available to assist with any such queries and (b) if such query relates solely to the CMC Information, the Manufacturing Dossier, and/or preclinical studies, PB will prepare the applicable response and provide SFJ with a copy thereof.

### 3.9 IDMC

3.9.1 PB will establish an IDMC for the Clinical Trials, [\*\*\*]. For clarity, [\*\*\*].

3.9.2 PB will ensure that the IDMC is provided with all information and data that it requires [\*\*\*], and SFJ will reasonably cooperate with PB in such regard.

### 3.10 Environmental Health and Safety.

3.10.1 In conducting the Clinical Trials, each Party will comply with all Applicable Laws relating to environmental, health and/or safety matters and will be solely responsible for establishing material and specimen handling guidelines and for ensuring use of controls, including appropriate personal protective equipment, that minimize potential worker exposure, obtaining the material safety data sheets and providing the appropriate training for workers who will be potentially exposed to the Product.

3.10.2 Each Party will promptly notify the JDC, in writing, of any worker claims of suspected occupational illnesses related to working with the Product, regardless of whether such claims are received during the Development Term or any time thereafter. After termination of this Agreement for whatever reasons, or expiration of this Agreement, each Party will promptly notify the other Party of any worker claims of suspected occupational illnesses related to working with the Product during the Development Term, of which it has knowledge.

### 3.11 Completion of the Clinical Trials.

3.11.1 PB will use Commercially Reasonable Efforts to keep the Sites participating in the Phase 3 Trial in the US, and SFJ will use Commercially Reasonable Efforts to keep the Sites participating in each Clinical Trial in European Clinical Trial Countries and the SFJ Territory, operational, including continuing to dose Subjects with the Product in accordance with the Protocol and conducting any follow-up work required, until the Completion Date for such Clinical Trial. As a Clinical Trial is completed or otherwise terminated at each Site for which a Party is responsible, such Party will close out such Clinical Trial as specified in the Protocol, including performing all Subject follow-up and providing the other Party with all Clinical Trial data not provided as of such date. For clarity, copies of documents, including any CRFs and the Clinical Trials Master File will be made available and/or transferred to the other Party upon the other Party's request, or at the other Party's option, destroyed (provided that such destruction is in compliance with ICH guidelines). Notwithstanding the foregoing, neither Party will provide the other Party with any Personally Identifiable Information.

3.11.2 Upon the Completion Date of a Clinical Trial, SFJ will return to the location specified by PB at such time, or, at PB's option, destroy, any unused Product from such Clinical Trial (SFJ's expenses in doing so will be included in Development Costs), and will comply with all Applicable Laws in so returning or destroying such Product.

3.11.3 The CSR for the Phase 3 Trial will be prepared by PB, with support from SFJ, in compliance with all Applicable Laws, including ICH E3 guidelines. The final, signed CSR for the Phase 3 Trial (the "Final Phase 3 Trial CSR") will be provided to SFJ promptly following the Completion Date of the Phase 3 Trial. In the event that there are any additional safety or efficacy data pertaining to the Phase 3 Trial that come into the possession of PB after it has provided SFJ with the Final Phase 3 Trial CSR, PB will prepare and promptly provide SFJ with a supplement to such CSR. The CSR for each Clinical Trial (other than the Phase 3 Trial) conducted in the SFJ Territory will be prepared by SFJ, with support from PB, in compliance with all Applicable Laws, including ICH E3 guidelines. The final, signed CSR for each such Clinical Trial conducted in the SFJ Territory (each, a "Final SFJ Territory CSR") will be provided to PB promptly following the Completion Date of such Clinical Trial. In the event that there are any additional safety or efficacy data pertaining to any such other Clinical Trial conducted in the PB Territory that come into the possession of SFJ after it has provided PB with the Final SFJ Territory CSR for such Clinical Trial, SFJ will prepare and promptly provide PB with a supplement to such CSR.

### 3.12 Commercially Reasonable Efforts.

3.12.1 Timely performance of the Clinical Trials and receipt of Regulatory Approval is important to the success of this Agreement. Each Party will use Commercially Reasonable Efforts to complete the Clinical Trials according to the Timeline and, if the Clinical Trials is successful, to obtain Regulatory Approval, in such Party's Territory. In the event that either Party fails to complete the Clinical Trials in their respective Territory according to the Timeline and this failure is not cured as set forth in Section 14.2.1, the other Party may terminate this Agreement pursuant to Section 14.2.1, or following discussion by the JSC that such Party failed to use Commercially Reasonable Efforts, the other Party may assume the roles and responsibilities of such Party; provided that in the event of such failure by SFJ, SFJ will remain obligated to pay the costs under Section 4.2.2(ii).

3.12.2 In the event of Successful Phase 3 Interim Analysis, PB will use Commercially Reasonable Efforts to obtain Regulatory Approval for the Product for the Indication (a) by the FDA in the US, including the obligation to file a BLA for the Product for the Indication with the FDA within [\*\*\*] of Successful Phase 3 Interim Analysis, provided that PB shall not be required to file such BLA earlier than the estimated date for BLA filing in the US based on Successful Phase 3 Interim Analysis set forth in the Timeline, and (b) by EMA in the EU (or, as applicable, by the applicable national Regulatory Authorities in one or more Designated European Countries), including the obligation to file a BLA for the Product for the Indication with EMA (or the applicable national Regulatory Authorities in one or more Designated European Countries) within [\*\*\*] of Successful Phase 3 Interim Analysis, provided that PB shall not be required to file such BLA earlier than the estimated date for BLA filing in the EU based on Successful Phase 3 Interim Analysis set forth in the Timeline.

In the event that PB fails to use Commercially Reasonable Efforts to so obtain Regulatory Approval for the Product for the Indication, including the obligation to file a BLA for the Product for the Indication with each of the FDA and EMA (or the applicable national Regulatory Authorities in one or more Designated European Countries) by the dates set forth in this Section 3.12.2, and this failure is not cured within [\*\*\*] after receipt of written notice from SFJ requesting such cure, SFJ may either terminate this Agreement pursuant to Section 14.2.1, or assume PB's regulatory filing activities (in which event SFJ's expenses in assuming such regulatory filing activities shall be deemed to be Development Costs).

3.12.3 Upon achievement of the Phase 3 Success Criteria, PB will use Commercially Reasonable Efforts to obtain Regulatory Approval for the Product for the Indication by the FDA in the US and by EMA in the EU (or, as applicable, by the applicable national Regulatory Authorities in one or more Designated European Countries), including the obligation to file a BLA for the Product for the Indication with each of the FDA and EMA (or the applicable national Regulatory Authorities in one or more Designated European Countries) within [\*\*\*] of the date of achievement of the Phase 3 Success Criteria. In the event that PB fails to use Commercially Reasonable Efforts to so obtain Regulatory Approval for the Product for the Indication, including the obligation to file a BLA for the Product for the Indication with each of the FDA and EMA (or the applicable national Regulatory Authorities in one or more



Designated European Countries) within [\*\*\*] of the date of achievement of the Phase 3 Success Criteria, and this failure is not cured as set forth in Section 14.2.1, SFJ may either terminate this Agreement pursuant to Section 14.2.1, or assume PB's regulatory filing activities (in which event SFJ's expenses in doing so shall be deemed to be Development Costs).

3.12.4 Upon achievement of the Phase 3 Success Criteria or Successful Phase 3 Interim Analysis if conditional approval based on interim data is allowed by the relevant Regulatory Authority (or, if later, achievement of the primary endpoint(s) of any other Japan-specific or China-specific Clinical Trial, as applicable, being conducted by SFJ in the applicable country that is necessary for filing of a BLA with PMDA or NMPA, respectively), SFJ will use Commercially Reasonable Efforts to obtain Regulatory Approval for the Product for the Indication by the PMDA in Japan and by the NMPA in China, including the obligation to file a BLA for the Product for the Indication with each of the PMDA and the NMPA within [\*\*\*] of the date of achievement of the Phase 3 Success Criteria, provided that SFJ shall not be required to file such BLA earlier than the estimated date for BLA filing in Japan or China (as applicable) based on the Phase 3 Success Criteria or Successful Phase 3 Interim Analysis if conditional approval based on interim data is allowed by the relevant Regulatory Authority as set forth in the Timeline or, if later, achievement of the primary endpoint(s) of any other Japan-specific or China-specific Clinical Trial, as applicable, being conducted by SFJ in the applicable country that is necessary for filing of a BLA with PMDA or NMPA, respectively. In the event that SFJ fails to use Commercially Reasonable Efforts to so obtain Regulatory Approval for the Product for the Indication, including the obligation to file a BLA for the Product for the Indication with each of the PMDA and the NMPA within [\*\*\*] of (a) the date of achievement of the Phase 3 Success Criteria or, (b) if later, achievement of the primary endpoint(s) of any other Japan-specific or China-specific Clinical Trial, as applicable, being conducted by SFJ in the applicable country that is necessary for filing of a BLA with PMDA or NMPA, respectively, or Successful Phase 3 Interim Analysis if conditional approval based on interim data is allowed by the relevant Regulatory Authority, and this failure is not (i) caused by PB's failure to perform its obligations hereunder or (ii) cured as set forth in Section 14.2.1, PB may either terminate this Agreement pursuant to Section 14.2.1, or assume SFJ's regulatory filing activities, in which event an amount equal to PB's expenses in doing so [\*\*\*]. In no event will any such costs incurred by PB be included in actual Development Costs for purposes of Section 14.2.

3.12.5 Regulatory Approvals. The Parties acknowledge that regulatory matters with respect to the Product will reasonably require coordination with regulatory matters with respect to the AstraZeneca Product, and SFJ agrees to cooperate in good faith with PB and MedImmune as reasonably necessary for and in relation to each of PB and SFJ, on the one hand, and MedImmune, on the other hand, to obtain and maintain regulatory approvals (including Regulatory Approvals) with respect to the Product in the case of PB and SFJ and with respect to the AstraZeneca Product in the case of MedImmune. Prior to submitting any written or electronic communication to a Regulatory Authority in a country of the Territory with respect to AstraZeneca Product that would reasonably be expected to require a change to the Regulatory Authority-approved full prescribing information for the AstraZeneca Product for such country, SFJ shall cooperate with PB in PB's consultation with MedImmune. SFJ shall keep PB reasonably informed of its efforts to obtain and maintain Regulatory Approval for the Product in

the SFJ Territory and developments with respect thereto, including SFJ's expected timing with respect to submission and receipt of any and all Regulatory Approvals.

### 3.13 Pharmacovigilance and Safety Information Exchange.

3.13.1 SFJ acknowledges that PB is bound by the pharmacovigilance and safety information exchange requirements of Sections 3.4.4(b) through 3.4.4(h) of the AZ License and the terms of the MedImmune Pharmacovigilance Agreement (a copy of which is attached hereto as Exhibit N) relating both to the Product and the AstraZeneca Product and that, in order to comply with its obligations to MedImmune, PB must obtain SFJ's commitment to provide adverse event and other safety information relating to the Product and to AstraZeneca Product to PB in a form and within the applicable time periods necessary for PB to comply with Sections 3.4.4(b) through 3.4.4(h) of the AZ License and the terms of the MedImmune Pharmacovigilance Agreement.

3.13.2 The safety reporting units from each of the Parties shall meet and shall within [\*\*\*] of the Effective Date agree upon a written agreement for exchanging adverse event and other safety information relating to the Product (the "Pharmacovigilance Agreement"). The Pharmacovigilance Agreement will ensure that adverse event and other safety information are exchanged upon terms that will permit (a) PB to comply with Sections 3.4.4(b) through 3.4.4(h) of the AZ License and the terms of the MedImmune Pharmacovigilance Agreement, and (b) each Party to comply with Applicable Laws and requirements of Regulatory Authorities.

3.13.3 Each Party agrees not to enter in to any clinical activity implicating pharmacovigilance obligations for the Product in its respective Territory prior to execution of the Pharmacovigilance Agreement.

### 3.14 Product.

#### 3.14.1 Supply of the Product.

3.14.1.1 PB will be the GMP Manufacturer of the Product for the Clinical Trials, either directly or through an Approved Vendor. In particular, with respect to the Clinical Trials, PB will maintain in force a clinical supply agreement with a CMO that has sufficient capacity to manufacture and supply GMP-compliant Product for the Clinical Trials in a timely manner in accordance with a clinical supply schedule approved by the JDC (as amended by the JDC from time to time, the "Clinical Supply Schedule").

3.14.1.2 During the Development Term, PB will supply, as determined by the JDC, or cause to be supplied, as determined by the JDC to SFJ GMP-compliant Product manufactured in compliance with the then-current CMC Information included in the IND submitted to the applicable Regulatory Authority for the Clinical Trials in the European Clinical Trial Countries or the SFJ Territory, as applicable, in accordance with the Clinical Supply Schedule as set forth in a clinical supply agreement to be entered into between the Parties within [\*\*\*] after the Effective Date (the "Clinical Supply Agreement"). The costs for the supply of the Product for the Clinical Trials in the US, the European Clinical Trial Countries and the SFJ

Territory (the “Product Supply Costs”) will be borne by PB. Each Party will provide the JDC at each JDC meeting with quarterly reports regarding inventory of the Product and the reasonably anticipated needs for the Product to ensure that PB can supply the Product in accordance with the Clinical Supply Schedule.

### 3.14.2 Use of the Product.

3.14.2.1 SFJ will (i) in conducting the Clinical Trials, only use Product supplied by PB or such Third Parties designated by PB; (ii) only use the Product supplied by PB or Third Parties designated by PB, and require that its Permitted Third Parties that receive any of the Product supplied by PB or Third Parties designated by PB only use such Product, for the sole purpose of conducting the Clinical Trials in accordance with the respective Protocols; and (iii) ensure subject dosing compliance per the respective Protocols for the Clinical Trials conducted in the European Clinical Trial Countries or the SFJ Territory. Dosage and Administration Instructions will be provided to SFJ by PB sufficiently in advance of the Clinical Trials’ commencement.

3.14.2.2 PB in the US, and SFJ in the European Clinical Trial Countries and the SFJ Territory, will be responsible for ensuring that the Product is administered solely to the Subjects in Clinical Trials conducted by such Party in accordance with the respective Protocols. For each dose administered to a Subject in a Clinical Trial conducted by such Party, such Party will implement procedures and ensure that records are maintained specifying the date and time that such dose of the Product is administered, the amount of the Product administered to such Subject, the lot number of the Product from which such dosage came, and the number of the Subject to which such dosage was administered. Each Party shall provide copies of such records to the other Party upon the other Party’s reasonable request.

3.15 Complaints Related to the Product. During the Development Term, each Party will promptly forward to the other Party any complaints that it receives related to the Product. PB in the US, and SFJ in European Clinical Trial Countries and the SFJ Territory, will respond to any complaints of which such Party becomes aware relating to the Product provided that the other Party will provide reasonable cooperation in connection therewith. Notwithstanding the foregoing, if a complaint pertains to the manufacturing, appearance or general physical characteristics of the Product or other processes at the manufacturing facility, PB will be solely responsible for responding to such complaint.

3.16 Recall of the Product in Connection with Study Prior to Approval. If the Product is recalled for safety reasons or GMP non-compliance prior to Regulatory Approval, PB in the US, and SFJ in European Clinical Trial Countries and the SFJ Territory, will be responsible for the operational execution of such recall. PB will cooperate with SFJ in connection with any such recall in European Clinical Trial Countries or the SFJ Territory. The costs for such any such recall will be at PB’s expense and not be a Development Cost, unless such recall and/or costs were based on the material breach of this Agreement, intentional misconduct, or gross negligence of SFJ or any of its Affiliates or Permitted Third Parties, in which case, SFJ will bear the expense of any such recall and such expense will not be a Development Cost.

3.17 Compliance with Laws. SFJ and its Affiliates and PB and its Affiliates will comply, and each Party will use Commercially Reasonable Efforts to ensure that all Permitted Third Parties utilized by such Party comply, with all Applicable Laws with respect to the storage, handling, disposal and transfer of the Product, and each Party assumes sole responsibility for the violation of such Applicable Laws by such Party or any of its Affiliates or its Permitted Third Parties.

3.18 Disclosures.

3.18.1 During the Development Term, each Party shall provide the other Party at meetings of the JSC (or in advance of such meetings as part of the information that may be distributed to JSC members prior to such meetings or, if no such meeting is held in a [\*\*\*], directly to the other Party) at least once during each [\*\*\*] with summaries of all data known to such Party material to obtaining Regulatory Approval, and material Product safety data in all indications (including but not limited to Serious Safety Issues), including such material data relating to efficacy, clinical sites, patient enrollment and drop-out rates, CMC and other material manufacturing data, and material communications with Regulatory Authorities.

3.18.2 PB shall (a) provide SFJ with quarterly unaudited financial statements and annual audited financial statements (the "PB Financial Statements") promptly following the availability thereof (and no later than the date filed with the SEC) and provide to SFJ on a quarterly basis concurrently with the applicable PB Financial Statements [\*\*\*], (b) promptly notify SFJ of achieving the Successful Phase 3 Interim Analysis and the Phase 3 Success Criteria, and (c) on or prior to the end of each [\*\*\*] during the Term [\*\*\*]. At least [\*\*\*] during the Term, upon SFJ's request, Executive Officers of PB shall meet with Executive Officers of SFJ to review and discuss PB's financial condition and operations. [\*\*\*].

3.18.3 PB shall provide prompt written notice (a "Going Concern Notice") to SFJ if (i) PB determines in accordance with GAAP that it is probable that PB will be unable to meet its obligations as they become due within one year after the date that PB's financial statements for the then-current quarter are issued, or available to be issued or (ii) a "Going Concern" footnote is included in any of the PB Financial Statements required to be delivered by PB to SFJ pursuant to Section 3.18.2 (a "Going Concern Condition"). During the applicable Going Concern Cure Period (as defined below), PB shall have the ability to remedy the Going Concern Condition through a restructuring of PB's costs and operations (provided that such restructuring does not adversely impact PB's ability to perform its obligations hereunder) or through raising additional capital in one or more financing or strategic transactions so as to enable PB to meet its obligations as they become due within such one year period including performing all of PB's obligations hereunder. "Going Concern Cure Period" shall mean the [\*\*\*] period following delivery of a Going Concern Notice, provided that if SFJ does not offer and fund Going Concern Funding as set forth in Section 4.2.4 sufficient to remedy the Going Concern Condition within such [\*\*\*] period, the Going Concern Cure Period shall be extended to [\*\*\*] following delivery of such Going Concern Notice.

3.19 Exclusivity Commitment of SFJ. During the applicable Exclusive Period, SFJ shall not, and shall cause its Affiliates not to, either by itself or through a Third Party, conduct human clinical trials of, or sell, offer for sale or have sold:

3.19.1 any Competing Product (other than Product) alone or in combination (whether fixed dose or co-packaged) with one (1) or more other active ingredients;

3.19.2 any combination (whether fixed dose or co-packaged) with one (1) or more other active ingredients of the Product and a Competing Product;

3.19.3 any agent that is intended as an antidote to, or is intended to neutralize, abrogate or reverse the antiplatelet activity of, (i) any Brilinta Competing Product alone or in combination (whether fixed dose or co-packaged) with one (1) or more other active ingredients or (ii) both the Ticagrelor Compound and a Brilinta Competing Product;

3.19.4 without limitation to the foregoing, any agent with dual activity as (i) an antidote to, or for use as an agent to neutralize, abrogate or reverse the antiplatelet activity of, the Ticagrelor Compound and (ii) an antidote to, or for use as an agent to neutralize, abrogate or reverse the antiplatelet activity of, any Brilinta Competing Product; or

3.19.5 any Brilinta Competing Product.

3.20 Program Transfer. In the event that, at any time after payment to PB of the Initial Development Cost Payment on the Initial Funding Date, PB shall (a) fail to pay any amounts payable to SFJ hereunder within [\*\*\*] of the date such payment is due, or (b) become in default of its obligations under the AZ License (excluding (x) any such default that would not entitle AZ to terminate the AZ License and (y) any such default that is caused by SFJ's breach of its obligations under this Agreement), or (c) (i) fail to remedy the Going Concern Condition within the Going Concern Cure Period as set forth in Section 3.18.3 or (ii) refuse to accept the Going Concern Funding if offered by SFJ as set forth in Section 4.2.4, then, SFJ may deliver written notice to PB electing to cause PB's business related to the Product to be transferred to SFJ (the "Program Transfer Notice"), and shall deliver a copy of the Program Transfer Notice to MedImmune concurrently with delivery to PB, and within [\*\*\*] following the delivery of the Program Transfer Notice, PB and SFJ shall execute and deliver a Program Transfer Agreement in the form attached hereto as Exhibit O (the "Program Transfer Agreement") which shall effect the Program Transfer effective as of the date SFJ delivers the Program Transfer Notice to PB. For clarity, this Section 3.20 shall not be effective prior to payment to PB of the Initial Development Cost Payment on the Initial Funding Date.

## ARTICLE 4

### DEVELOPMENT COSTS

4.1 Development Costs. SFJ will be obligated to pay or incur up to One Hundred Twenty Million U.S. Dollars (\$120,000,000.00) of Development Costs ("Maximum Development Costs") in accordance with the funding schedule set forth in Section 4.2. Any

Development Costs in excess of the sum of the Maximum Development Costs and any Going Concern Funding will be borne by PB.

#### 4.2 Funding Schedule.

4.2.1 Subject to Section 4.2.4 below, SFJ will pay or incur up to a total of \$120 million of Development Costs as set forth in the table below and as detailed below, as set forth in Sections 4.2.2 and 4.2.3. For clarity, this Section 4.2.1 sets forth a summary of the payments due under Sections 4.2.2 and 4.2.3 only, and does not create any additional obligation to pay or incur development costs in excess of those obligations set forth in Sections 4.2.2 and 4.2.3.

To be paid 45 days after the later of (a) the Effective Date, and (b) the date that PB has obtained the SVB Consent, as set forth in Section 4.2.2(i)	To be paid prior to the date of Successful Phase 3 Interim Analysis, as set forth in Section 4.2.2(ii)	To be paid after the date of Successful Phase 3 Interim Analysis, as set forth in Section 4.2.3	Total
\$10 Million	Up to \$80 Million*	At least \$20 Million and up to \$30 Million	Up to \$120 Million

\* In addition to initial \$10 Million.

4.2.2 Following the Effective Date and prior to the date of first availability of the Phase 3 Interim Data (the “Interim Period”), SFJ shall pay or incur up to \$90 million of Development Costs as follows:

(i) The initial payment of Ten Million U.S. Dollars (\$10,000,000.00) set forth in the table above, to reimburse PB for development costs incurred by PB prior to the Effective Date (the “Initial Development Cost Payment”), shall be payable on the date (“Initial Funding Date”) that is forty-five (45) days after the later of (a) the Effective Date, and (b) the date that PB has obtained the SVB Consent.

(ii) Following payment to PB of the Initial Development Cost Payment on the Initial Funding Date:

(1) SFJ shall promptly pay all Approved Third Party Vendor Costs incurred by SFJ or PB in connection with the Clinical Trials during the Interim Period.

(2) SFJ shall pay to SFJ Affiliates the amount of [\*\*\*] to reimburse such SFJ Affiliates for their internal costs of overseeing the CROs in European Clinical Trial Countries and the SFJ Territory and for the management of the Clinical Trials in European Clinical Trial Countries and the SFJ Territory during the Interim Period (the “SFJ Interim Management Fee”).

(3) SFJ shall pay PB an amount equal to \$90 million, less (a) the Initial Development Cost Payment, (b) the SFJ Interim Management Fee, and (c) the Approved Third Party Vendor Costs paid or incurred by SFJ during the Interim Period, (which Approved Third Party Vendor Costs amount shall be estimated and agreed to by the Parties no later than [\*\*\*]) to be paid pro rata in six (6) equal quarterly payments within [\*\*\*] after the end of each Calendar Quarter beginning with the Calendar Quarter ending September 30, 2020 through the Calendar Quarter ending December 31, 2021.

Notwithstanding anything else contained herein to the contrary, in no event shall SFJ be required to pay or incur Development Costs in excess of \$90 million during the Interim Period. If the Development Costs during the Interim Period exceed \$90 million, PB shall pay or incur all such excess Development Costs including continuing to provide the PB Services during the Interim Period at the expense of PB unless otherwise agreed to in writing by SFJ. For the avoidance of doubt, if the Successful Phase 3 Interim Analysis is not achieved, SFJ shall have no obligation to pay or incur any further Development Costs.

4.2.3 Following the date of the Successful Phase 3 Interim Analysis and until the end of the Development Term (the "Final Period"):

(i) SFJ shall pay to SFJ Affiliates the amount of [\*\*\*] to reimburse such SFJ Affiliates for their internal costs of overseeing the CROs in European Clinical Trial Countries and the SFJ Territory and for the management of the Clinical Trials in European Clinical Trial Countries and the SFJ Territory during the Final Period (the "SFJ Final Management Fee").

(ii) SFJ shall pay PB the amount (the "PB Costs") by which the Elected Total Amount (defined below) exceeds the sum of (a) the Initial Development Cost Payment, (b) the SFJ Interim Management Fee, (c) the SFJ Final Management Fee, and (d) all Approved Third Party Vendor Costs (as estimated and agreed to by the Parties prior to the start of the Final Period which are expected to be paid by SFJ through the end of the Development Term) paid or incurred by SFJ (including Approved Third Party Vendor Costs paid by SFJ during the Interim Period) and (e) the amounts paid to PB pursuant to Section 4.2.2(ii)(3), which PB Costs shall be paid pro rata in five (5) equal quarterly payments within [\*\*\*] after the end of each Calendar Quarter beginning for the Calendar Quarter ending March 31, 2022 through the Calendar Quarter ending March 31, 2023, provided however, in no case earlier than forty-five (45) days after the later of (i) Approved Third Party Vendor Costs have been agreed to by the Parties and (ii) PB has elected and informed SFJ of the Elected Total Amount. Within [\*\*\*] after achievement of the Successful Phase 3 Interim Analysis, PB shall notify SFJ in writing of the total amount of Development Costs (inclusive of all Development Costs paid or incurred since the Effective Date) that PB elects to have SFJ fund (the "Elected Total Amount"), which shall be no less than \$110 million and no more than \$120 million.

(iii) In the event that the Development Costs paid by SFJ after paying all required payments under the preceding provisions of this Section 4.2 shall be less than the Elected Total Amount then any remaining balance of the Elected Total Amount shall be paid to PB by SFJ within [\*\*\*] of the last payment under Section 4.2.3(ii), to be used by PB for

commercialization activities, and such amount paid by SFJ shall be deemed to be included in Development Costs.

Subject to Section 4.2.4 below, but notwithstanding anything else contained herein to the contrary, in no event shall SFJ be required to pay or incur Development Costs in excess of \$120 million in total. If the total Development Costs exceed \$120 million, PB shall pay or incur all such excess Development Costs including paying all excess Approved Third Party Vendor Costs and Product Supply Costs and continuing to provide the PB Services at the expense of PB unless otherwise agreed to in writing by SFJ. In connection with the Development, manufacture and Commercialization of the Product and fulfillment of PB's obligations hereunder, PB shall spend at least an amount equal to the amount of funding paid by SFJ to PB pursuant to this Section 4.2.

4.2.4 If PB has not eliminated a Going Concern Condition by the expiration of the applicable Going Concern Cure Period, SFJ shall have the option, but not the obligation, to pay PB an additional amount (the "Going Concern Funding") up to the amount necessary to eliminate the Going Concern Condition as reasonably determined by SFJ after consultation with PB, which amount (if any) must be accepted by PB and shall be included in Development Costs and shall be paid by SFJ within [\*\*\*] after the expiration of the Going Concern Cure Period. The Going Concern Funding shall be placed in an escrow account established by PB with the JSC to have sole authority to release funds from escrow to be spent as directed by the JSC to fulfill PB's obligations hereunder.

4.3 Pre-Commercialization Costs. During the Term, PB will be solely responsible at its own cost (subject to Sections 4.2) for performing those activities reasonably necessary to prepare for Commercial Launch of the Product in the Territory (the "Pre-Approval Commercialization Activities"). Such Pre-Approval Commercialization Activities may include at PB's sole discretion creating educational or marketing materials, establishing distribution channels and designing packaging and labeling, in each case as reasonably necessary to Commercialize the Product in the Territory.

## ARTICLE 5

### GOVERNANCE

#### 5.1 Joint Steering Committee.

5.1.1 Representatives. Within [\*\*\*] after the Effective Date, the Parties will establish a joint steering committee to oversee and manage the collaboration (the "JSC"). Each Party initially will appoint [\*\*\*] to serve as representatives to the JSC (the "JSC Representatives"), with each JSC Representative having knowledge and expertise regarding developing products similar to the Product and sufficient decision-making authority within the applicable Party to make decisions on behalf of such Party within the scope of the JSC's decision-making authority and, if any such representative is not an employee of the appointing Party, such representative shall execute a confidentiality agreement in form and substance acceptable to the other Party (and, for the avoidance of doubt, the appointing Party shall remain



responsible to the other Party for any noncompliance by such representative with such confidentiality obligations). Each Party may replace its JSC Representatives at any time upon written notice to the other Party.

5.1.2 Chairperson. The JSC chairperson (“JSC Chairperson”) shall be designated from the Parties’ JSC Representatives and shall serve for a term of one (1) year. SFJ shall appoint the first JSC Chairperson and subsequent appointments will rotate on an annual basis between PB and SFJ. The JSC Chairperson will be responsible for drafting and circulating the draft agenda and ensuring minutes are prepared.

5.1.3 Meetings. From the Effective Date, through the date of the Regulatory Approval in the US, at least one Designated European Country, and either Japan or China, the JSC will meet at least [\*\*\*] (and for clarity, such meetings are intended to be conducted via teleconference) unless the Parties mutually agree otherwise. Either Party may call a special meeting of the JSC (by videoconference or teleconference) during the Development Term by providing at least [\*\*\*] prior written notice to the other Party, which notice shall include a reasonably detailed description of the matter, in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting.

5.1.4 Participants. The JSC may invite individuals who are not JSC Representatives to participate in JSC meetings; provided that (a) all JSC Representatives of both Parties consent to such non-member’s participation; and (b) such non-member has executed a confidentiality agreement in form and substance acceptable to the non-inviting Party (and, for the avoidance of doubt, the inviting Party shall remain responsible to the non-inviting Party for any noncompliance by such individual with such confidentiality obligations). For clarity, such non-members will have no voting rights at the JSC.

5.1.5 Alliance Managers. Each Party shall appoint an individual to act as an alliance manager for such Party (each, an “Alliance Manager”) by providing the name and contact information for the Alliance Manager to the JSC. Each Party may change its Alliance Manager from time to time in its sole discretion upon written notice to the JSC. The Alliance Managers shall be the primary point of contact for the Parties regarding the activities contemplated by the Agreement, and the Parties shall use reasonable efforts to ensure that any requests for information and data made outside of the JSC are made through the Alliance Managers. The Alliance Managers shall attend all meetings of the JSC. For clarity, the Alliance Managers may also be members of the JSC.

5.1.6 Costs. Each Party will bear its own expenses relating to the meetings and activities of the JSC.

## 5.2 JSC Responsibilities and Decision-Making.

5.2.1 Responsibilities (Review and Discuss). The JSC’s responsibilities will include reviewing and discussing (but not approving) the following:

5.2.1.1 Oversight of the Parties' collaboration including (i) overall strategic direction, (ii) developing strategies to maximize the value of the Product for the Indication, and (iii) reviewing and commenting on the Development Program and Regulatory Approval strategies;

5.2.1.2 material changes in the Development Program, including changes required by, or made to respond to comments from, a Regulatory Authority, that do not require approval pursuant to Section 5.2.2.2;

5.2.1.3 the activities related to, the progress of, and the costs incurred in connection with, the Development Program;

5.2.1.4 summaries of the Research Results;

5.2.1.5 forecast of the estimated timeline (on at least a [\*\*\*] basis) for its development activities with respect to the Product for the Indication;

5.2.1.6 the addition to the Development Program of any new Clinical Trials testing the efficacy of the Product for the Indication; and

5.2.1.7 any other matters the Parties mutually agree in writing will be, or are expressly provided in this Agreement to be, reviewed and discussed by the JSC.

5.2.2 Responsibilities (Review and Approve). The JSC's responsibilities will include reviewing and approving (in each case, such approval not to be unreasonably withheld, conditioned or delayed) the following:

5.2.2.1 the Protocols;

5.2.2.2 [\*\*\*]:

(a) [\*\*\*];

(b) [\*\*\*];

(c) [\*\*\*];

(d) [\*\*\*];

(e) [\*\*\*]; or

(f) [\*\*\*].

(g) commercially reasonable budgets of CRO and Third Party Vendor costs (the "Approved Third Party Vendor Costs") and Product Supply Costs.

5.2.2.3 any other matters the Parties mutually agree in writing will be, or are expressly provided in this Agreement to be, reviewed and approved by the JSC.

The JSC shall use good faith efforts to approve budgets for the Approved Third Party Vendor Costs and the Product Supply Costs no later than [\*\*\*].

5.2.3 Limitation on Authority. Notwithstanding anything to the contrary set forth in this Agreement, the JSC will have no authority to (x) amend, modify or waive compliance with this Agreement, or (y) resolve any dispute concerning the validity, interpretation, construction of, or breach of this Agreement.

5.2.4 Decision-Making. PB shall retain sole decision-making authority over all matters within the scope of the JSC's oversight other than the matters described in the foregoing 5.2.2. The unanimous approval of the JSC will be required with respect to all matters within its decision-making authority as described in the foregoing Section 5.2.2. The JSC Representatives of each Party will collectively have one (1) vote. The presence of at least one of each Party's JSC representatives constitutes a quorum for the conduct of business at any JSC meeting, and no vote of the JSC may be taken without a quorum present. If the JSC cannot reach consensus on an issue for which it has decision-making authority, then PB shall have the final decision-making authority, provided that if SFJ disagrees with any such PB decision with regard to any of the matters set forth in Section 5.2.2, then, at SFJ's request, the matter shall be escalated to the Executive Officers for attempted resolution by good faith negotiations during a period of [\*\*\*]. If, notwithstanding such good faith negotiations, the Executive Officers fail to resolve such matter prior to expiration of such [\*\*\*] negotiation period, and SFJ in good faith continues to disagree with such PB decision, then SFJ shall have the right to terminate this Agreement as provided in Section 14.2.10 upon written notice to PB delivered within [\*\*\*] after expiration of such [\*\*\*] negotiation period.

### 5.3 Reports to be Provided to the JSC.

Except as may otherwise be agreed by the Parties, at each JSC meeting PB with regard to the PB Territory and SFJ with regard to the SFJ Territory will provide an update on the progress of the Clinical Trials and PB with regard to the U.S. and the Designated European Countries and SFJ with regard to Japan and China will report on progress toward obtaining Regulatory Approvals.

### 5.4 Joint Development Committee.

5.4.1 Representatives. Within [\*\*\*] of the Effective Date, the Parties will establish a joint development committee to oversee the conduct of the Clinical Trials (the "JDC"). Each Party initially will appoint [\*\*\*] to serve as representatives to the JDC (the "JDC Representatives"), with each JDC Representative having knowledge and expertise regarding developing products similar to the Product and sufficient seniority within the applicable Party to make decisions within the scope of the JDC's decision-making authority. Each Party may replace its JDC Representatives at any time upon written notice to the other Party.

5.4.2 Chairperson. The JDC chairperson ("JDC Chairperson") shall be designated from the Parties' JDC Representatives and shall serve for a term of [\*\*\*]. [\*\*\*] shall

appoint the first JDC Chairperson and subsequent appointments will rotate on [\*\*\*] basis between SFJ and PB. The JDC Chairperson will be responsible for drafting and circulating the draft agenda and ensuring minutes are prepared.

#### 5.4.3 Meetings.

##### 5.4.3.1 Timing.

(i) From the Effective Date through the date of first Regulatory Approval, the JDC will meet at least once every [\*\*\*] (and for clarity, such meetings are intended to be conducted via teleconference) unless the Parties mutually agree otherwise.

(ii) Either Party may call a special meeting of the JDC (by videoconference or teleconference) during the Development Term by at least [\*\*\*] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting.

5.4.3.2 Participants. The JDC may invite individuals who are not JDC Representatives to participate in JDC meetings; provided that (a) the JDC Representatives of both Parties consent to such non-member's participation; and (b) such non-member is subject to confidentiality obligations consistent with those described in ARTICLE 11 of this Agreement. For clarity, such non-members will have no voting rights at the JDC.

5.4.3.3 Costs. For clarity, each Party will bear its own expenses relating to the meetings and activities of the JDC and such costs will not be Development Costs hereunder.

#### 5.4.4 Notice to be Provided to the JDC.

5.4.4.1 Unusual or Unforeseen Events. Each Party will promptly notify the JDC of any unforeseen or unusual events that occur in connection with the Clinical Trials that may affect the quality, integrity, or timeliness of the Clinical Trials.

5.4.4.2 Urgent Safety Measures or Serious Breaches. If either Party becomes aware of (a) any urgent safety measures taken by a Clinical Investigator to protect Subjects against immediate hazard or (b) any serious breaches of the Protocol or any Applicable Laws (including ICH GCP guidelines), such Party will immediately inform the JDC.

5.4.4.3 Regulatory Inspections. Each Party will promptly notify the JDC within [\*\*\*] of any inspection by any Governmental Authority, including any Regulatory Authority, in connection with the Clinical Trials. Each Party will promptly forward to the JDC copies of any inspection findings that a Site receives from any Regulatory Authority.

5.4.4.4 Government Investigations. Each Party will promptly notify the JDC upon learning of any investigations by any Governmental Authority in connection with the Clinical Trials.

5.4.4.5 Notification of Error. If either Party learns of an error or omission in the conduct of the Clinical Trials that could call into question the validity, or otherwise compromise the quality and/or integrity, of part or all of the Clinical Trials or activities conducted in connection therewith, such Party will inform the JDC in writing within [\*\*\*] of either Party learning of such error and/or omission. The members of the JDC will discuss in good faith a remediation plan to address such error within [\*\*\*] of such written notification. Such remediation plan will not be effective unless and until approved by the JDC (such approval not to be unreasonably withheld or delayed). If the JDC approves such remediation plan, the JDC will provide each Party with written notice thereof, specifying the dates on which, and the detail with which the Party responsible for such Clinical Trial will be required to update the JDC of its progress with respect thereto. If the JDC is not able to approve such remediation plan, the matter will be decided by the JSC pursuant to the procedure described in Section 5.2.4.

5.4.4.6 Compliance with Laws. With respect to each of the foregoing Sections 5.4.4.1 through 5.4.4.5, the Party responsible for notifying the JDC will notify the Person to whom notice is required to comply with all Applicable Laws.

5.4.4.7 Progress Reports. Except as may otherwise be agreed to by the Parties, at each JDC meeting the Party responsible for such Clinical Trial will provide an update on the progress and cost of such Clinical Trial and Regulatory Approval as measured against the Timeline.

5.4.4.8 Post-Development Term Notices. Following completion of the Development Term and through the end of the Term, any and all notices required pursuant to this Section 5.4 will be provided to the JSC instead of the JDC.

#### 5.4.5 Responsibilities and Decision-Making.

5.4.5.1 Responsibilities. The JDC's responsibilities will include: (a) approving the initial Protocol (b) approving any changes to the Protocol that requires a submission to a Regulatory Authority, an IRB or other ethics committees; (c) discussing the activities in connection with, the progress of, and the costs incurred in connection with, the Clinical Trials, including updates from any Clinical Investigator Meetings; (d) reviewing and discussing any notices that it receives pursuant to the foregoing Section 5.4.4; (e) discussing and reviewing the Research Results; (f) reviewing and discussing on at least a quarterly basis the forecast Development Costs and Timeline; (g) reviewing and discussing (as necessary) proof of submission of any safety reports to the Regulatory Authorities, Clinical Investigators, IRBs and any other ethics committees; (h) reviewing certain data to be provided by each Party at each JDC meeting as requested by the other Party and in accordance with all Applicable Laws; (i) reviewing performance and progress of the Clinical Trials and Regulatory Approval process; and (j) any other matters the Parties mutually agree will be, or are expressly provided in this Agreement to be, within the responsibilities of the JDC.

5.4.5.2 Decision-Making. The unanimous approval of the JDC will be required with respect to all matters within its decision-making authority as described in the foregoing Section 5.4.5.1. The JDC Representatives of each Party will collectively have one (1)

vote. The presence of at least one of each Party's JDC representatives constitutes a quorum for the conduct of business at any JDC meeting, and no vote of the JDC may be taken without a quorum present. If the JDC cannot reach consensus on an issue for which it has decision-making authority, then such matter will be escalated to the JSC.

#### 5.5 Joint Commercialization Committee.

5.5.1 Representatives. By [\*\*\*], the Parties will establish a joint commercialization committee (the "JCC") to oversee and manage the Commercialization of the Product (excluding direct oversight and management of commercial manufacture of Product, provided that PB shall keep the JCC reasonably informed of commercial manufacturing activities), including PB's compliance with its diligence obligations under the AZ License. Each Party will initially appoint [\*\*\*] to serve as representatives on the JCC (the "JCC Representatives"), with each JCC Representative having knowledge and expertise regarding Commercializing products similar to the Product or knowledge of PB's Commercialization plans and activities for the Product (as applicable) and being reasonably acceptable to the other Party. If any such representative is not an employee of the appointing Party, such representative shall execute a confidentiality agreement in form and substance acceptable to the other Party (and, for the avoidance of doubt, the appointing Party shall remain responsible to the other Party for any noncompliance by such representative with such confidentiality obligations). Each Party may replace its JCC Representatives at any time upon written notice to the other Party.

5.5.2 Information. PB shall provide to the JCC a draft of each Commercialization Plan (as defined in the AZ License) at least [\*\*\*] in advance of the date PB is required to deliver such Commercialization Plan to MedImmune. The JCC shall promptly review and discuss each draft Commercialization Plan.

5.5.3 Chairperson. PB shall designate the JCC chairperson ("JCC Chairperson") from its JCC Representatives. The JCC Chairperson will be responsible for drafting and circulating its Party's draft agenda and ensuring minutes are prepared.

5.5.4 Meetings. From the Effective Date through the date of the Final Approval Payment, the JCC will meet at least every two months (and for clarity, such meetings are intended to be conducted via teleconference), unless the Parties mutually agree otherwise. Either Party may call a special meeting of the JCC (by videoconference or teleconference) by providing at least five (5) Business Days' prior written notice to the other Party, which notice shall include a reasonably detailed description of the matter, in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting.

5.5.5 Participants. The JCC may invite individuals who are not JCC Representatives to participate in JCC meetings; provided that (a) all [\*\*\*] JCC Representatives of both Parties consent to such non-member's participation; and (b) such non-member has executed a confidentiality agreement in form and substance acceptable to the non-inviting Party (and, for the avoidance of doubt, the inviting Party shall remain responsible to the non-inviting Party for any noncompliance by such individual with such confidentiality obligations).

5.5.6 Costs. Each Party will bear its own expenses relating to the meetings and activities of the JCC.

## 5.6 JCC Responsibilities and Decision-Making.

5.6.1 Responsibilities. The JCC's responsibilities will include the following:

5.6.1.1 [\*\*\*].

5.6.1.2 [\*\*\*];

5.6.1.3 [\*\*\*];

5.6.1.4 [\*\*\*];

5.6.1.5 [\*\*\*]; and

5.6.1.6 Any other matters the Parties mutually agree will be, or are expressly provided in this Agreement to be, reviewed and discussed by the JCC.

5.6.2 Decision Making. The unanimous approval of the JCC will be required with respect to all matters within its decision-making authority as described in the foregoing Section 5.6.1. The JCC Representatives of each Party will collectively have one (1) vote. The presence of at least one of each Party's JCC representatives constitutes a quorum for the conduct of business at any JCC meeting, and no vote of the JCC may be taken without a quorum present. If the JCC cannot reach consensus on an issue for which it has decision-making authority, then such matter will be escalated to the JSC.

## ARTICLE 6

### PAYMENTS TO SFJ

6.1 Regulatory Approval. In exchange for the purchase of the Trial Data Package as set forth in Section 11.1.1.4, PB will pay to SFJ, in US Dollars:

6.1.1 following Regulatory Approval by the FDA, an initial payment in the amount set forth below to be made within [\*\*\*] after the date of the Regulatory Approval by the FDA as shown in the table below (the "Initial US Payment") and annual payments in the amounts set forth below on or before each applicable anniversary of the date of such Regulatory Approval (collectively but excluding the Initial US Payment, the "US Approval Payments");

6.1.2 following Regulatory Approval by the EMA, an initial payment in the amount set forth below to be made within [\*\*\*] after the date of the Regulatory Approval by the EMA (or, as applicable, by the national Regulatory Authority in any Designated European Country) as shown in the table below (the "Initial EU Payment") and annual payments in the amounts set forth below on or before each applicable anniversary of the date of the such

Regulatory Approval (collectively but excluding the Initial EU Payment, the “EU Approval Payments”); and

6.1.3 following Regulatory Approval by the PMDA or the NMPA, an initial payment in the amount set forth below to be made within [\*\*\*] after the date of first Regulatory Approval by the PMDA or the NMPA as shown in the table below (the “Initial Japan/China Payment”) and annual payments in the amounts set forth below shall be due on each applicable anniversary of the date of such Regulatory Approval (collectively but excluding the Initial Japan/China Payment, the “Japan/China Approval Payments”);

provided, in each case, that if conditional Regulatory Approval in a geographic territory specified above in Section 6.1.1, 6.1.2 or 6.1.3 is obtained on the basis of Successful Phase 3 Interim Analysis but unconditional Regulatory Approval is not obtained (*i.e.*, the accelerated Regulatory Approval is withdrawn by the applicable Regulatory Authority) in such geographic territory as a result of failure of the final results of the Phase 3 Trial to meet the Phase 3 Success Criteria or failure of any other human clinical trial that the applicable Regulatory Authority requires PB to conduct after the grant of conditional Regulatory Approval as a condition to the grant of unconditional Regulatory Approval to meet the primary endpoint(s) of such trial and the Product is required to be withdrawn from the market in such geographic territory, then PB shall have no obligation to make any additional Approval Payment for such geographic territory that would otherwise have become due during the period after withdrawal of such conditional Regulatory Approval and before such time (if ever) as Regulatory Approval for such geographic territory is again obtained (and for so long thereafter as such Regulatory Approval remains in effect), provided further that with regard to withdrawal of such conditional Regulatory Approval in [\*\*\*].

The Initial US Payment, Initial EU Payment, Initial Japan/China Payment, US Approval Payments, EU Approval Payments and Japan/China Approval Payments are collectively referred to as the “Approval Payments”, and shall be subject to adjustment as provided in Section 6.2. For the sake of clarity, the Initial Japan/China Payment and each of additional Japan/China Approval Payment set forth in the table below shall only be paid once regardless of receipt of Regulatory Approval in both Japan and China.

Approval Payment Schedule	Upon Approval	1yr Anniversary	2yr Anniversary	3yr Anniversary	4yr Anniversary	5yr Anniversary	6yr Anniversary	7yr Anniversary	8yr Anniversary	Total
FDA Approval	5,000,000	[***]	[***]	[***]	[***]	[***]	[***]	[***]	0	330,000,000
EMA Approval	5,000,000	[***]	[***]	[***]	[***]	[***]	[***]	[***]	0	210,000,000
First Approval by either PMDA or NMPA	1,000,000	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	60,000,000
<b>Total</b>	<b>11,000,000</b>	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	<b>600,000,000</b>

6.2 Payment Adjustments. In the event that the actual Development Costs paid or incurred by SFJ hereunder are lower or greater than One Hundred Twenty Million U.S. Dollars (\$120,000,000.00), including by reason of any amount of Going Concern Funding paid by SFJ to



PB in accordance with Section 4.2.4, or in the event that such actual Development Costs are subject to adjustment pursuant to Section 2.3.3, Section 3.12.2 and/or Section 3.12.3, the Approval Payments will be multiplied by a fraction, the numerator of which is such actual amount of Development Costs paid or incurred by SFJ hereunder (as adjusted, to the extent applicable, pursuant to Section 2.3.3, Section 3.12.2 and/or Section 3.12.3) and the denominator of which is One Hundred Twenty Million U.S. Dollars (\$120,000,000.00). In the event that Regulatory Approval is obtained in a particular jurisdiction while Development Costs for other jurisdiction(s) are still being paid or incurred, in which case the Parties shall recalculate the applicable adjustment at such time as the final amount of actual Development Costs is known and determine any true-up payments required to be made by PB with respect to any payment made pursuant to Section 6.1 prior to such time, and PB shall pay any such true-up payment to SFJ within [\*\*\*] after receipt of invoice from SFJ.

6.3 Method and Timing of Payment. The US Approval Payments, EU Approval Payments and Japan/China Approval Payments to SFJ will be due as of the applicable annual anniversary of the date of the applicable Regulatory Approval. SFJ shall deliver invoices to PB for the US Approval Payments, EU Approval Payments and Japan/China Approval Payments at least [\*\*\*] before the applicable anniversary of the date of Regulatory Approval, and such payments will be made by PB on or before the later of (a) [\*\*\*] and (b) [\*\*\*] following delivery of such invoices, by wire transfer to SFJ's account that SFJ shall designate on such invoice. PB will provide SFJ with written notice of each wire transfer to SFJ's account. All amounts payable and calculations under this Agreement shall be in US dollars.

6.4 Late Payments. If PB fails to pay any amount due under this Agreement on the due date therefore, then, without prejudice to any other remedies that SFJ may have, that amount will bear interest from the due date until payment of such amount is made, both before and after any judgment, at a rate equal to, [\*\*\*] percent ([\*\*\*]%) per annum computed on the basis of a year of 360 days for the actual number of days payment is delinquent or if such rate exceeds the maximum amount permitted by Applicable Law, at such maximum rate.

6.5 Taxes. The Parties hereby acknowledge and agree that payments made under this Agreement will be made without reduction for withholding or similar taxes, unless such withholding or similar tax is required (x) by a taxing authority as a result of an audit or examination, (y) due to the assignment of this Agreement or any payment obligation hereunder (to the extent permitted) by SFJ to an Affiliate or Third Party, or (z) as a result of a change in Applicable Laws at any time during the Term. In such case, the Parties shall use commercially reasonable and legal efforts to mitigate the amount of such taxes that would need to be withheld and/or paid. Any amounts withheld pursuant to this Section 6.5 will be timely paid over to the appropriate taxing authority, and will be treated for purposes of this Agreement as having been paid to the Party that otherwise would have received such amounts. In the event of a "determination" within the meaning of Section 1313(a) of the Code that withholding or similar taxes were required but were not properly withheld, the Party that received the relevant payment will indemnify and hold the other Party harmless with respect to such taxes and related Losses.

6.6 Tax Cooperation. The Parties will cooperate and produce on a timely basis any tax forms or reports, including any IRS Forms W-8BEN or W-9, as applicable, reasonably requested by the other Party in connection with any payment made under this Agreement. Each Party will provide to the other Party any tax forms that may be reasonably necessary in order for such Party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party will provide to the other Party any tax forms at least [\*\*\*] prior to the due date for any such payments. Each Party will provide the other with commercially reasonable assistance to enable the recovery, as permitted by law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT. Each Party will provide commercially reasonable cooperation to the other Party, at the other Party's expense, in connection with any official or unofficial tax audit or contest relating to tax payments made with respect to amounts paid or payable to such other Party under this Agreement.

#### 6.7 Buy-Out Option.

6.7.1 Approval Buy-Out Option. Within one hundred and twenty (120) days following the receipt of Regulatory Approval with respect to each of the US, Designated European Countries, and Japan/China, PB shall have the right to make a one-time payment (each, an "Approval Buy-Out Payment") in lieu of all (but not less than all) Approval Payments (as adjusted in accordance with Section 6.2) for the applicable country(ies) (other than the Initial US Payment, Initial EU Payment or Initial Japan/China Payment, as applicable, payable pursuant to Section 6.1 as a result of such Regulatory Approval, in each case, as adjusted in accordance with Section 6.2) by written notice delivered to SFJ no later than [\*\*\*] after the date of such Regulatory Approval, which written notice shall set forth the amount of the applicable Approval Buy-Out Payment, the proposed date of closing (which shall occur within [\*\*\*] after the date of the Regulatory Approval), and the calculation of the Approval Buy-Out Payment in reasonable detail based upon the proposed closing date. The Approval Buy-Out Payment will be calculated as follows:

[\*\*\*]

Each Approval Buy-Out Payment will be payable in one installment in cash at the closing to an account specified by SFJ. The discount rate used to calculate each Approval Buy-Out Payment shall be [\*\*\*] percent ([\*\*\*]%).

6.7.2 Change of Control Buy-Out Option. Within one hundred and twenty (120) days following the closing of a Change of Control, PB or its successor shall have the right to make a one-time payment (the "Change of Control Buy-Out Payment") in lieu of all (but not less than all) remaining Approval Payments for the applicable country(ies) in which Regulatory Approval has been received as of the date of closing of such Change of Control, provided that SFJ has not previously assigned the right to receive the Approval Payments to a Third Party, in which event PB or its successor shall not have such right. To exercise its right to make the Change of Control Buy-Out Payment, PB or its successor shall provide written notice to SFJ (the "Change of Control Buy-Out Notice") no later than [\*\*\*] after the date of closing of such Change of Control, which written notice shall set forth the amount of the applicable Change of

Control Buy-Out Payment, the proposed date of closing of the buy-out (which shall occur within [\*\*\*] after the date of closing of such Change of Control), and the calculation of the Change of Control Buy-Out Payment in reasonable detail based upon the proposed closing date of the buy-out. The Change of Control Buy-Out Payment will be calculated as follows:

[\*\*\*]

The Change of Control Buy-Out Payment will be payable in one installment in cash at the closing to an account specified by SFJ. The discount rate used to calculate each Change of Control Buy-Out Payment shall be [\*\*\*] percent ([\*\*\*]%). For the avoidance of doubt, the Change of Control Buy-Out Payment shall only apply with regard to Approvals which have already been obtained prior to the Change of Control.

## ARTICLE 7

### SECURITY INTEREST

7.1 Grant of Security Interest. As security for the payment and performance of the PB Obligations, PB hereby grants to SFJ, effective upon PB's receipt of the Initial Development Cost Payment on the Initial Funding Date, a security interest in all of PB's right, title and interest (excluding any leasehold interest) in, to and under all of its property, wherever located and whether now existing or owned or hereafter acquired or arising, including all goods, accounts (including health-care receivables), equipment, inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, general intangibles, intellectual property (including, for the avoidance of doubt, all PB Intellectual Property), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts, certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and all of PB's books and records relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing (collectively, the "SFJ Collateral"). Anything herein to the contrary notwithstanding, in no event shall the SFJ Collateral include, and PB shall not grant and shall not be deemed to have granted a security interest in, (1) any property to the extent that such grant of security interest is prohibited by any Applicable Law of a Governmental Authority or constitutes a breach or default under or results in the termination of or requires any consent not obtained under, any contract, license, agreement, instrument or other document evidencing or giving rise to such property, except to the extent that such Applicable Law or the term in such contract, license, agreement, instrument or other document providing for such prohibition, breach, default or termination or requiring such consent is ineffective under Section 9-406, 9-407, 9-408 or 9-409 of the Uniform Commercial Code in effect in the State of Delaware (or any successor provision or provisions) of any relevant jurisdiction or any other Applicable Law (including bankruptcy or insolvency statutes) or principles of equity; provided, however, that such security interest shall attach immediately at such time as such Applicable Law

is not effective or applicable, or such prohibition, breach, default or termination is no longer applicable or is waived, and to the extent severable, shall attach immediately to any portion of the SFJ Collateral that does not result in such consequences or (2) any of PB's rights, title or interest in any of the outstanding voting capital stock or other ownership interests of a CFC in excess of 65% of the voting power of all classes of capital stock or other ownership interests of CFC entitled to vote. This Agreement shall create a continuing security interest in the SFJ Collateral which shall remain in effect until all PB Obligations (other than contingent indemnity obligations) have been paid or otherwise satisfied in full in accordance with this Agreement and/or, if applicable, the Program Transfer Agreement. Upon payment or other satisfaction of all PB Obligations (other than contingent obligation), SFJ shall, at the sole cost and expense of PB, release its Liens in the SFJ Collateral and all rights therein shall revert to PB.

7.2 Priority of Security Interest. PB represents, warrants and covenants that, subject to fulfilment of PB's obligations under Section 7.4 and SFJ making any filings necessary to achieve such perfection, the security interest granted to SFJ pursuant to this ARTICLE 7 (the "SFJ Security Interest") on the Initial Funding Date shall be and shall at all times thereafter continue to be a first-priority perfected security interest in the SFJ Collateral (subject only to the lien of SVB arising under the SVB Loan Agreement, subject in all respects to the terms and conditions of the subordination agreement contemplated by Section 7.4 hereof, and other Permitted Liens that are permitted pursuant to the terms of this Agreement).

7.3 Authorization to File Financing Statements. PB hereby authorizes SFJ to file, on or at any time from time to time after PB's receipt of the Initial Development Cost Payment on the Initial Funding Date, and PB shall execute and deliver to SFJ (as applicable), financing statements, amendments to financing statements, continuation financing statements, termination statements, security agreements relating to the SFJ Collateral constituting intellectual property, fixture filings (if applicable), notices and other documents and instruments, in form satisfactory to SFJ as SFJ may reasonably request, to perfect and continue perfected, maintain the priority of or provide notice of SFJ's security interest in the SFJ Collateral and to accomplish the purpose of this Agreement, without notice to PB, with all appropriate jurisdictions located within the United States and the Designated European Countries. Such financing statements may indicate the SFJ Collateral as substantially the same as the SFJ Collateral described in Section 7.1 or words of similar effect, or as being of an equal or lesser scope, or with greater detail, all in SFJ's reasonable discretion.

7.4 Subordination to SVB Loan. On or before the Initial Funding Date, PB shall negotiate in good faith and enter into a subordination agreement with SVB and SFJ reflecting in all material respects the terms described on Exhibit P attached hereto, pursuant to which SFJ will subordinate to SVB all PB Obligations and all Liens in the SFJ Collateral in favor of SFJ of indebtedness of PB to SVB, which agreement shall (a) limit the aggregate principal amount of indebtedness of PB to SVB that will be senior to SFJ at [\*\*\*], (b) include a provision pursuant to which in certain circumstances SFJ shall be entitled in its discretion to purchase or repay all obligations (other than contingent indemnity obligations) owing by PB to SVB arising under or in connection with the SVB Loan Agreement in exchange for a release of SVB's Liens on PB's assets, (c) include an obligation on the part of SFJ to, in connection with any refinancing or

replacement of the SVB Loan Agreement, enter into a new subordination agreement with a new lender(s) on terms and conditions that are taken as a whole not less favorable in any material respect to SFJ than those set forth in the subordination agreement to be entered into with SVB, and (d) otherwise be in form and substance reasonably satisfactory to SFJ. Upon the execution of such new subordination agreement with such new lender(s), references herein to "SVB" shall refer to such new lender(s), references herein to the "SVB Loan" shall refer to the loans provided by such new lender (provided that the aggregate principal amount of such loans shall not exceed [\*\*\*]), references herein to the "SVB Collateral" shall refer to the collateral securing such new loan, and references herein to the "SVB Loan Agreement" shall refer to such loan and security agreement or similar document entered into with such new lender(s).

#### 7.5 Negative Covenants.

7.5.1 Incurrence of Certain Indebtedness. PB shall not, without SFJ's prior written consent, create, incur, assume, or be liable for any Indebtedness, or permit any subsidiary of PB to do so, other than Permitted Indebtedness.

7.5.2 Subordinated Debt. PB shall not (a) make or permit any payment on any Subordinated Debt, except to the extent permitted by the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to Subordinated Debt which would provide for earlier or greater principal, interest, or other cash payments thereon, or materially adversely affect the subordination thereof to PB Obligations owed to SFJ.

7.5.3 Encumbrances. PB shall not, without SFJ's prior written consent:

7.5.3.1 create, incur, allow, or suffer any Lien on any of the PB Intellectual Property, or assign or convey any right to receive income with respect to the PB Intellectual Property (other than royalty and other license fee obligations to licensors thereof in accordance with the applicable license agreement), including the sale of any PB Intellectual Property, or permit any of its subsidiaries to do so, other than Liens in favor of SVB (subject in all respects to the terms and conditions of the subordination agreement contemplated by Section 7.4 hereof) and other Permitted Liens that are permitted pursuant to the terms of this Agreement; or

7.5.3.2 except as and to the extent permitted by Section 7.5.6, enter into any agreement, document, instrument or other arrangement (except with or in favor of SFJ or SVB) with any Person which directly or indirectly prohibits or has the effect of prohibiting PB or any subsidiary of PB from assigning, mortgaging, pledging, granting a security interest in or upon or encumbering any proceeds from PB Intellectual Property.

7.5.4 Distributions; Investments. PB shall not, without SFJ's prior written consent, (a) pay any dividends or make any distribution or payment on account of or redeem, retire or purchase any capital stock, provided that (i) PB may convert any of its equity convertible securities into other equity securities (or cash for partial shares) pursuant to the terms of such equity convertible securities or otherwise in exchange thereof, (ii) PB may pay dividends

solely in common stock, and (iii) PB may repurchase the stock of former employees or consultants pursuant to stock repurchase agreements, provided that the aggregate amount of all such repurchases does not exceed [\*\*\*] Dollars (\$[\*\*\*]) per fiscal year; or (b) directly or indirectly make any Prohibited Investment (including, without limitation, by the formation of or through any subsidiary), or permit any of its subsidiaries to do so. For the avoidance of doubt, nothing in this Section 7.5.4 shall limit the ability of PB to pay or settle on conversion (in cash or equity) any convertible indebtedness.

7.5.5 Licensing Transactions. PB shall have the right, without SFJ's consent, to enter into any Excluded Licensing Transaction. PB shall not, without SFJ's prior written consent, enter into a Licensing Transaction unless such Licensing Transaction is an Excluded Licensing Transaction (in which case such prohibition shall not apply and no such consent of SFJ shall be required); provided that SFJ shall only be entitled to withhold such consent as to a Licensing Transaction other than an Excluded Licensing Transaction in the event SFJ reasonably determines, and provides PB with written notice of its determination within [\*\*\*] of PB providing to SFJ a non-binding term sheet or comparable document summarizing the material terms of the proposed Licensing Transaction [\*\*\*], that PB entering into such Licensing Transaction would [\*\*\*] ("Material Impact"). If PB disagrees with SFJ's determination, the matter shall be submitted to arbitration before a single neutral arbitrator under the American Arbitration Association's (AAA's) expedited arbitration rules, which arbitrator shall be mutually agreeable to both Parties and have significant expertise on the subject matter to be decided (provided that if the Parties have not mutually agreed on such arbitrator within [\*\*\*] after the applicable demand for arbitration, the AAA shall designate such arbitrator), such arbitration to be concluded and the arbitrator's award to be rendered within [\*\*\*] of the applicable demand for arbitration. The sole issue to be decided in the arbitration shall be whether the entry into such Licensing Transaction by PB would have a substantial likelihood of having a Material Impact. In the event the arbitrator agrees with SFJ, PB shall not be entitled to enter into such Licensing Transaction. In the event the arbitrator agrees with PB, PB shall be entitled to enter into the Licensing Transaction; [\*\*\*], and, [\*\*\*].

7.5.6 Sales of Royalty Streams. PB shall not sell, transfer or assign, directly or indirectly, in whole or in part, any rights to receive payments of royalties or license fees with respect to the Product or the PB Intellectual Property (including any Accounts with respect to such royalties or license fees), other than to a wholly owned direct or indirect subsidiary of PB (it being understood that the foregoing shall not restrict the creation of any Permitted Lien).

7.5.7 Further Negative Pledges. PB shall not, from and after the Effective Date, enter into any agreement that prohibits or limits the ability of PB to create, incur, assume or suffer to exist any Lien upon any PB Intellectual Property (including any Accounts with respect to such royalties or license fees), whether now owned or hereafter acquired, to secure the PB Obligations, other than (a) agreements with SFJ (including this Agreement), (b) any agreements governing purchase money Liens or capital lease obligations otherwise permitted hereby (in which case, any such prohibition or limitation shall only be effective on the assets financed thereby), (c) customary restrictions on assignment contained in leases, licenses or other

agreements or (d) the SVB Loan Agreement and any loan documents entered into in connection therewith.

7.6 Affirmative Covenants. PB shall do all of the following:

7.6.1 Execution of Additional Security Agreements and Other Further Assurances.

7.6.1.1 PB shall, upon request of SFJ from time to time hereafter, execute such security agreements, stock pledge agreements, deposit account control agreements, and take such further action, as reasonably required to perfect or continue the SFJ Security Interest or to effect the purposes of this ARTICLE 7, including without limitation by taking the following actions:

(a) (i) PB shall execute and deliver to SFJ, promptly upon PB's receipt of the Initial Development Cost Payment on the Initial Funding Date, such patent and trademark security agreements as SFJ may reasonably request, in each case in form and substance reasonably acceptable to SFJ (each an "IP Security Agreement"), and shall record such agreements with the U.S. Patent and Trademark Office, and shall take such other action as may be necessary or as SFJ may reasonably request to perfect SFJ's security interest in any Intellectual Property of PB in existence as of the Effective Date constituting SFJ Collateral. (ii) Within [\*\*\*] of the last day of [\*\*\*], PB shall notify SFJ in writing of [\*\*\*], and [\*\*\*].

(b) No later than [\*\*\*] after PB's receipt of the Initial Development Cost Payment on the Initial Funding Date, PB shall deliver to SFJ fully executed deposit account control agreements or securities account control agreements, as applicable, in favor of SFJ in form and substance reasonably satisfactory to SFJ with respect to all deposit accounts (as such term is defined in the UCC, each a "Deposit Account") and securities accounts (as such term is defined in the UCC, each a "Securities Account" and collectively with any Deposit Account, each a "Collateral Account") maintained within the United States by PB, including without limitation the Collateral Accounts set forth on Schedule 7.6.1.1(b) to that certain disclosure letter, dated as of the Effective Date, delivered by PB to SFJ (the "Disclosure Letter"). PB represents and warrants to SFJ that, as of the Effective Date, it maintains no Collateral Accounts other than the Collateral Accounts described on Schedule 7.6.1.1(b) to the Disclosure Letter. In addition to and without limiting the foregoing, PB shall provide SFJ with [\*\*\*] prior written notice before establishing any additional Collateral Account at or with any bank or financial institution. For each such additional Collateral Account that PB at any time maintains after PB's receipt of the Initial Development Cost Payment on the Initial Funding Date, PB shall cause the applicable bank or financial institution at or with which any Collateral Account is maintained to execute and deliver a deposit account control agreement, securities account control agreement or other appropriate instrument with respect to such account to perfect SFJ's Lien in such account in accordance with the terms hereunder within [\*\*\*] after the opening of each such account (or, if later, [\*\*\*] after PB's receipt of the Initial Development Cost Payment on the Initial Funding Date), which agreement may not be terminated without the prior written consent of SFJ. The provisions of this Section 7.6.1.1(b) shall not apply to deposit accounts exclusively used for payroll, payroll taxes, and other employee wage and benefit

payments to or for the benefit of SFJ employees and identified to SFJ by PB as such. Except to the extent permitted by the preceding sentence, PB shall [\*\*\*]:

- (i) [\*\*\*] prior to [\*\*\*];
- (ii) [\*\*\*] after [\*\*\*]; and
- (iii) [\*\*\*] after [\*\*\*].

For the avoidance of doubt, the Parties agree that [\*\*\*].

7.6.1.2 PB shall obtain such consents from SVB and WestRiver Innovation Lending Fund VIII, L.P. as are required by the SVB Loan Agreement to grant a security interest in the SFJ Collateral to SFJ and to incur the PB Obligations as set forth herein (the “SVB Consent”). The failure of PB to obtain the SVB Consent within [\*\*\*] of the Effective Date shall be deemed to be a Material Adverse Event.

#### 7.6.2 Government Compliance.

7.6.2.1 Maintain its and all its subsidiaries’ legal existence and good standing in their respective jurisdictions of formation and maintain qualification in each jurisdiction in which the failure to so qualify would reasonably be expected to have a material adverse effect on PB’s business or operations, provided that any subsidiary may liquidate or dissolve so long as such liquidation or dissolution would not reasonably be expected to have a material adverse effect on PB’s consolidated business or operations, and provided that in connection with such liquidation or dissolution all assets and property of any such subsidiary shall be transferred to PB or another subsidiary of PB. PB shall comply, and shall cause each subsidiary to comply, in all material respects, with all laws, ordinances and regulations to which it is subject noncompliance with which would reasonably be expected to have a material adverse effect on PB’s business.

7.6.2.2 Obtain all of the Governmental Approvals, if any, necessary for the grant of a security interest to SFJ in the SFJ Collateral.

7.6.3 Regulatory Compliance. PB shall not become an “investment company” or a company “controlled” by an “investment company” under the Investment Company Act of 1940, as amended. PB shall not become engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Neither PB’s nor any of its Subsidiaries’ properties or assets shall be used by PB or any Subsidiary in disposing, producing, storing, treating, or transporting any hazardous substance other than legally. PB and each of its subsidiaries shall obtain all consents, approvals and authorizations of, make all declarations or filings with, and give all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted, unless such failure could not reasonably be expected to have a material adverse effect on PB’s business.



7.6.4 Protection of Intellectual Property Rights. PB shall use Commercially Reasonable Efforts in the exercise of its business judgment to prosecute, protect, defend and maintain the validity and enforceability of the PB Intellectual Property.

7.6.5 Acceleration. In the event that, following an applicable Regulatory Approval, PB shall fail to make any Approval Payment associated with such Regulatory Approval within [\*\*\*] of the due date therefor in accordance with ARTICLE 6, all remaining unpaid Approval Payments that are based on such Regulatory Approval shall become immediately due and payable; provided that, in the event of any such acceleration, SFJ's rights to receive such Approval Payments, if any, shall be adjusted as set forth in Section 6.2 and reduced by any amounts previously paid to SFJ.

7.7 Certain Defined Terms. As used in this ARTICLE 7 and elsewhere in this Agreement:

7.7.1 "PB Obligations" means all indebtedness, liabilities and other obligations of PB to SFJ under or in connection with this Agreement and any other documents executed in connection herewith, including, without limitation, all amounts payable to SFJ pursuant to ARTICLE 6 hereof, all interest accrued thereon, all fees and all other amounts payable by PB to SFJ thereunder or in connection therewith, whether now existing or hereafter arising, and whether due or to become due, absolute or contingent, liquidated or unliquidated, determined or undetermined, and including interest that accrues after the commencement by or against PB of any bankruptcy or insolvency proceeding naming such individual or entity as the debtor in such proceeding, and including performing the PB Services but excluding obligations under the Warrant.

7.7.2 "Contingent Obligation" is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, letter of credit or other Indebtedness of another Person, in each case, directly or indirectly guaranteed, endorsed or co-made by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices, but only to the extent such transaction is entered into for speculative purposes (and not to mitigate any risk to which PB or any subsidiary is subject). The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

7.7.3 "Indebtedness" means (a) indebtedness for borrowed money or the deferred price of property or services (excluding accounts payable incurred in the ordinary course of business, earn-out or similar obligations with respect to deferred purchase price and deferred compensation), (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations (as such term is understood under GAAP as in effect on

the date of this Agreement, but excluding obligations treated as operating leases prior to adoption of changes described by ASC Topic 842) and (d) Contingent Obligations.

7.7.4 “Investment” means any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance or capital contribution to any Person.

7.7.5 “Lien” means a mortgage, deed of trust, levy, charge, pledge, security interest or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

7.7.6 “Permitted Indebtedness” means:

7.7.6.1 PB Obligations;

7.7.6.2 Indebtedness owed to SVB pursuant to the SVB Loan Agreement, subject in all respects to the terms and conditions of the subordination agreement contemplated by Section 7.4 hereof;

7.7.6.3 Subordinated Debt;

7.7.6.4 unsecured Indebtedness;

7.7.6.5 Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business;

7.7.6.6 Indebtedness secured by Liens permitted under subsections 7.7.7.1 and 7.7.7.3 of the definition of “Permitted Liens” hereunder;

7.7.6.7 Letters of credit issued for the payment of purchase obligations for equipment, materials and inventory and for the payment of equipment and real estate lease obligations (including security deposits in connection therewith); and

7.7.6.8 Other Indebtedness not to exceed [\*\*\*] in the aggregate at any time outstanding.

7.7.7 “Permitted Liens” means:

7.7.7.1 Liens in favor SVB pursuant to the SVB Loan Agreement (subject in all respects to the terms and conditions of the subordination agreement contemplated by Section 7.4 hereof) and Liens in favor of SFJ;

7.7.7.2 Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which PB maintains adequate reserves on its books and records, provided that no notice of any such Lien has been filed or recorded under the IRC;

7.7.7.3 Purchase money Liens or capital leases (i) on equipment acquired or held by PB incurred for financing the acquisition of the equipment securing no more than [\*\*\*] in the aggregate amount outstanding, or (ii) existing on equipment when acquired, if the Lien is confined to the property and improvements and the proceeds of the equipment;

7.7.7.4 Leases or subleases of real property granted in the ordinary course of PB's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of PB's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting SFJ a security interest therein;

7.7.7.5 Interests of lessors and licensors under leases and licenses to PB of real property and personal property;

7.7.7.6 The Existing Licenses;

7.7.7.7 Excluded Licensing Transactions;

7.7.7.8 Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to inventory, securing liabilities in the aggregate amount which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

7.7.7.9 Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

7.7.7.10 Liens arising from attachments or judgments, orders, or decrees occurring after the Effective Date in circumstances not constituting or arising from a Fundamental Breach by PB;

7.7.7.11 Liens in favor of financial institutions arising in connection with PB's deposit and/or securities accounts held at such institutions, provided that SFJ has a first priority perfected security interest in the amounts held in such deposit and/or securities accounts;

7.7.7.12 Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in Sections 7.7.7.1 through 7.7.7.11 (excluding Liens securing the SVB Loan, solely to the extent of any obligations thereunder permitted in accordance with the terms and conditions of the subordination agreement contemplated by Section 7.4 hereof), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

7.7.7.13 Deposits securing bids or contracts;

7.7.7.14 Liens securing the payment of purchase obligations for equipment, materials and inventory and for the payment of equipment and real estate lease obligations (including security deposits in connection therewith); and

7.7.7.15 Other Liens securing liabilities in an aggregate amount not to exceed [\*\*\*].

7.7.8 “Prohibited Investment” means:

7.7.8.1 Investments in equity interests including convertible notes of privately held companies (other than wholly owned subsidiaries of PB and, where Applicable Law prevents whole ownership, other than subsidiaries that are wholly owned by PB except for nominal Third Party ownership that is required under Applicable Law);

7.7.8.2 Investments in or purchases of any real property (excluding real property to be occupied or used by PB or its subsidiaries) commercial or residential mortgages or mortgage backed securities;

7.7.8.3 Investments in auction rate securities, corporate high yield bonds (i.e. less than BBB quality), precious metals, derivatives including margin trades, options, futures, options on futures, short sales, forward contracts, swaps, repurchase agreements and reverse repurchase agreements (but excluding, in each case, interest rate, currency or commodity swap agreements, interest rate caps or collar agreements, or other agreements or arrangements designed to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices not entered into for speculative purposes); and

7.7.8.4 [\*\*\*].

7.7.9 “SFJ Collateral” has the meaning set forth in Section 7.1.

7.7.10 “Subordinated Debt” means indebtedness incurred by PB that is subordinated to any PB Obligations (pursuant to a subordination, intercreditor, or other similar agreement in form and substance reasonably satisfactory to SFJ entered into between SFJ and the other creditor), on terms reasonably acceptable to SFJ.

## ARTICLE 8

### WARRANT ISSUANCE

8.1 Warrant Issuance. PB shall issue to SFJ on the Effective Date a warrant (“Warrant”) exercisable for two million two hundred thousand (2,200,000) shares of PB common stock (“Stock”) at an exercise price per share (“Exercise Price”) equal to the greater of (a) five dollars (\$5.00) or (b) 120% of the volume weighted average closing price of the Stock over the thirty (30) consecutive trading days ending on the last trading day immediately preceding the Effective Date and exercisable as follows:  
(i) one million one hundred thousand (1,100,000)

shares may be exercised at any time after the Effective Date provided that any such shares may be transferred by SFJ to its Affiliates but may not be resold by SFJ or its Affiliates until one (1) year after the Effective Date and (ii) one million one hundred thousand (1,100,000) shares may be exercised at any time after the date of Successful Phase 3 Interim Analysis.

8.2 Form of Warrant. The Warrant shall in the form attached hereto as Exhibit H, shall have a term of ten (10) years, and shall contain “net-exercise” issuance provisions.

## ARTICLE 9

### RECORDS

9.1 Accounting. Each Party will maintain materially complete and accurate accounting records related to this Agreement in accordance with GAAP. Each Party will retain such records for [\*\*\*] after the earlier of expiration or early termination of this Agreement.

9.2 Clinical Trials-Related Records. Each Party shall, and shall cause its Affiliates and its and their Permitted Third Parties conducting Development of the Product to, maintain, in good scientific manner, complete and accurate books and records pertaining to Development of the Product hereunder, in sufficient detail to verify compliance with its obligations under this Agreement. Such books and records shall (a) be appropriate for patent and regulatory purposes, (b) be in compliance with Applicable Law, (c) properly reflect all work done and results achieved in the performance of its Development activities hereunder, and (d) be retained by such Party for such period as may be required by Applicable Law.

## ARTICLE 10

### CONFIDENTIAL INFORMATION

10.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties (including, if applicable, in the Program Transfer Agreement), each Party (each, a “Receiving Party”) agrees that, during the Term and for the [\*\*\*] period following the expiration or termination of this Agreement (except that the obligations will survive thereafter with respect to any Confidential Information that constitutes a trade secret under Applicable Law) or such longer periods for which such Confidential Information may be maintained pursuant to ARTICLE 9, it will keep confidential and will not publish or otherwise disclose and will not use for any purpose other than as provided for in this Agreement or, if applicable, the Program Transfer Agreement (which includes the exercise of any rights or the performance of any obligations hereunder or thereunder) any Confidential Information furnished to it by or on behalf of the other Party (each, a “Disclosing Party”) or its Affiliates in connection with this Agreement or, if applicable, the Program Transfer Agreement. The foregoing obligations will not apply to any portion of such information or materials that the Receiving Party can demonstrate:

10.1.1 was publicly disclosed by the Disclosing Party before or after such Confidential Information becomes known to the Receiving Party;

10.1.2 was already known to the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality or non-use, prior to when it was received from the Disclosing Party;

10.1.3 is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof without obligation to keep such Confidential Information confidential;

10.1.4 has been published by a Third Party or otherwise enters the public domain through no fault of the Receiving Party or any of its Affiliates in breach of this Agreement; or

10.1.5 has been independently developed by the Receiving Party or any of its Affiliates, without the aid, application or use of any Confidential Information of the other Party.

10.2 Authorized Disclosure. Each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary for complying with Applicable Laws, including regulations promulgated by securities exchanges, provided that the Party required to disclose such information promptly notifies the Disclosing Party prior to making any such disclosure and cooperates with the Disclosing Party's efforts to seek confidential treatment or to otherwise limit disclosure. Each Receiving Party may disclose the other Party's Confidential Information to its Affiliates, employees, agents, advisors, and independent contractors (including Permitted Third Parties) engaged by such Receiving Party, in each case (a) only to the extent such Persons need to know the Confidential Information solely in connection with the performance of this Agreement or, if applicable, the Program Transfer Agreement and (b) provided that each Person receiving Confidential Information must be bound by obligations of confidentiality and non-use at least as stringent as an equivalent in scope to those set forth in this ARTICLE 10 prior to any such disclosure and the Party making such disclosure to such Person shall be liable to the other Party for any breach of such obligations by such disclosee. PB may disclose SFJ Confidential Information to MedImmune as necessary to comply with PB's obligations or exercise PB's rights under the AZ License (it being understood that any such disclosure will be made under the terms of Article 6 of the AZ License and that PB shall not be required to enter into any further confidentiality agreement with MedImmune for such purpose). Each Party may also disclose the material terms of this Agreement (including the form of Program Transfer Agreement) or provide a copy of this Agreement or a summary of such Party's findings during its due diligence investigation of the Products (if applicable) to any bona fide potential or actual investor, investment banker, acquirer, provider of debt or royalty financing, or other potential or actual financial partner without consent of the other Party, and provided that in connection with such disclosure, each disclosee must be bound by obligations of confidentiality and non-use at least as stringent as an equivalent in scope to those set forth in this ARTICLE 10 prior to any such disclosure and the Party making such disclosure to such disclosee shall be liable to the other Party for any breach of such obligations by such disclosee. Notwithstanding anything in the foregoing to the contrary, Exhibit D constitutes PB's Confidential Information and not SFJ's Confidential Information, and PB may disclose Exhibit D to Third Parties as determined by PB in its sole discretion. In any event, each Party agrees to

take all reasonable action to avoid unauthorized use or disclosure of Confidential Information of the other Party hereunder.

10.3 Return of Confidential Information. Except as otherwise provided herein, upon expiration or earlier termination of this Agreement, all Confidential Information (including any copies thereof) in written or other tangible form will, at the Disclosing Party's direction, be returned to the Disclosing Party or destroyed by the Receiving Party, and any Person(s) to whom the Receiving Party disclosed (with such destruction being certified in writing by an authorized officer of the Receiving Party), except (i) to the extent such Confidential Information is necessary to exercise any license and/or rights hereunder that survive such expiration or earlier termination; and (ii) one (1) copy of each document may be retained by the Receiving Party solely to the extent necessary to permit it to comply with any ongoing rights and responsibilities with respect to such Confidential Information.

10.4 MedImmune Confidential Information. With respect to any Confidential Information of PB that constitutes MedImmune Confidential Information, SFJ hereby agrees to be bound by the provisions of Sections 6.1, 6.2 and 6.7 of the AZ License to the same extent as PB is.

10.5 Confidential Status of the Agreement. Subject to Section 10.2 and Section 10.6, the terms of this Agreement, including the form of Program Transfer Agreement (whether or not executed by the Parties), are deemed to be Confidential Information and will be subject to the confidentiality requirements of this ARTICLE 10, with each Party being deemed a Receiving Party for such purposes. The Parties each acknowledge that it will be necessary for PB to file this Agreement with the US Securities and Exchange Commission and to make other required public disclosures regarding the terms of this Agreement, and accordingly PB shall prepare a confidential treatment request in connection with such filing and provide SFJ a reasonable opportunity to review and comment on such filing as well as on such other required public disclosures and thereafter use Commercially Reasonable Efforts to obtain confidential treatment as to the terms of this Agreement.

10.6 Publicity. The Parties recognize that following the Effective Date the Parties (either individually or jointly) shall issue mutually agreed press release(s) announcing the execution of this Agreement, and thereafter each Party may from time to time desire to issue additional press releases and make other public statements or disclosures regarding the subject matter of this Agreement, and hereby agree that such additional press releases, public statements and disclosures regarding the terms of this Agreement will be permitted only with the other Party's written consent (which shall not be unreasonably withheld, conditioned or delayed). Any publication, news release or other public announcement relating to the terms of this Agreement will first be reviewed and approved in writing by both Parties; provided, however, that any disclosure of the minimum information which is required by Applicable Law (including the rules of a securities exchange), as reasonably advised by the disclosing Party's counsel, may be made without the prior consent of the other Party, although the other Party will be given prompt notice of any such legally required disclosure and to the extent practicable will be provided an opportunity to comment on the proposed disclosure and the disclosing Party will consider in

good faith any comments provided by the other Party on such proposed disclosure. For avoidance of doubt, this Section 10.6 shall not restrict PB from releasing public statements or disclosures regarding PB's development and Commercialization activities with respect to the Product.

10.7 Use of Name. Unless otherwise expressly permitted herein, PB will obtain the written consent of SFJ (which consent will not unreasonably be withheld, conditioned or delayed) prior to referring to SFJ in any correspondence with any Regulatory Authority or Governmental Authority, except as may be required by Applicable Law. SFJ agrees to be bound by Section 6.3 of the AZ License to the same extent as PB is.

## ARTICLE 11

### INTELLECTUAL PROPERTY AND PERSONALLY IDENTIFIABLE INFORMATION

#### 11.1 Ownership and Rights.

##### 11.1.1 Ownership.

11.1.1.1 Existing Intellectual Property. Subject to Section 11.1.1.2, it is agreed between the Parties that each Party will retain all right, title and interest in, to and under all Intellectual Property that is Controlled by such Party as of the Effective Date.

(a) Without limiting the generality of the foregoing, as between the Parties, PB shall be and remain the sole and exclusive owner of all right, title and interest in and to all PB Intellectual Property existing as of the Effective Date ("Existing PB Intellectual Property"), including, in the case of Patents within the Existing PB Intellectual Property ("Existing PB Patents"), all patent applications filed after the Effective Date that claim priority to, or are foreign counterparts of, patent applications within the Existing PB Patents ("Corresponding PB Patent Applications") and all Patents that may issue or be granted from any patent application within the Existing PB Patents or any Corresponding PB Patent Application after the Effective Date. In addition, PB shall be and remain the sole and exclusive owner of all right, title and interest in and to all PB Intellectual Property arising during the term of this Agreement independent of the conduct of the activities contemplated by this Agreement.

(b) SFJ acknowledges that the PB Intellectual Property includes Licensed Know-How and Licensed Patents licensed to PB pursuant to, and subject to the terms and conditions of, the AZ License. SFJ further acknowledges and agrees that, as required by the AZ License, MedImmune shall own and retain all right, title and interest in and to any and all Licensed Know-How and Licensed Patents (including Patents that become Licensed Patents pursuant to the last two sentences of Section 5.1.2 of the AZ License). SFJ shall, and hereby does, assign to MedImmune and will cause each of its officers, directors, employees and Affiliates, and its and their respective Permitted Third Parties, to assign to MedImmune all right, title and interest in and to all Patents filed by or on behalf of PB claiming any Licensed Know-How, without additional compensation, as is necessary to fully effect the



sole ownership provided for in the second sentence of this Section 11.1.1.1(b). In the event of any conflict between the terms of this Agreement (including the form of Program Transfer Agreement) and the terms of the AZ License, in each case, as applicable to Licensed Know-How or Licensed Patents, the terms of the AZ License shall prevail.

11.1.1.2 MedImmune Intellectual Property.

(a) SFJ acknowledges and agrees that, as required by the AZ License, MedImmune shall own and retain all right, title and interest in and to any and all AstraZeneca Product Improvements, AstraZeneca Product Know-How and AstraZeneca Product Patents. SFJ shall, and hereby does, assign to MedImmune and will cause each of its officers, directors, employees and Affiliates, and its and their respective Permitted Third Parties, to assign to MedImmune all right, title and interest in and to all (i) AstraZeneca Product Improvements that are conceived, discovered, developed or otherwise made by or on behalf of SFJ or any of its Affiliates (including by any of their respective Third Party contractors), (ii) AstraZeneca Product Know-How generated by or on behalf of SFJ or any of its Affiliates (including by any of their respective Third Party contractors), and (iii) AstraZeneca Product Patents claiming any such AstraZeneca Product Improvement(s) or AstraZeneca Product Know-How; in each case, without additional compensation, as is necessary to fully effect the sole ownership provided for in the first sentence of this Section 11.1.1.2(a).

(b) SFJ shall cause each employee, individual consultant and Third Party contractor that SFJ or its Affiliate proposes to engage to conduct any Clinical Trial activity under or in connection with this Agreement (including, if applicable, in connection with the Program Transfer Agreement) on its behalf who conceives, discovers, develops or otherwise makes any AstraZeneca Product Improvement under or in connection with activities conducted pursuant to this Agreement to be under an obligation to assign to PB their rights in any such AstraZeneca Product Improvement, so that PB may comply with its obligations with respect to AstraZeneca Improvements, AstraZeneca Product Know-How and AstraZeneca Product Patents under the AZ License. If (i) SFJ is unable to cause any such Third Party contractor or consultant (including any contractor who is, or a consultant who is employed by, a governmental, not-for-profit, or public institution that has standard policies against such an assignment) to agree to such assignment obligation with respect to AstraZeneca Product Improvements despite SFJ's using commercially reasonable efforts to negotiate such assignment obligation, or (ii) Applicable Law would prohibit SFJ from requiring such an assignment from such Third Party contractor or consultant, in each case ((i) and (ii)), SFJ and its Affiliates shall refrain from using such Third Party contractor or consultant to conduct activities pursuant to this Agreement unless PB obtains MedImmune's written consent thereto.

(c) The Parties acknowledge and agree that in the event of any conflict between the terms of this Agreement and the terms of the AZ License, in each case, as applicable to AstraZeneca Product Improvements, AstraZeneca Product Know-How or AstraZeneca Product Patents, the terms of the AZ License shall prevail.

#### 11.1.1.3 Trial Inventions.

(a) PB shall be the exclusive and sole owner of, and retain all right, title and interest in and to, all Trial Inventions (which shall constitute PB Intellectual Property), regardless of inventorship. SFJ will promptly disclose, and will cause its Affiliates and all Permitted Third Parties engaged by SFJ or its Affiliates to perform any of SFJ's obligations hereunder promptly to disclose, to PB in writing in reasonable detail each Trial Invention made, developed, created, generated, conceived or reduced to practice in whole or in part by or on behalf of SFJ, such Affiliate or such Permitted Third Party, which written disclosure shall include all available information and data necessary to support the filing of patent applications Covering such Trial Invention. SFJ, for itself and on behalf of its Affiliates, hereby assigns, and shall cause such other Permitted Third Parties to assign (subject to Section 11.1.1.3(c)), to PB all its right, title and interest in and to Trial Inventions and all information and data necessary to support the filing of patent applications Covering such Trial Inventions. SFJ will cooperate, and will cause the foregoing Persons to cooperate, with PB to effectuate and perfect the foregoing ownership, including by promptly executing and recording assignments and other documents consistent with such ownership.

(b) SFJ shall cause each employee and individual consultant of such SFJ or its Affiliates (but excluding Permitted Third Parties of SFJ and its Affiliates, which are separately addressed in Section 11.1.1.3(c)) who conceives, discovers, develops or otherwise makes any Trial Invention to be under an obligation to assign to PB their rights in any such Trial Invention. In the case of any individual consultant of SFJ or its Affiliates (excluding SFJ's and its Affiliates' Permitted Third Parties), if SFJ is unable to cause such consultant to agree to such assignment obligation despite SFJ's using commercially reasonable efforts to negotiate such assignment obligation, then SFJ shall either: (A) cause such consultant to grant an exclusive, worldwide, royalty-free, fully-paid, freely-assignable license, with the right to sublicense through multiple tiers, under their rights in such Trial Invention to develop, make, have made, use, sell, have sold, offer for sale and import the Product for any and all uses, except where Applicable Law requires otherwise and except in the case of consultants who are employed by governmental, not-for-profit, or public institutions that have standard policies against such an assignment (in which case, SFJ shall use commercially reasonable efforts to obtain a suitable license, or right to obtain such a license); or (B) refrain from using such consultant to conduct activities pursuant to this Agreement unless PB obtains MedImmune's written consent thereto.

(c) SFJ shall use commercially reasonable efforts to obtain from each Third Party contractor that SFJ or its Affiliate proposes to engage to conduct activities under or in connection with this Agreement on behalf of SFJ or its Affiliates (i) an assignment, (ii) an exclusive, worldwide, royalty-free, fully-paid, freely-assignable license, with the right to sublicense through multiple tiers, or (iii) a non-exclusive, worldwide, royalty-free, fully-paid, freely-assignable license, with the right to sublicense through multiple tiers ((i) through (iii) in order of preference), to PB of any Trial Invention that such Third Party contractor conceives, discovers, develops or otherwise makes in connection with activities conducted relating to this Agreement. The Parties acknowledge that it may not be possible to obtain such assignment or license from any such Third Party contractor with respect to technology of broad applicability to

the operation of such Third Party contractor's business or improvements, or improvements to such Third Party contractor's own proprietary technology used in the performance of services on behalf of SFJ or its Affiliate, in each case, on acceptable terms or at all, and accordingly, the Parties agree that the inability of SFJ or its Affiliate, despite the use of commercially reasonable efforts, to obtain such assignment or license from a Third Party contractor on acceptable terms or at all shall not constitute a breach of SFJ's obligations under this Agreement.

11.1.1.4 Trial Data Package. SFJ shall be the sole and exclusive owner of the Trial Data Package including the Research Results included therein. In consideration of the Approval Payments to be made under this Agreement (if and to the extent applicable), and in further consideration of the payment by PB to SFJ of [\*\*\*], SFJ shall sell and transfer to PB, and PB shall acquire from SFJ, the sole and exclusive ownership, even as to SFJ, of the Trial Data Package including all Research Results as set forth below in this Section 11.1.1.4. Upon the earliest of (A) receipt of Regulatory Approval of the Product for the Indication in at least one of the US, the EU, any Designated European Country, Japan or China or (B) termination of this Agreement in accordance with any termination clause or section of this Agreement, in each case, PB and SFJ will promptly enter into the Trial Data Package Purchase Agreement attached hereto as Exhibit K, and PB will purchase, and SFJ will sell to PB, sole and exclusive ownership of all Research Results, including the Trial Data Package.

11.1.1.5 Inventorship; Further Assurances. Inventorship of Trial Inventions will be determined according to the principles of US patent law. SFJ agrees to cooperate fully, to cause its Affiliates to cooperate fully, and to use Commercially Reasonable Efforts to cause its and their respective Permitted Third Parties to cooperate fully, in each case: (a) with PB in the preparation, filing, prosecution and maintenance of Patents Covering Trial Inventions; and (b) with MedImmune in the preparation, filing, prosecution and maintenance of Patents (x) Covering AstraZeneca Product Improvements described in clause (i) of Section 11.1.1.2(a) or AstraZeneca Product Know-How described in clause (ii) of Section 11.1.1.2(a) or (y) filed by or on behalf of PB claiming any Licensed Know-How. Such cooperation includes executing all papers and instruments, or requiring its employees, consultants and Permitted Third Parties, to execute such papers and instruments, so as to (i) effectuate (A) the ownership of AstraZeneca Product Improvements, AstraZeneca Product Know-How and AstraZeneca Product Patents set forth in Section 11.1.1.2, (B) the ownership of Patents that become Licensed Patents pursuant to the last two sentences of Section 5.1.2 of the AZ License as set forth in Section 11.1.1.1(b), and (C) the ownership of Trial Inventions set forth in Section 11.1.1.3(a), including Patents claiming or disclosing Trial Inventions, and (ii) enable (A) MedImmune to apply for and to prosecute patent applications claiming AstraZeneca Product Improvements and Patents that become Licensed Patents pursuant to the last two sentences of Section 5.1.2 of the AZ License in any country and (B) PB to apply for and to prosecute patent applications claiming Trial Inventions in any country.

11.1.1.6 No Other Rights. The delivery or disclosure by or on behalf of PhaseBio to SFJ of any information or materials hereunder will not be construed to grant SFJ any rights or license to use any Intellectual Property Controlled by PB other than as necessary to comply with its obligations hereunder or as expressly set forth herein. Except as otherwise

expressly permitted in this Agreement, SFJ may not use, publish or otherwise disclose any Intellectual Property Controlled by PB without PB's prior written consent.

11.2 Patent Prosecution. As between SFJ and PB, PB will have sole and exclusive right to prepare, file, prosecute and maintain all Patents within the PB Intellectual Property, including all Patents that cover the Trial Inventions, at its own expense (provided that PB shall use Commercially Reasonable Efforts to prosecute and maintain such Patents). At PB's request and expense (for reasonable out-of-pocket expenses), SFJ will reasonably cooperate with PB in preparing, filing, prosecuting, and maintaining such Patents.

### 11.3 Intellectual Property Enforcement.

11.3.1 PB Intellectual Property. PB will use Commercially Reasonable Efforts to enforce Intellectual Property Controlled by PB, including Intellectual Property that covers the Trial Inventions, against Third Party Infringements.

11.3.2 Infringement of Third Party Rights. If either Party learns of Third Party allegations that it or the other Party or any of its or the other Party's Affiliates or Permitted Third Parties, have infringed, misappropriated or otherwise violated, or are infringing, misappropriating or otherwise violating, any Intellectual Property of a Third Party in connection with either the Clinical Trials or performing its obligations or duties hereunder, such Party will promptly notify the other Party. PB will have sole control and responsibility of, and discretion with respect to, such allegations and any related actions and/or litigation.

### 11.4 Personally Identifiable Information.

11.4.1 In conducting the Clinical Trials and its other obligations under this Agreement and, if applicable, the Program Transfer Agreement, each Party will comply, and will use Commercially Reasonable Efforts to require each applicable Permitted Third Party of such Party to comply, with Applicable Laws relating to privacy or data protection applicable to such Party or the Clinical Trials being conducted by or on behalf of such Party, including ensuring that all necessary (a) consents from Clinical Investigators, Subjects and any others from whom Personally Identifiable Information will be received are obtained; (b) regulatory notifications are filed in all countries for which Sites have been selected; and (c) approvals are obtained in all countries for which Sites have been selected, prior to collection or transfer of such Personally Identifiable Information. Without prejudice to the generality of the foregoing, each Party shall (i) work together with the other Party in good faith to ensure the information referred to in applicable laws and, if applicable, in particular Articles 13 and 14 of the General Data Protection Regulation (2016/679) ("GDPR") is made available to data subjects (as defined in the GDPR) in relation to the processing of their Personally Identifiable Information by either Party when acting as a data controller (as defined in the GDPR), and the information is in a concise, transparent, intelligible and easily accessible form, using clear and plain language as required by Article 12 of the GDPR; (ii) if either Party (the "Data Receiving Party") receives any complaint, notice or communication from a supervisory authority (as defined in the GDPR) which relates directly or indirectly to the other Party's (A) processing of the Personally Identifiable Information; or (B) potential failure to comply with the provisions of the GDPR, the Data Receiving Party shall,

to the extent permitted by law, promptly forward the complaint, notice or communication to the other Party and provide the other Party with reasonable co-operation and assistance in relation to the same; (iii) if a data subject makes a written request to a Party to exercise their rights in relation to their Personally Identifiable Information that concerns processing in respect of which the other Party is the data controller, that Party shall forward the request to the other Party promptly and in any event within [\*\*\*] from the date on which it received the request and, upon the other Party's reasonable written request, provide that other Party with reasonable co-operation and assistance in relation to that request to enable the other to respond to such request and meet applicable timescales set out under the GDPR; (iv) if either Party becomes aware of a personal data breach (as defined in the GDPR), it shall notify the other Party without undue delay, and each Party shall co-operate with the other, to the extent reasonably requested, in relation to any notifications to supervisory authorities or to data subjects which either Party is required to make under the GDPR.

11.4.2 Each Party will not process, and will use Commercially Reasonable Efforts to require each applicable Permitted Third Party of such Party to not process, any Personally Identifiable Information in a way that is contrary to Applicable Laws or any Informed Consent.

11.4.3 Each Party will use Commercially Reasonable Efforts to maintain, and will use Commercially Reasonable Efforts to require each applicable Permitted Third Party of such Party to maintain, appropriate and sufficient technical and organizational security measures to maintain the confidentiality of Personally Identifiable Information and to protect such data against accidental or unlawful destruction or accidental loss, damage, alteration, unauthorized disclosure or access, in particular where such data is transmitted over a network. These technical and organizational security measures shall ensure a level of security appropriate to the risk, including, as appropriate, (a) pseudonymisation and encryption; (b) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services; (c) the ability to restore the availability and access to the Personally Identifiable Information in a timely manner in the event of a physical or technical incident; and (d) a process for regularly testing, assessing and evaluating the effectiveness of those measures.

11.4.4 Each Party shall notify the other Party of: (a) any unauthorized use or disclosure or breach of any Personally Identifiable Information promptly upon discovery of such occurrence; and (b) the transmittal of any related breach notification to any affected person, Governmental Authority or the media. Each Party will use Commercially Reasonable Efforts to require each applicable Permitted Third Party of such Party to notify the such Party of: (i) any unauthorized use or disclosure or breach of any Personally Identifiable Information promptly upon discovery of such occurrence and (ii) the transmittal of any related breach notification to any affected person, Governmental Authority or the media.

## ARTICLE 12

### INDEMNIFICATION AND INSURANCE

#### 12.1 Indemnification by Each Party.

12.1.1 By SFJ. SFJ will indemnify and hold PB; its Affiliates and their respective officers, directors, employees and agents (the "PB Indemnified Parties"), harmless from any and all Losses, net of any related tax benefit actually realized in the same year as the payment or incurrence of such Losses or any prior year, arising or resulting from any Claims by a Third Party against any PB Indemnified Parties to the extent arising from (a) the gross negligence or willful misconduct of SFJ or any of its Affiliates or any of its or their respective Permitted Third Parties in performing SFJ's obligations under this Agreement or, if applicable, the Program Transfer Agreement; (b) SFJ's material breach of this Agreement or, if applicable, the Program Transfer Agreement; (c) any material breach of a Protocol by SFJ, or its Affiliate, or any of its or their respective Permitted Third Parties; (d) any breach by SFJ of any provision of the AZ License by which SFJ has agreed to be bound in this Agreement; (e) a physical injury or death of a subject that is caused by the subject's participation in any clinical trial conducted by or on behalf of SFJ or any of its Affiliates after a Program Transfer whether or not directly attributable to the Product (other than the Product manufactured by PB); and/or (f) from any after any Program Transfer, product liability claims resulting from the Commercialization of Product other than Product manufactured by PB by or on behalf of SFJ or any of its Affiliates, licensees or sublicensees; except to the extent that any of the foregoing (a) through (f) was caused by (i) the gross negligence or willful misconduct of any PB Indemnified Party, or (ii) material breach of this Agreement, or, if applicable, the Program Transfer Agreement, by PB.

12.1.2 By PB. PB will indemnify and hold SFJ, its Affiliates, SFJ's investors and their respective officers, directors, employees and agents (the "SFJ Indemnified Parties"), harmless from any and all Losses, net of any related tax benefit actually realized in the same year as the payment or incurrence of such Losses or any prior year, arising or resulting from any Claims by a Third Party against any SFJ Indemnified Parties to the extent arising from (a) a Product supplied by PB; (b) a physical injury or death of a Subject that is caused by the Subject's participation in the Clinical Trials whether or not directly attributable to the Product (excluding any Clinical Trial conducted by or on behalf of SFJ or its Affiliate after a Program Transfer); (c) PB's gross negligence or willful misconduct in performing its obligations under this Agreement or, if applicable, the Program Transfer Agreement; (d) PB's material breach of this Agreement or, if applicable, the Program Transfer Agreement, (e) any material breach of a Protocol by PB, or its Affiliate, or of its or their respective Permitted Third Parties, (f) actual or alleged infringement of any Third Party's Intellectual Property by the Product or by either Party in performing its duties or obligations hereunder with respect to the Product; and (g) injuries sustained by Subjects in connection with the Clinical Trials, including Claims arising prior to the Effective Date based upon physical injury or death of a Subject in connection with the Clinical Trials, or from the Commercialization of the Product; except to the extent that any of the foregoing (a) through (g) were caused by (i) the gross negligence or willful misconduct of any

SFJ Indemnified Party, or (ii) material breach of this Agreement, or, if applicable, the Program Transfer Agreement by, SFJ.

## 12.2 Indemnification Procedure.

12.2.1 Notice of Claim. A Party believing that it is entitled to indemnification under Section 12.1.1 or 12.1.2 (an “Indemnified Party”) will give prompt written notice (each, an “Indemnification Claim Notice”) to the other Party (the “Indemnifying Party”) upon receipt of notice of the commencement of any Claim for which indemnification may be sought, or if earlier, upon the assertion of any such Claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Claim of a Third Party as provided in this Section 12.2.1 will not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give notice). Each Indemnification Claim Notice will contain a description of the Claim and the nature and amount of the Loss (to the extent that the nature and amount of such Loss are known at such time). The Indemnified Party will furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses.

12.2.2 Control of Defense. At its option, the Indemnifying Party may assume the defense of any Claim by giving written notice to the Indemnified Party within [\*\*\*] after the Indemnifying Party’s receipt of an Indemnification Claim Notice. The assumption of the defense of a Claim by the Indemnifying Party will not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify the Indemnified Party in respect of the Claim, nor will it constitute a waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party’s claim for indemnification. Upon assuming the defense of a Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Claim any legal counsel selected by the Indemnifying Party that is reasonably satisfactory to the Indemnified Party. In the event the Indemnifying Party assumes the defense of a Claim, the Indemnified Party will promptly deliver to the Indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Claim. Should the Indemnifying Party assume the defense of a Claim, the Indemnifying Party will not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of such Claim.

12.2.3 Right to Participate in Defense. Without limiting Section 12.2.2, the Indemnified Party will be entitled to (a) participate in, but not control, the defense of such Claim and to engage counsel of its choice for such purpose; provided, however, that such engagement will be at the Indemnified Party’s own expense unless the engagement thereof has been specifically authorized by the Indemnifying Party in writing, and (b) control its defense of such Claim and to engage counsel of its choice for such purpose, at the expense of the Indemnifying Party, if the Indemnifying Party has failed to assume the defense and engage counsel in accordance with Section 12.2.2.

12.2.4 Settlement. With respect to any Losses related solely to payment of money damages in connection with a Claim and that includes a complete and unconditional

release of the Indemnified Party, will not result in the Indemnified Party admitting liability, becoming subject to injunctive or other equitable relief that will otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the Indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party will have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, will deem appropriate. With respect to all other Losses in connection with Claims, where the Indemnifying Party has assumed the defense of the Claim in accordance with Section 12.2.2, the Indemnifying Party will have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (which consent will not be unreasonably withheld, conditioned or delayed). The Indemnifying Party will not be liable for any settlement or other disposition of a Loss by the Indemnified Party that is reached without the written consent of the Indemnifying Party (which consent will not be unreasonably withheld, conditioned or delayed). Regardless of whether the Indemnifying Party chooses to defend or prosecute any Claim, the Indemnified Party will not admit any liability with respect to, or settle, compromise or discharge, any Claim without the prior written consent of the Indemnifying Party, not to be unreasonably withheld or delayed.

12.2.5 Cooperation. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Claim, the Indemnified Party will reasonably cooperate in the defense or prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation will include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Claim, and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party will reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

### 12.3 Insurance.

12.3.1 Generally. Commencing as of the Effective Date and thereafter during the Development Term, and subject to Section 12.3.2 below, each Party will carry and maintain, at its own expense, insurance coverage of the kind and with liability limits that, at a minimum, satisfy the requirements of Section 12.3.2, to protect itself and the other Party against any claims or liabilities that may arise from the conduct of the Clinical Trials and all other rights and obligations hereunder with insurers with a minimum "A-" A.M. Best rating. Any deductibles for such insurance policies will be assumed by the insuring Party. Such insurance policies will be primary and non-contributing with respect to any other similar insurance policies available to other Party and their Affiliates. Prior to the Effective Date, and annually, at each anniversary of the Effective Date (unless, during such year, expiration of the applicable policy occurs first, in which case, on such expiration date), at a Party's written request the other Party will supply documentation of such insurance coverage via original certificates of insurance, if applicable.



Each Party will provide the other Party a minimum of [\*\*\*] prior written notice if it is unable to obtain appropriate insurance coverage or if its coverage is canceled, unable to be renewed or materially changed. For clarity, any insurance coverage or the failure to maintain adequate insurance coverage does not limit or reduce a Party's liability under this Agreement. Each Party will ensure that no subcontractor, including any Permitted Third Party, will continue to perform the work unless such subcontractor is insured as deemed appropriate by the Party engaging the Permitted Third Party.

12.3.2 Minimum Requirements. Commencing as of the start of the Clinical Trials and thereafter, during the Term (or longer if otherwise stated below), at a minimum, each Party will maintain the following types of insurance coverage at a minimum level that is the greater of (a) the highest minimum level required by Applicable Law in the countries in which the Clinical Trials and other obligations hereunder are being performed or (b) the following (to the extent different).

12.3.2.1 Commercial General Liability: [\*\*\*] dollars (\$[\*\*\*]) per occurrence; [\*\*\*] dollars (\$[\*\*\*]) Product and Completed Operations aggregate, including Premises & Operations, Personal Injury, Product and Completed Operations; [\*\*\*] dollars (\$[\*\*\*]) combined single limit on all owned, non-owned and hired vehicles of such Party.

12.3.2.2 Umbrella Excess Liability: [\*\*\*] dollars (\$[\*\*\*]) per occurrence.

12.3.2.3 Clinical Trials Liability: [\*\*\*] dollars (\$[\*\*\*]) per occurrence. PB will obtain such Clinical Trials Liability insurance on a global basis, and, if required, supplemented Clinical Trials Liability Insurance in the US, at its expense and SFJ will obtain supplemental Clinical Trials Liability insurance for the SFJ Territory and on a country specific basis in the European Clinical Trial Countries as required by Applicable Law at its expense, which will be considered Development Costs. Coverage must be maintained for as long as required by Applicable Law in each country after release of the last Subject from the Clinical Trials or where there is no legal requirement at least [\*\*\*] after the termination of this Agreement.

12.3.2.4 Professional Liability: Any subcontractor, including any Permitted Third Party, who provides professional services to such Party for the Clinical Trials, will obtain Professional Liability Insurance in lieu of Clinical Trial Insurance, with a minimum limit of [\*\*\*] dollars (\$[\*\*\*]) per occurrence. Coverage must be maintained for at least [\*\*\*] after the later of (i) expiration or early termination of this Agreement and (ii) release of the last Subject from the Clinical Trials.

12.3.3 Additional Insured. Each Party will include the other Party and its Affiliates as additional insured parties on such Party's Clinical Trial Liability insurance, as set forth in Section 12.3.2.3 for [\*\*\*] after the later of termination of this Agreement or release of the last Subject from the Clinical Trials.

12.3.4 Product Liability Insurance. Prior to a Program Transfer, PB will be responsible for maintaining product liability insurance related to the Development and

Commercialization of the Product at its expense with SFJ to be named as an additional insured party. From and after a Program Transfer, SFJ will be responsible for maintaining product liability insurance related to the Development and Commercialization of the Product at its expense with PB to be named as an additional insured party.

## ARTICLE 13

### REPRESENTATIONS AND WARRANTIES

#### 13.1 Representations, Warranties and Covenants of Both Parties.

13.1.1 Each Party hereby represents and warrants that it has the requisite corporate power and authority to enter into this Agreement and that this Agreement constitutes a legal and valid obligation binding upon such Party, enforceable in accordance with its terms.

13.1.2 Each Party hereby represents and warrants that it is not a party to any agreement that would prevent it from fulfilling its obligations under this Agreement.

13.1.3 Each Party agrees, on behalf of itself and its Affiliates, and its and their respective officers, directors, employees, agents, representatives, consultants, and Permitted Third Parties engaged in connection with the subject matter of this Agreement (“Representatives”), that for the performance of its obligations hereunder:

13.1.3.1 such Party, its Affiliates and its and their respective Representatives shall comply with the Anti-Corruption Laws and shall not take any action that will, or would reasonably be expected to, cause the other Party or its Affiliates to be in violation of any Anti-Corruption Laws; and

13.1.3.2 such Party shall promptly provide the other Party with written notice of the following events: (a) upon becoming aware of any breach or violation by such Party, its Affiliate or any of its or their respective Representatives of any representation, warranty or undertaking set forth in Section 13.1.3.1, or (b) upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of its Representatives connected with this Agreement that any of them is the target of a formal investigation by a governmental authority for a Material Anti-Corruption Law Violation.

13.1.4 Each Party certifies that neither it, nor its Affiliates, nor to its knowledge any Permitted Third Parties engaged by it to perform activities in relation to the Product are debarred under subsections 306(a) or (b) of the US Federal Food, Drug, and Cosmetic Act (US Generic Drug Enforcement Act of 1992; 21 USC 335a (a) or (b)), and that it has not and will not knowingly use in any capacity the services of any Person or Permitted Third Party debarred under this law to conduct the Clinical Trials. Each Party further certifies that neither it, nor any of its Affiliates are excluded from any federal health care program, including but not limited to Medicare and Medicaid. Each Party will notify the JSC immediately if either of these certifications needs to be amended in light of new information.

13.1.5 Each Party further covenants that it and its Permitted Third Parties have, or will have at the required times, such certifications, permits, and authorizations as are required to conduct the Clinical Trials and perform any and all of their obligations in connection with the Clinical Trials supervised by it.

### 13.2 Additional PB Representations, Warranties and Covenants.

13.2.1 Licensure, Registration and Accreditation. PB hereby represents and warrants that it is licensed, registered, or otherwise qualified in all material respects under all Applicable Laws to do business in each jurisdiction where such licenses, registrations or other qualifications are required. PB further represents and warrants that there has not been and covenants that there will not be during the Term any breach or default by PB under AZ License which has not been or will not be, as applicable, timely cured as permitted thereunder, and that the AZ License is and shall continue to be in full force and effect during the Term, except to the extent that such a breach, default or failure as to the AZ License would not have a material adverse effect on PB's ability to satisfy its obligations under this Agreement. During the Term, PB shall: (a) not take any action that would entitle MedImmune to terminate the AZ License pursuant to Section 9.2.3 thereof (b) take such actions as are necessary to cure any action by a Sublicensee (as defined in the AZ License) that would entitle MedImmune to terminate the AZ License; and (c) not mutually agree with MedImmune to terminate the AZ License, without the prior written consent of SFJ, to be given or withheld in its sole discretion. In addition, during the Term, PB shall not take any action to terminate the AZ License without providing [\*\*\*] prior written notice to SFJ of PB's intent to terminate so that SFJ may, in its sole discretion, elect to obtain the Program Transfer, and if SFJ elects in writing within such [\*\*\*] period to obtain the Program Transfer, then PB shall not terminate the AZ License but shall assign it to SFJ in accordance with the Program Transfer Agreement and in such event PB shall not be entitled to any royalty payments as set forth in Section 3 of the Program Transfer Agreement.

13.2.2 Disclosure of Regulatory Notices and Communications. PB hereby represents and warrants that, as of [\*\*\*] prior to the Effective Date, the regulatory communications and, if any, notices of inspection, inspection reports, warning letters and deficiency letters related to the Product made available by PB in the Data Room were true and complete copies of such documents. To the knowledge of PB, such documents comprise all material written regulatory communications related to Clinical Trials design or the chemistry, manufacturing or controls of the Product from all Regulatory Authorities in the possession of PB as of [\*\*\*] prior to the Effective Date.

13.2.3 CRO Inquiry. PB hereby represents and warrants that, up to and as at the Effective Date, after due inquiry to its CRO responsible for conducting the Clinical Trials, PB has not received any verbal or written notice of the occurrence of any Serious Safety Issue in the Clinical Trials.

13.2.4 Compliance. PB represents and warrants that, prior to the Effective Date, (a) it has conducted all preclinical and clinical activities related to the development of the Product for the Indication in material compliance with Applicable Laws, and (b) to PB's knowledge, all Third Parties utilized by PB to perform any portion of the preclinical and clinical

activities have conducted such portion of such preclinical activities in material compliance with Applicable Laws. PB will manufacture or have manufactured the Product for the Clinical Trials in accordance with GMP.

13.2.5 Intellectual Property. PB [\*\*\*]. The development, manufacture and commercialization of the Product by PB [\*\*\*]. There are no outstanding options, licenses or agreements of any kind granted by PB relating to the development, manufacture and commercialization of the Product. PB has not received any communications alleging that PB has violated or that the development, manufacture and commercialization of the Product would violate any of the patents, trademarks, service marks, trade names, copyrights, trade secrets or other proprietary rights of any Third Party.

13.2.6 PB Data Provided as of the Effective Date. PB hereby represents and warrants that, up to and as of the Effective Date, (i) the CMC Information set forth in the Data Room is accurate in all material respects, (ii) the descriptions of, protocols for, and data and other results of, the Clinical Trials of the Product for the Indication conducted by or on behalf of PB set forth in the Data Room are accurate and complete in all material respects and there are no material omissions from such documents, data and other results that render such documents, data or other results materially misleading and (iii) the summaries of primary data regarding the Product and the Comparators set forth in the Data Room are accurate and complete in all material respects, and there are no material omissions from such summaries as so presented that render such summaries materially misleading.

13.3 Outstanding Indebtedness. PB hereby represents and warrants that, as at the Effective Date, PB and its subsidiaries have no indebtedness for borrowed money other than indebtedness under the SVB Loan Agreement and obligations in respect of corporate credit cards.

13.4 Contingent Liabilities. PB hereby represents and warrants that, except as reflected in PB's consolidated balance sheet for the quarter ended September 30, 2019 included in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, as of the Effective Date, PB and its subsidiaries do not have any Contingent Liabilities that would be required to be reflected on PB's balance sheet in accordance with GAAP except for (i) obligations in connection with this Agreement, and (ii) other Contingent Liabilities incurred in the ordinary course of business that are not material to the business of PB and its subsidiaries, taken as a whole.

13.5 SFJ Representation, Warranty and Covenant. SFJ hereby represents, warrants and covenants that it will have, as and when needed, sufficient funds to satisfy its obligations hereunder.

### 13.6 DISCLAIMER OF REPRESENTATIONS AND WARRANTIES.

13.6.1 Each Party hereby agrees and understands that because the Clinical Trials and the Product are experimental in nature, the outcome is inherently uncertain and unpredictable. Each Party hereby agrees and understands that the other Party makes no

representation, guarantee or warranty, express or implied, regarding the outcome of the Clinical Trials (including achievement of the Phase 3 Success Criteria), any Research Results generated after the Effective Date, the ability to obtain Regulatory Approval or the patentability, legal protectability or usefulness of any Intellectual Property arising from the Clinical Trials.

13.6.2 EXCEPT AS OTHERWISE SET FORTH IN THIS ARTICLE 13, NEITHER PARTY MAKES, AND EACH PARTY EXPRESSLY DISCLAIMS, ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT, EITHER ORAL OR WRITTEN, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING ANY REPRESENTATION OR WARRANTY REGARDING THE USE, RESULTS OR EFFICACY OF THE PRODUCT.

## ARTICLE 14

### TERM AND TERMINATION

14.1 Term. The term of this Agreement (the "Term") will commence on the Effective Date and will expire upon the earliest of (i) termination of this Agreement in accordance with Section 14.2, or (ii) the date of payment of the last Approval Payment due based on all applicable Regulatory Approvals which have been received.

#### 14.2 Termination.

##### 14.2.1 Termination for Breach.

Either Party may terminate this Agreement immediately in the event of a material breach of this Agreement by the other Party provided that the breaching Party has received written notice from the non-breaching Party of such breach, specifying in the reasonable detail the particulars of the alleged breach and such breach has not been cured within [\*\*\*] after the date of the relevant notice. The non-breaching Party shall have the right to pursue remedies it may have at law or equity for such breach, including the right to seek damages from the breaching Party. In the event that SFJ terminates this Agreement pursuant to this Section 14.2.1 then in exchange for purchasing the Trial Data Package including the Research Results included therein as set forth in Section 11.1.1.4, PB will pay SFJ, within [\*\*\*] of the date of termination, an amount equal to three hundred percent (300%) of Development Costs paid or incurred by SFJ prior to such termination. Additionally, if PB elects to continue development of the Product and obtains Regulatory Approval following such termination, PB will remain obligated to pay any Approval Payments that become due and payable pursuant to ARTICLE 6 at such time as such payments become due and payable (if ever) (except to the extent PB pays any Buy-Out Payment(s) pursuant to Section 6.7), provided that each Approval Payment (or Buy-Out Payment, as applicable) shall be adjusted as set forth in Section 6.2, and reduced by the amount previously paid by PB to SFJ pursuant to this Section 14.2.1.

In the event that PB terminates this Agreement pursuant to this Section 14.2.1 then, if PB elects to continue development of the Product and obtains Regulatory Approval following such termination, in exchange for purchasing the Trial Data Package including the Research Results

therein as set forth in Section 11.1.1.4, PB shall remain obligated to pay to SFJ any Approval Payments that become due and payable (if ever) pursuant to ARTICLE 6 (except to the extent of the amount of any Buy-Out Payment pursuant to Section 6.7), provided that such Approval Payments (or Buy-Out Payment paid by PB, as applicable) shall be adjusted as set forth in Section 6.2.

Notwithstanding the foregoing, if PB terminates this Agreement pursuant to this Section 14.2.1 above based on SFJ's failure to make any payment due to PB in accordance with ARTICLE 4, then, if PB elects to continue development of the Product and obtains Regulatory Approval following such termination, PB shall remain obligated to pay to SFJ fifty percent (50%) of any Approval Payments that become due and payable pursuant to ARTICLE 6 at such time that such payments become due and payable (if ever) pursuant to ARTICLE 6 (or, as applicable, fifty percent (50%) of any Buy-Out Payment that PB elects to pay pursuant to Section 6.7), provided that such Approval Payments (or Buy-Out Payment, as applicable) shall also be adjusted as set forth in Section 6.2.

14.2.2 At-Will Termination by PB. PB may terminate this Agreement at any time after SFJ has paid or incurred a total of \$60 million of Development Costs and prior to the date of receipt of the first Regulatory Approval upon [\*\*\*] prior written notice to SFJ. In the event that PB terminates this Agreement pursuant to this Section 14.2.2 then in exchange for purchasing the Trial Data Package including the Research Results included therein as set forth in Section 11.1.1.4, PB will pay SFJ, within [\*\*\*] of the date of termination, an amount equal to three hundred percent (300%) of Development Costs paid or incurred by SFJ prior to such termination. Additionally, if PB elects to continue development of the Product and obtains Regulatory Approval following such termination, PB will remain obligated to pay any Approval Payments that become due and payable pursuant to ARTICLE 6 at such time as such payments become due and payable (if ever) pursuant to ARTICLE 6 (except to the extent of the amount of any Buy-Out Payment paid by PB pursuant to Section 6.7), provided that each Approval Payment (or the Buy-Out Payment, as applicable) shall be adjusted as set forth in Section 6.2, and reduced by the amount previously paid by PB to SFJ pursuant to this Section 14.2.2.

14.2.3 Termination by SFJ for Material Adverse Event. SFJ may terminate this Agreement at any time in the event of a Material Adverse Event immediately upon written notice to PB. In the event that SFJ terminates this Agreement pursuant to this Section 14.2.3, then, if PB elects to continue development of the Product and obtains Regulatory Approval following such termination, in exchange for purchasing the Trial Data Package including the Research Results included therein as set forth in Section 11.1.1.4, PB shall remain obligated to pay SFJ an amount equal to fifty percent (50%) of the Approval Payments (as adjusted as set forth in Section 6.2, subject, to the extent applicable, to Sections 2.3.3 and 3.12.2) that become due and payable under ARTICLE 6 at such time as they become due and payable (if ever) pursuant to ARTICLE 6 (or, as applicable, 50% of any Buy-Out Payment that PB elects to pay pursuant to Section 6.7), provided that such Approval Payments (or Buy-Out Payment, as applicable) shall also be adjusted as set forth in Section 6.2.

#### 14.2.4 Termination for Failure to Receive Regulatory Approval.

14.2.4.1 This Agreement will, upon written notice from either Party to the other Party, terminate with no further action from either Party if the Product has not received Regulatory Approval from at least one of (i) the FDA, (ii) EMA, (iii) PMDA, or (iv) NMPA after completion of the Clinical Trials, submission by PB of applications for Regulatory Approval to the FDA and EMA, and submission by SFJ of applications for Regulatory Approval to the PMDA and NMPA, and after Commercially Reasonable Efforts to obtain such Regulatory Approvals based on such submitted applications as may be amended from time to time. For the avoidance of doubt, if Regulatory Approval is received from any of the FDA, EMA, PMDA, or NMPA then this Agreement may not thereafter be terminated pursuant to this Section 14.2.4.1.

14.2.4.2 This Agreement will, upon written notice from either Party to the other Party, terminate with no further action from either Party, if the Phase 3 Trial is completed or terminated and either (a) the primary endpoint in the Phase 3 Trial is not achieved or (b) SFJ reasonably determines that the Research Results of the Phase 3 Trial do not support Regulatory Approval. For avoidance of doubt, if an application for Regulatory Approval is submitted to any of the FDA, EMA, PMDA or NMPA then this Agreement may not thereafter be terminated pursuant to this Section 14.2.4.2.

14.2.4.3 In the event that this Agreement is terminated pursuant to this Section 14.2.4, then, if PB elects to continue development of the Product and obtains Regulatory Approval following such termination, in exchange for purchasing the Trial Data Package including the Research Results included therein as set forth in Section 11.1.1.4, PB shall remain obligated to make any Approval Payments that become due and payable pursuant to ARTICLE 6 at such time that such payments become due and payable (if ever) pursuant to ARTICLE 6 (except to the extent of the amount of any Buy-Out Payment paid by PB pursuant to Section 6.7), provided that such Approval Payments (or Buy-Out Payment, as applicable) shall be adjusted as set forth in Section 6.2.

14.2.5 Termination for Bankruptcy. Either Party may terminate this Agreement upon written notice to the other Party if the other Party makes an assignment for the benefit of creditors, or commences a case or proceeding under any bankruptcy, reorganization, insolvency, or similar laws, has a trustee or receiver or similar officer of any court appointed for such Party, or for substantial part of the property of such Party, or bankruptcy, reorganization, insolvency, or liquidation proceedings are instituted by or against such Party without such proceedings being dismissed, in each of the foregoing cases for a period of at least [\*\*\*].

14.2.5.1 In the event that PB terminates this Agreement pursuant to this Section 14.2.5, then, if PB elects to continue development of the Product and obtains Regulatory Approval following such termination, in exchange for purchasing the Trial Data Package including the Research Results included therein as set forth in Section 11.1.1.4, PB shall remain obligated to pay to SFJ any Approval Payments that become due and payable pursuant to ARTICLE 6 at such time as such Approval Payments become due and payable (if ever) pursuant to ARTICLE 6 (except to the extent of the amount of any Buy-Out Payment paid by PB pursuant

to Section 6.7), provided that such Approval Payments (or Buy-Out Payment, as applicable) shall be adjusted as set forth in Section 6.2.

14.2.5.2 In the event SFJ terminates this Agreement pursuant to this Section 14.2.5, then in exchange for purchasing the Trial Data Package including the Research Results included therein as set forth in Section 11.1.1.4, PB will pay SFJ within [\*\*\*] of the date of termination an amount equal to three hundred percent (300%) of Development Costs paid or incurred by SFJ prior to such termination. Additionally, PB will remain obligated to pay any Approval Payments that become due and payable pursuant to ARTICLE 6 at such time as such payments become due and payable (if ever) pursuant to ARTICLE 6 (except to the extent of the amount of any Buy-Out Payment paid by PB pursuant to Section 6.7), provided that such Approval Payments (or Buy-Out Payment, as applicable) shall be adjusted as set forth in Section 6.2, and reduced by the amount previously paid by PB to SFJ pursuant to this Section 14.2.5.2.

14.2.6 Termination for Change of Control of PB. PB will notify SFJ in writing promptly (and in any event within [\*\*\*]) following the entering into of a definitive agreement with respect to a Change of Control of PB. SFJ may, in its sole discretion, terminate this Agreement in its entirety at any time following a Change of Control of PB that occurs prior to the date of payment by PB of the final Approval Payment. In the event that SFJ terminates this Agreement pursuant to this Section 14.2.6, then, in exchange for purchasing the Trial Data Package including the Research Results included therein as set forth in Section 11.1.1.4, PB will pay to SFJ within [\*\*\*] of the date of termination an amount equal to one hundred fifty percent (150%) of Development Costs which were paid or incurred by SFJ. PB or its successor (whose performance shall be guaranteed by PB) shall be obligated to continue to exercise Commercially Reasonable Effort to develop the Product and seek Regulatory Approval as set forth herein following the date of such termination including the Trial Data Package including the Research Results included therein as set forth in Section 11.1.1.4, PB shall remain obligated to pay any Approval Payments that become due and payable pursuant to ARTICLE 6 at such time as such Approval Payments become due and payable (if ever) pursuant to ARTICLE 6 (except to the extent of the amount of any Buy-Out Payment paid by PB pursuant to Section 6.7), provided that such Approval Payments (or Buy-Out Payment, as applicable) shall be adjusted as set forth in Section 6.2, and shall be reduced by the amount previously paid to SFJ as set forth in this Section 14.2.6.

14.2.7 Termination for Safety Concerns. Either Party may terminate this Agreement upon written notice to the other Party if (a) the independent data monitoring committee for the Phase 3 Trial recommends termination of the Phase 3 Trial for reasons pertaining to the health or safety of the Subjects or for futility, or (b) the Parties mutually agree a material health or safety concern with respect to the Subjects exists. In the event that this Agreement terminates pursuant to this Section 14.2.7, then PB will not be obligated to pay to SFJ any Development Costs or Approval Payments. Notwithstanding the foregoing, (A) if this Agreement terminates pursuant to this Section 14.2.7 and such termination: (i) arises as a result of gross negligence on the part of PB; or (ii) is due to (x) the applicable independent data monitoring committee recommending termination of the Phase 3 Trial or (y) PB and SFJ



mutually agreeing to terminate the Phase 3 Trial, in either case ((x) or (y)), due to a Serious Safety Issue that was previously known, demonstrated or identified by PB as being material as of the Effective Date and the material data showing, demonstrating, or identifying such Serious Safety Issue were not included in the Data Room, disclosed in writing to SFJ or otherwise publicly known prior to the Effective Date; then, in either case ((i) or (ii)), PB will pay SFJ within [\*\*\*] of the date of termination an amount equal to three hundred percent (300%) of Development Costs paid or incurred by SFJ, and (B) if PB elects to continue development of the Product and obtains Regulatory Approval following such termination, in exchange for purchasing the Trial Data Package including the Research Results included therein as set forth in Section 11.1.1.4, PB will remain obligated to pay any Approval Payments that become due and payable pursuant to ARTICLE 6 at such time as such Approval Payments become due and payable (if ever) pursuant to ARTICLE 6 (except to the extent of the amount of any Buy-Out Payment paid by PB pursuant to Section 6.7), provided that such Approval Payments (or Buy-Out Payment, as applicable) shall be adjusted as set forth in Section 6.2 and shall be reduced by the amount previously paid by PB to SFJ pursuant to this Section 14.2.7.

#### 14.2.8 Termination for Certain Breaches/Actions.

14.2.8.1 SFJ may terminate this Agreement if (i) PB has breached by its own actions, or by the actions of any of its Representatives, either of Section 13.1.3 or Section 13.1.4 in any material respect, (ii) a Representative of PB has breached the policy attached as Exhibit F-1 in any material respect and such breach results in a Material Anti-Corruption Law Violation, or (iii) SFJ learns (a) that improper payments are being or have been made to Government Officials or any other person by PB or any of its Representatives on behalf of PB or (b) that PB or any of its Representatives with respect to services performed on behalf of PB has accepted any payment, item, or benefit, regardless of value, as an improper inducement to award, obtain or retain business or otherwise gain or grant an improper business advantage from or to any other person or entity (in any such case ((i), (ii) or (iii)), a “PB Compliance Breach”), unless such PB Compliance Breach can be cured without having a materially adverse impact on the probability of completing the Clinical Trials or obtaining Regulatory Approval for the Product. In the event of such termination, PB will not be entitled to any further payments under ARTICLE 4, regardless of any activities undertaken or agreements with additional Third Parties entered into prior to termination. In the event that SFJ terminates this Agreement pursuant to this Section 14.2.8.1, then (a) in exchange for purchasing the Trial Data Package including the Research Results included therein as set forth in Section 11.1.1.4, PB will pay SFJ, within [\*\*\*] of the date of termination, an amount equal to one hundred fifty percent (150%) of Development Costs paid or incurred to PB by SFJ prior to such termination, and (b) if PB elects to continue development of the Product and obtains Regulatory Approval following such termination, PB shall remain obligated to pay to SFJ any Approval Payments that become due and payable pursuant to ARTICLE 6 at such time that such payments become due and payable (if ever) pursuant to ARTICLE 6 (except to the extent of the amount of any Buy-Out Payment paid by PB pursuant to Section 6.7), provided that such Approval Payments (or Buy-Out Payment, as applicable) shall be adjusted as set forth in Section 6.2, and reduced by the amount previously paid by PB to SFJ pursuant to this Section 14.2.8.1.

14.2.8.2 PB may terminate this Agreement if (i) SFJ has breached by its own actions, or by the actions of any of its Representatives, either of Section 13.1.3 or Section 13.1.4 in any material respect, (ii) a Representative of SFJ has breached the policy attached as Exhibit F-2 in any material respect and such breach results in a Material Anti-Corruption Law Violation, or (iii) PB learns (a) that improper payments are being or have been made to Government Officials or any other person by SFJ or any of its Representatives on behalf of SFJ or (b) that SFJ or any of its Representatives with respect to services performed on behalf of SFJ has accepted any payment, item, or benefit, regardless of value, as an improper inducement to award, obtain or retain business or otherwise gain or grant an improper business advantage from or to any other person or entity (in any such case ((i), (ii) or (iii)), an “SFJ Compliance Breach”), unless such SFJ Compliance Breach can be cured without having a materially adverse impact on the probability of completing the Clinical Trials or obtaining Regulatory Approval for the Product. In the event of such termination, SFJ will not be entitled to any further payments hereunder except as set forth below. In the event that PB terminates this Agreement pursuant to this Section 14.2.8.2, then, if PB elects to continue development of the Product and obtains Regulatory Approval following such termination, in exchange for purchasing the Trial Data Package including the Research Results included therein as set forth in Section 11.1.1.4, PB shall remain obligated to pay to SFJ any Approval Payments that become due and payable pursuant to ARTICLE 6 at such time that such payments become due and payable (if ever) pursuant to ARTICLE 6 (except to the extent of the amount of any Buy-Out Payment paid by PB pursuant to Section 6.7), provided that such Approval Payments (or Buy-Out Payment, as applicable) shall be (A) adjusted as set forth in Section 6.2, and (B) reduced by the amount of all documented out-of-pocket expenses incurred by or on behalf of PB as a result or arising out of such violation by SFJ or any of its Representatives (including any and all amounts paid by PB as penalties or fines for such violation, in settlement of legal or administrative proceedings relating to such violation, or otherwise).

14.2.8.3 If a Party learns that any of its Permitted Third Parties has materially breached Section 13.1.3 or Section 13.1.4, or Exhibit F-1 or Exhibit F-2, as applicable, or that improper payments are being or have been made to Government Officials by any of its Permitted Third Parties with respect to services performed on behalf of such Party or in connection with the Clinical Trials, such Party will notify the other Party and, at the other Party’s option, such Party will terminate its relationship with such Permitted Third Party with respect to the Clinical Trials.

14.2.9 Termination Because of Adverse Patent Impact. SFJ may terminate this Agreement if (a) PB is enjoined from further developing or commercializing the Product for the Indication in any of the US, the Designated European Countries or the Designated Asian Countries or (b) the future value of the Product is materially adversely affected due to (i) Third Party patents that were not publicly disclosed or known to SFJ at the Effective Date that would be infringed by the manufacture, use, sale, offer for sale or import of the Product for the Indication in any of the US, the Designated European Countries or the Designated Asian Countries or (ii) invalidity or unenforceability of all Patents within the PB Intellectual Property Covering the Product for the Indication in any of the US, the Designated European Countries or the Designated Asian Countries (in either case ((a) or (b)), “Adverse Patent Impact”), upon

written notice to PB if PB does not cure such Adverse Patent Impact within a period of six (6) months from the date of SFJ's notice to PB of an Adverse Patent Impact. In the event that SFJ terminates this Agreement pursuant to this Section 14.2.9, then in exchange for purchasing the Trial Data Package including the Research Results included therein as set forth in Section 11.1.1.4, PB shall pay to SFJ, within [\*\*\*] of the date of termination, an amount equal to all Development Costs paid or incurred by SFJ as of the date of termination.

14.2.10 Termination for JSC Decision. SFJ may, in its sole discretion, terminate this Agreement in its entirety at any time prior to the date of receipt of the first Regulatory Approval in the event PB exercises its decision-making authority under Section 5.2.4 to approve a matter set forth in Section 5.2.2 and, after escalation to the Executive Officers in accordance with Section 5.2.4, SFJ continues in good faith to disagree with such decision. In the event that SFJ terminates this Agreement pursuant to this Section 14.2.10, then in exchange for purchasing the Trial Data Package including the Research Results included therein as set forth in Section 11.1.1.4, PB will pay to SFJ, within [\*\*\*] of the date of termination, an amount equal to the Development Costs paid or incurred by SFJ plus interest at the annual rate of twenty-five percent (25%) from the date such Development Costs were paid or incurred by SFJ and, if PB elects to continue development of the Product and obtains Regulatory Approval following such termination, PB shall remain obligated to pay any Approval Payments that become due and payable pursuant to ARTICLE 6 at such time as such Approval Payments become due and payable (if ever) pursuant to ARTICLE 6 (except to the extent of the amount of any Buy-Out Payment paid by PB pursuant to Section 6.7), provided that such Approval Payments (or Buy-Out Payment, as applicable) shall be adjusted as set forth in Section 6.2, and reduced by the amount previously paid to SFJ as set forth in this Section 14.2.10.

14.3 Certain Additional Consequences of Termination. In the event of any termination of this Agreement pursuant to Section 14.2, then, if SFJ has not caused a Program Transfer to occur pursuant to Section 3.20:

14.3.1 to the extent not previously assigned to PB pursuant to Section 11.1.1.4, SFJ shall, and it hereby does, assign sole and exclusive ownership of the Trial Data Package including the Research Results included therein to PB, such assignment to be effective in accordance with Section 11.1.1.4;

14.3.2 effective as of such termination, SFJ shall, and it hereby does, assign to PB all of SFJ's and its Affiliates' right, title and interest in and to all Product Filings then owned or Controlled by SFJ or any of its Affiliates; *provided* that if any such Product Filing is not immediately transferable in a country, SFJ shall provide PB with all benefit of such Product Filing and such assistance and cooperation as necessary or reasonably requested by PB to timely transfer such Product Filing to PB or its designee or, at PB's option, to enable PB to obtain a substitute for such Product Filing without disruption to PB's development or Commercialization of the Product in the SFJ Territory;

14.3.3 within [\*\*\*] after assignment of the Product Filings pursuant to Section 14.3.2, SFJ shall deliver to PB: (a) true, correct and complete copies of all Product Filings in such country (in each case, whether held in the name of SFJ or any of its Affiliates),

and disclose to PB in writing all previously-undisclosed Research Results within the Trial Data Package; (b) formally transfer or assign, or cause to be formally transferred or assigned, into the name of PB or its designee all Product Filings in such country (in each case, whether held in the name of SFJ or any of its Affiliates); and (c) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect, evidence, register and record the transfer, assignment or other conveyance of such rights to PB or its designee;

14.3.4 at PB's written request and election in PB's sole discretion, SFJ shall and hereby does, and shall cause its Affiliates to either: (i) wind down in accordance with Applicable Law and observing applicable ethical and regulatory guidelines any or all Clinical Trials being conducted by or on behalf of SFJ or its Affiliate as of the effective date of termination, at SFJ's cost and expense; or (ii) (x) transfer control to PB of any or all Clinical Trials being conducted by or on behalf of SFJ or its Affiliate as of the effective date of termination and (y) continue to conduct such Clinical Trials being conducted by or on behalf of SFJ or an Affiliate as of the effective date of termination for up to [\*\*\*] to enable such transfer to be completed without interruption of any such Clinical Trial, in each case ((x) and (y)), at PB's cost and expense; and

14.3.5 SFJ shall, and shall cause its Affiliates to, promptly assign to PB or its designee any and all Clinical Trial Agreements, CRO Agreements and other Vendor Agreements to which any of them is a party and cooperate in good faith with PB to provide appropriate notice and new contact information to the applicable Sites, Clinical Investigators, CROs and other Vendors and PB shall accept such assignment of all obligations of SFJ and its Affiliates thereunder without recourse to SFJ other than any indemnification obligations which SFJ may be liable for thereunder.

#### 14.4 Surviving Obligations.

14.4.1 Accrued Rights and Obligations. Except as expressly set forth in Sections 3.20 and 14.4.2, and, if applicable, the Program Transfer Agreement, expiration or termination of this Agreement for any reason will not release either Party from any obligation or liability which, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination.

14.4.2 Exclusive Remedy. Notwithstanding anything herein to the contrary, termination of this Agreement by a Party will be without prejudice to other remedies such Party may have at law or equity; provided that the payment by PB to SFJ of the amounts specified as being payable upon a given termination in Section 14.2 shall be in lieu of any claim for damages that SFJ may have arising out of or in connection with the circumstances that formed the basis for such termination..

14.4.3 Surviving Obligations. The following provisions of this Agreement, together with any other provisions that expressly specify that they survive, will survive expiration or earlier termination of this Agreement:

14.4.3.1 ARTICLE 1, ARTICLE 9, ARTICLE 10, ARTICLE 11, ARTICLE 12, Section 13.1, Section 13.6, Section 14.4 and ARTICLE 15; and

14.4.3.2 solely in the case of termination of this Agreement after payment by SFJ to PB of the Initial Development Cost Payment on the Initial Funding Date, but not in the case of expiration of this Agreement, Sections 3.20, 6.1–6.7, 7.1–7.7 (in the case of such Sections 7.1–7.7, such provisions shall terminate only after all PB Obligations, other than contingent indemnity obligations, have been paid to SFJ or otherwise satisfied in accordance with this Agreement in full), 14.2 and 14.3.

## ARTICLE 15

### MISCELLANEOUS

15.1 Relationship with Affiliates. Each Party will be responsible for any breach by its Affiliates of its obligations in connection with this Agreement, and each such Party will remain responsible for any responsibilities that it has delegated to an Affiliate as though such Party had performed (or failed to perform) such responsibilities itself.

15.2 Prior Agreements. The Parties agree on behalf of themselves and their respective Affiliates that any prior Confidentiality Agreement, by and between PB and SFJ (the “Prior CDA”) is hereby terminated and superseded by this Agreement and that all Information disclosed under or pursuant to the Prior CDAs will constitute Confidential Information disclosed pursuant to this Agreement and will be subject to the terms of ARTICLE 10, with the confidentiality and non-use provisions of ARTICLE 10 applying retroactively to such Confidential Information from the date of disclosure.

15.3 Notices. Any notice or other communication required or permitted to be given by either Party under this Agreement will be in writing and will be effective when delivered if delivered by fax, e-mail, hand, reputable courier service, or five (5) days after mailing if mailed by registered or certified mail, postage prepaid and return receipt requested, addressed to the other Party at the following addresses or such other address as may be designated by notice pursuant to this Section 15.3.:

15.3.1 If to PB:

PhaseBio Pharmaceuticals, Inc.  
1 Great Valley Parkway, Suite 30  
Malvern, PA 19355  
USA  
Attn: Chief Executive Officer

with a copy to:

Attn: Vice President, Head of Legal (at the address set forth above)

and to:

Cooley LLP  
11951 Freedom Drive  
Reston, VA 20190  
USA  
Attn: Christian E. Plaza

15.3.2 If to SFJ:

SFJ Pharmaceuticals X, Ltd  
SIX, 2<sup>nd</sup> Floor, Cricket Square  
PO Box 2681  
Grand Cayman, KY1-1111  
Cayman Islands

Attn: Robert DeBenedetto

with a copy to:

Morrison & Foerster LLP  
755 Page Mill Road  
Palo Alto, CA 94304-1018  
Attention: Michael O'Donnell

15.4 Force Majeure. Neither Party will be liable for any breach or delay in performance of any obligation under this Agreement to the extent caused by any of the following: war, terrorism, riot, fire, explosion, accident, flood, sabotage, changes in Applicable Laws, actions of Governmental Authorities, or any other event beyond the reasonable control of such Party. The Party invoking this Section 15.4 must provide prompt written notice and full particulars of such event to the other Party and will use diligent and commercially reasonable efforts to mitigate the effects of any such force majeure event on such Party's compliance with and performance under this Agreement.

15.5 Use of Names. Neither Party will use the other Party's nor any of its Affiliates' (including the limited partners of SFJ's or its Affiliates') names or trademarks in any promotional materials or advertising without the prior written consent of the other Party except as otherwise expressly permitted in this Agreement.

15.6 Assignment. Without the prior written consent of the other Party hereto, neither Party will sell, transfer, assign, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; *provided, however*, that either Party may assign, sublicense or transfer this Agreement and all of its rights and obligations hereunder, in their entirety, to any of its Affiliates or to a successor in connection with the sale or other transfer of all or substantially all of its business or assets to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise, and

whether this Agreement is actually assigned or is assumed by a Third Party acquirer or the surviving corporation resulting from such transaction by operation of law (e.g., in the context of a reverse triangular merger). Notwithstanding the foregoing, any assignment of the rights or obligations under this Agreement by a Party (i) to an Affiliate shall require such Party to guarantee the performance of such Affiliate's financial and performance obligations hereunder or (ii) in connection with the sale or other transfer of all or substantially all of such Party's business or assets to which this Agreement relates shall require the ultimate Affiliate controlling the other party in such transaction to guarantee such Party's financial and performance obligations hereunder and such Party shall remain liable for such financial and performance obligations notwithstanding such sale or other transfer of all or substantially all of such Party's business or assets to which this Agreement relates. Notwithstanding any of the foregoing, without the consent of PB, which consent may be withheld in PB's sole discretion, SFJ shall not sell, assign, sublicense or otherwise transfer this Agreement to an entity whose primary business is the development or commercialization of pharmaceutical or biotechnology products prior to the date of Program Transfer. For the avoidance of doubt the preceding sentence shall not apply after the date of Program Transfer. Furthermore, notwithstanding any of the foregoing, SFJ may assign its right to receive Approval Payments to (a) the limited partners in SFJ, provided that such limited partners agree that a majority in interest shall be entitled to take all actions and make any consents on behalf of SFJ hereunder and provided that such limited partners notify PB of a single account to which PB can make all payments that may become due hereunder and assume sole responsibility for distributing all such payments, or to a liquidating trust or similar entity that is established to receive and distribute Approval Payments for the benefit of the limited partners in SFJ, that is required to carry out such responsibilities as a single entity, and provided that such limited partners or liquidating trust takes such rights to receive and distribute Approval Payments subject to all of PB's rights and defenses hereunder (and in any case under this clause (a), PB shall have the unconditional right to follow any instruction it receives or rely on any actions, consents and communications received from or taken by such limited partners or liquidating trust or similar entity without any duty to verify or otherwise determine the validity thereof) or (b) an other Third Party to which SFJ assigns this Agreement in its entirety as permitted by the preceding provisions of this Section 15.6, provided that, following any assignment of this Agreement by SFJ to a Third Party pursuant to the foregoing clause (b) the JSC shall terminate, such assignee shall not have any further rights under ARTICLE 5, such assignee shall not have any further rights to approve or consent (and PB shall not have any further obligation to seek SFJ's approval or consent) as to any matter relating to PB's development and Commercialization of the Product, [\*\*\*]. This Agreement is binding upon and will inure to the benefit of each of the Parties, its successors and permitted assigns.

15.7 Further Assurances. The Parties will execute such further reasonable documents and perform such further reasonable acts as may be necessary to comply with or more fully effectuate the terms of this Agreement.

15.8 Fees and Expenses. Each Party to this Agreement will bear its own costs and expenses, including attorneys' fees and expenses, in connection with the closing of the transactions contemplated hereby.

15.9 Governing Law. The construction and validity of this Agreement and the provisions hereof, and the rights and obligations of the Parties hereunder, will be governed by the internal laws of the State of Delaware, USA, and, to the extent applicable to Patents and Trademarks, the applicable federal laws of the USA, in each instance without regard to conflict of laws principles.

15.10 Dispute Resolution. The Parties recognize that disputes as to certain matters relating to this Agreement may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes in an expedient manner by mutual cooperation and without resort to litigation. Accordingly, the Parties agree that any dispute, controversy or claim arising under, out of or in connection with this Agreement, including any subsequent amendments, or the validity, enforceability, construction, performance or breach hereof (and including the applicability of this Section 15.10 to any such dispute, controversy or claim) (each a “Dispute”) shall be resolved as follows:

15.10.1 Either Party shall have the right to refer such Dispute to the Executive Officers for attempted resolution by good faith negotiations for a period of [\*\*\*]. Any final decision mutually agreed to by the Executive Officers in writing shall be conclusive and binding on the Parties. With respect to any Dispute that remains unresolved after the expiration of [\*\*\*] after a Dispute is notified to the Executive Officers, then such Dispute shall be submitted to the International Centre for Dispute Resolution (“ICDR”) for final and binding arbitration pursuant to the arbitration clause set forth in Section 15.10.2. Notwithstanding the foregoing, no matters relating to breach or alleged breach of the ownership of intellectual property or rights in intellectual property or the validity or enforceability thereof shall be resolved by arbitration, but rather shall be determined by a U.S. federal court of appropriate jurisdiction. Notwithstanding the foregoing, any dispute between the Parties as to whether entering into a Licensing Transaction would have a Material Impact shall be resolved as set forth in Section 7.5.5. Notwithstanding anything in this Agreement to the contrary, either Party shall be entitled to seek preliminary injunctive relief in any court of competent jurisdiction immediately if necessary to prevent irreparable harm to that Party.

15.10.2 Arbitration Process.

15.10.2.1 Either Party shall have the right to initiate arbitration at any time after the expiration of thirty (30) days after a Dispute is notified to the Executive Officers. Any disputes concerning the propriety of the commencement of the arbitration shall be finally settled by the arbitral tribunal.

15.10.2.2 Any Dispute including the determination of the scope or applicability of this agreement to arbitrate, shall be determined by the ICDR in accordance with its International Arbitration Rules, except as they may be modified herein. The seat, or legal place, of arbitration shall be New York, and the language of the arbitration shall be English. References herein to any arbitration rules or procedures mean such rules or procedures as amended from time to time, including any successor rules or procedures, and references herein to the ICDR include any successor thereto. The arbitration shall be before a tribunal comprised of three (3) arbitrators. Each Party shall select one arbitrator and within fifteen (15) days of the



second arbitrator's appointment, the two (2) Party appointed arbitrators shall select the third, who shall serve as the tribunal's chair or president. All three (3) arbitrators shall be professionals with substantial experience in development and Commercialization of biopharmaceutical products. An arbitrator shall be deemed to meet these qualifications unless a Party objects within fifteen (15) after the arbitrator is appointed. This arbitration provision, and the arbitration itself, shall be governed by the Federal Arbitration Act, 9 U.S.C. §§ 1 *et. seq.*

15.10.2.3 Consistent with the expedited nature of arbitration, each Party will, upon the written request of the other Party, promptly provide the other with copies of documents on which the producing Party may rely in support of or in opposition to any claim or defense. At the request of a Party, the arbitrators shall have the discretion to order examination by deposition of witnesses to the extent the arbitrator deems such additional discovery relevant and appropriate. [\*\*\*]. All objections are reserved for the arbitration hearing except for objections based on privilege and proprietary or confidential information. [\*\*\*]. Any Dispute regarding discovery, or the relevance or scope thereof, shall be determined by the arbitrators, which determination shall be conclusive. All discovery shall be completed within [\*\*\*] following the appointment of the arbitrators. All costs and/or fees relating to the retrieval, review and production of electronic discovery shall be paid by the Party requesting such discovery.

15.10.2.4 The arbitrators shall have no authority to award punitive or other damages not measured by the prevailing Party's actual damages, except as may be required by statute. Each Party expressly waives and foregoes any right to consequential, punitive, special, exemplary or similar damages or lost profits. The arbitrators shall have no power or authority, under the ICDR rules and procedures or otherwise, to relieve the Parties from their agreement hereunder to arbitrate or otherwise to amend or disregard any provision of this Agreement. The cost of the arbitration, including the fees of the arbitrators and reasonable attorney's fees of the prevailing Party, shall be borne by the Party the arbitrator determines has not prevailed in the arbitration.

15.10.2.5 If an arbitral award does not impose an injunction on the losing Party or contain a money damages award in excess of [\*\*\*] dollars USD (\$[\*\*\*]), then the arbitral award shall be final and binding and shall only be subject to such challenges as would otherwise be permissible under the Federal Arbitration Act, 9 U.S.C. § 1 *et. seq.* . Judgment on such an award may be entered in any court of competent jurisdiction and the Parties undertake to carry out the award without delay. In the event that an arbitral award imposes an injunction or contains a monetary award in excess of [\*\*\*] dollars USD (\$[\*\*\*]), the Parties agree that such award may be appealed pursuant to the AAA's Optional Appellate Arbitration Rules ("Appellate Rules") and should not be considered to be final and binding until after the time for filing the notice of appeal under the Appellate Rules has expired. Appeals must be initiated within [\*\*\*] of receipt of the award, as defined by the Appellate Rules, by filing a Notice of Appeal within any AAA office. Following the appeal process, the decision rendered by the appeal tribunal shall be final and binding and judgment on that award may be entered in any court of competent jurisdiction and the Parties undertake to carry out the award without delay.

15.10.2.6 Except as may be required by law, or to protect or pursue a legal right to enforce or challenge an award in legal proceedings, where needed for the preparation or presentation of a claim or defense in this arbitration, or by order of the arbitral tribunal upon application of a Party, neither a Party nor an arbitrator may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of both Parties.

15.11 Limitation of Liability. TO THE MAXIMUM EXTENT PERMITTED BY LAW AND NOTWITHSTANDING ANY PROVISION IN THIS AGREEMENT TO THE CONTRARY, NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, RELIANCE OR PUNITIVE DAMAGES OR LOST OR IMPUTED PROFITS OR ROYALTIES OR COST OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCTS LIABILITY), INDEMNITY OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE. THE PARTIES AGREE THAT THE LIMITATIONS SPECIFIED IN THIS SECTION 15.11 WILL APPLY EVEN IF ANY LIMITED REMEDY SPECIFIED IN THIS AGREEMENT IS FOUND TO HAVE FAILED OF ITS ESSENTIAL PURPOSE. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, "CONSEQUENTIAL DAMAGES" WILL BE DEEMED TO INCLUDE, AND NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY OR ANY OF SUCH OTHER PARTY'S AFFILIATES, REPRESENTATIVES OR STOCKHOLDERS FOR ANY DAMAGES BASED ON OR MEASURED BY LOSS OF PROJECTED OR SPECULATIVE FUTURE SALES OF THE PRODUCT, ANY PAYMENT DUE UPON ANY UNACHIEVED EVENT UNDER ARTICLE 6, OR ANY OTHER UNEARNED, SPECULATIVE OR OTHERWISE CONTINGENT PAYMENTS PROVIDED FOR IN THIS AGREEMENT. FOR THE AVOIDANCE OF DOUBT, THIS SECTION 15.11 IS NOT MEANT TO LIMIT PB'S OBLIGATION TO PAY SFJ THE AMOUNTS SET FORTH IN ARTICLE 6 OR SECTION 14.2.

15.12 Cumulative Remedies. Unless expressly set forth in this Agreement, all rights and remedies of the Parties, including all rights to payment, rights of termination, rights to injunctive relief, and other rights provided under this Agreement, will be cumulative and in addition to all other remedies provided for in this Agreement, in law, and in equity.

15.13 Relationship of the Parties.

15.13.1 Independent Contractors. Nothing contained herein will be deemed to create a partnership, joint venture, or similar relationship between the Parties, including for tax purposes. Neither Party is the agent, employee, joint venturer, partner, franchisee, or representative of the other Party. Each Party specifically acknowledges that it does not have the authority to, and will not, incur any obligations or responsibilities on behalf of the other Party. Notwithstanding anything to the contrary in this Agreement, each Party (and its officers, directors, agents, employees, and members) will not hold themselves out as employees, agents,

representatives, or franchisees of the other Party or enter into any agreements on such Party's behalf.

15.13.2 Direction. Neither Party will be subject to the supervisory direction of the other Party in regard to the conduct of the Clinical Trials.

15.14 No Third Party Beneficiaries. This Agreement and the provisions herein are for the benefit of the Parties only, and are not intended to confer any rights or benefits to any Third Party.

15.15 Rights Reserved. No license or any other right is granted to either Party, by implication or otherwise, except as specifically set forth in this Agreement. All rights not exclusively granted to SFJ are reserved to PB and its Affiliates. Notwithstanding any other provision of this Agreement to the contrary, and for clarity, no Intellectual Property or other proprietary rights Controlled by PB or its Affiliates will be assigned or licensed to SFJ in connection with this Agreement, except, if executed by the Parties, as expressly set forth in the Program Transfer Agreement.

15.16 Nonsolicitation. During the Term and for a period of [\*\*\*] thereafter, neither Party shall solicit an employee of the other Party who is or has been involved in the performance or oversight of any of the development activities hereunder to terminate his or her employment and accept employment or work as a consultant with the soliciting Party. Notwithstanding the foregoing, nothing herein shall restrict or preclude the Parties' right to make generalized searches for employees by way of a general solicitation for employment placed in a trade journal, newspaper or website.

15.17 Amendments; No Waiver. Unless otherwise specified herein, no amendment, supplement, or modification of this Agreement will be binding on either Party unless it is in writing and signed by both Parties. No delay or failure on the part of a Party in the exercise of any right under this Agreement or available at law or equity will be construed as a waiver of such right, nor will any single or partial exercise thereof preclude any other exercise thereof. All waivers must be in writing and signed by the Party against whom the waiver is to be effective. Any such waiver will constitute a waiver only with respect to the specific matter described in such writing and will in no way impair the rights of the Party granting such waiver in any other respect or at any other time.

15.18 Severability. If any provision (or portion thereof) of this Agreement is determined by a court or arbitration to be unenforceable as drafted by virtue of the scope, duration, extent, or character of any obligation contained herein, it is the Parties' intention that such provision (or portion thereof) will be construed in a manner designed to effectuate the purposes of such provision to the maximum extent enforceable under such Applicable Law. The Parties will enter into whatever amendment to this Agreement as may be necessary to effectuate such purposes.

15.19 Entire Agreement. This Agreement, including all Exhibits hereto and the Disclosure Letter, contains the entire understanding of the Parties and supersedes, revokes, terminates, and cancels any and all other arrangements, understandings, agreements, term sheets,

or representations and warranties, whether oral or written, between the Parties relating to the subject matter of this Agreement.

15.20 Counterparts. This Agreement will be executed in two (2) counterparts, one (1) for either Party, which, taken together, will constitute one and the same agreement. This Agreement will not be binding on the Parties or otherwise effective unless and until executed by both Parties.

15.21 Construction. This Agreement has been negotiated by the Parties and their respective counsel. This Agreement will not be construed in favor of or against either Party by reason of the authorship of any provisions hereof.

*[Signature Page Follows]*

IN WITNESS WHEREOF, the Parties, intending to be legally bound hereby, have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the Effective Date.

PHASEBIO PHARMACEUTICALS, INC.

By: /s/ Jonathan Mow  
Name: Jonathan Mow  
Title: CEO

Date: January 9, 2020

**SIGNATURE PAGE TO THE CO-DEVELOPMENT AGREEMENT**

IN WITNESS WHEREOF, the Parties, intending to be legally bound hereby, have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the Effective Date.

SFJ PHARMACEUTICALS X, LTD.

By: /s/ Robert DeBenedetto  
Name: Robert DeBenedetto  
Title: Director

Date: January 9, 2020

**SIGNATURE PAGE TO THE CO-DEVELOPMENT AGREEMENT**

## EXHIBIT LIST

- Exhibit A The Product
- Exhibit B Current Approved CROs
- Exhibit C Current Approved Vendors
- Exhibit D Development Plan
- Exhibit E Executive Officers
- Exhibit F-1 PB Anti-Bribery and Anti-Corruption Practices
- Exhibit F-2 SFJ Anti-Bribery and Anti-Corruption Practices
- Exhibit G SFJ European Operational Support
- Exhibit H Warrant
- Exhibit I Timeline
- Exhibit J Manufacturer
- Exhibit K Trial Data Package Purchase Agreement
- Exhibit L AZ License
- Exhibit M Amendment to AZ License
- Exhibit N MedImmune Pharmacovigilance Agreement
- Exhibit O Program Transfer Agreement
- Exhibit P Terms of SVB Subordination Agreement

Certain information has been excluded from this agreement (indicated by “[\*\*\*]”) because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

### PROGRAM TRANSFER AGREEMENT

THIS PROGRAM TRANSFER AGREEMENT (this “**Agreement**”) is made and entered into as of [insert date that the Program Transfer Notice is delivered to PB], by and among PhaseBio Pharmaceuticals Inc., a Delaware corporation (“**PB**”), and SFJ Pharmaceuticals X, Ltd., a Cayman Islands company (“**SFJ**”). Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in (i) the Co-Development Agreement dated as of January 9, 2020 between PB and SFJ (the “**Co-Development Agreement**”) or (ii) if not defined in the Co-Development Agreement, the AZ License.

WHEREAS, pursuant to Section 3.20 of the Co-Development Agreement, SFJ delivered the Program Transfer Notice to PB, whereupon PB became obligated to cause PB’s business related to the Product to be transferred to SFJ in accordance with Section 1 of this Agreement, on the terms and subject to the conditions set forth in this Agreement (the “**Program Transfer**”).

NOW, THEREFORE, the parties hereto agree as follows:

1. Program Transfer.

1.1 Assignments. Effective upon delivery of the Program Transfer Notice to PB:

(a) PB shall, and it hereby does, assign to SFJ the AZ License and all of PB’s rights and obligations thereunder, and SFJ shall, and it hereby does, assume the AZ License and all of PB’s rights and obligations thereunder.

(b) PB shall, and it hereby does, assign to SFJ each Licensing Transaction Agreement that is then in effect and all of PB’s rights and obligations thereunder, and SFJ shall, and it hereby does, assume each such Licensing Transaction Agreement and all of PB’s rights and obligations thereunder.

1.2 Within [\*\*\*] after delivery of the Program Transfer Notice to PB, PB shall provide written notice to MedImmune of the assignment to SFJ of the AZ License in accordance with the terms of the AZ License and written notice to each counterparty to a Licensing Transaction Agreement assigned to SFJ of the assignment to SFJ of such Licensing Transaction Agreement.

1.3 Effective upon delivery of the Program Transfer Notice to PB, PB shall, and it hereby does, and shall cause its Affiliates to, effective upon delivery of the Program Transfer Notice:

(a) grant to SFJ an exclusive, perpetual, royalty-free (except to the extent set forth in Section 2) license, with the right to grant multiple tiers of sublicenses, under the Licensee Termination Know-How, Licensee Termination Patents, and PB’s interest in Joint Inventions and Joint Patents to Exploit and Manufacture in the “Territory” (as defined in the AZ License) any Licensed Compound or Licensed Product and grant to SFJ an exclusive perpetual, worldwide, royalty free (except to the extent set forth in Section 2) license, with the right to grant multiple tiers of sublicense, under the PB Intellectual Property and PB Confidential Information to Develop and Commercialize the Product,



provided that SFJ is not granted any license in this Agreement with respect to any active pharmaceutical ingredient other than a Licensed Compound. Notwithstanding the exclusivity of the foregoing license, PB hereby reserves the non-exclusive right under the Licensee Termination Know-How, Licensee Termination Patents, PB's interest in Joint Inventions and Joint Patents, the PB Intellectual Property and PB Confidential Information, to make and have made Licensed Compound and Licensed Product as necessary to perform PB's obligation to supply or have supplied the Licensed Compounds and Licensed Products to SFJ as set forth in Section 1.9; and

(b) assign to SFJ all of PB's right, title and interest in and to (i) each Product Trademark and (ii) all Regulatory Documentation (including any Regulatory Approvals and Licensee Regulatory Documentation) and the Clinical Trials Database, Clinical Trials Master File, and Case Report Forms applicable to any Licensed Compound or Licensed Product then owned or Controlled by PB or any of its Affiliates, subject, in each case, to SFJ's royalty payment obligations under Section 2; provided that if any such Regulatory Documentation is not immediately transferable in a country, PB shall provide SFJ with all benefit of such Regulatory Documentation and such assistance and cooperation as necessary or reasonably requested by SFJ to timely transfer such Regulatory Documentation to SFJ or its designee or, at SFJ's option, to enable SFJ to obtain a substitute for such Regulatory Documentation without disruption to SFJ's Exploitation or Manufacture of the applicable Licensed Compound(s) or Licensed Product(s). For the avoidance of doubt and notwithstanding anything else in the Co-Development Agreement or this Agreement to the contrary, in the event of Program Transfer SFJ shall not assign or transfer to PB and shall retain all right, title and interest to the Trial Data Package and the Product Filings notwithstanding any Approval Payments which may be made to SFJ, and if the Trial Data Package and the Product Filings have been assigned or transferred to PB, PB shall reassign and transfer the Trial Data Package and the Product Filings to SFJ.

1.4 Effective upon delivery of the Program Transfer Notice to PB, all Confidential Information of PB to the extent relating specifically to any Licensed Compound or Licensed Product or the Exploitation thereof shall thereafter be deemed Confidential Information of SFJ (provided that, for clarity in the case of Confidential Information consisting of PhaseBio Know-How that has uses or application to retained products or technology of PB, this Section 1.4 is not intended to cause such PhaseBio Know-How to constitute Confidential Information of SFJ for purposes of use or application of such Confidential Information relating to such retained products or technologies).

1.5 Notwithstanding any other provision of this Section 1 to the contrary, to the extent the Licensee Termination Patents include any Patent licensed to PB or its Affiliate by a Third Party (other than MedImmune) that is subject to royalty or milestone payment obligations to such Third Party with respect to the Product, then PB shall so notify SFJ within [\*\*\*] after delivery of the Program Transfer Notice to PB, which notice shall include a true, complete and correct description of such royalty and milestone payment obligations and a correct and complete copy of such Third Party agreement, and the continued inclusion of such Patent in the Licensee Termination Patents licensed to SFJ under Section 1.3(a) shall be subject to SFJ's agreeing, in writing in accordance with this Section 1.5, to pay all royalty and milestone payments that become due to such Third Party by reason of the Exploitation of the Product by or on behalf of PB or any of its Affiliates or (sub)licensees. SFJ shall pay such amounts in accordance with the terms and conditions of the applicable Third Party agreement, unless SFJ declines or terminates such sublicense rights in accordance with this Section 1.5. Within [\*\*\*] of SFJ's receipt of such notice regarding any such Third Party agreement, SFJ shall have the right, upon written notice to PB,

to decline any sublicense under such Third Party agreement, in which case SFJ will be deemed not to have received license rights under any such Third Party agreement as of the delivery of the Program Transfer Notice to PB. If SFJ does not decline any such Third Party agreement within such [\*\*\*] period, SFJ shall have the right in its sole discretion to terminate the sublicense under such Third Party agreement at any time following such [\*\*\*] period. For clarity, any such Third Party royalty obligations described in this Section 1.5 are in addition to the royalties payable by SFJ to PB for the licenses granted and assignments made by PB pursuant to the first sentence of Section 1.3(a) and pursuant to Sections 1.3(b) and 1.6.

1.6 PB shall and hereby does, and shall cause its Affiliates to, effective as of delivery of the Program Transfer Notice to PB, grant SFJ an exclusive, royalty-free (except as set forth in Section 2) right of reference, with the right to grant multiple tiers of further rights of reference, in and to all Regulatory Documentation (including any Regulatory Approvals) then owned or Controlled by PB or any of its Affiliates that are not assigned to SFJ pursuant to Section 1.3(b) above to Exploit and Manufacture in the "Territory" (as defined in the AZ License) any Licensed Compound or Licensed Product.

1.7 PB shall provide to SFJ a list of all clinical studies ongoing with respect to any Licensed Compound or Licensed Product and, unless expressly prohibited by any Regulatory Authority, at SFJ's written request and election in SFJ's sole discretion, PB shall and hereby does, and shall cause its Affiliates to either: (i) wind down in accordance with Applicable Law and observing applicable ethical and regulatory guidelines any or all clinical studies involving Licensed Products being conducted by or on behalf of PB or its Affiliate (but not by any counterparty to a Licensing Transaction Agreement assigned to SFJ pursuant to Section 1.1(b)) as of the date of delivery of the Program Transfer Notice to PB, at PB's cost and expense; or (ii) (x) transfer control to SFJ of any or all clinical studies involving Licensed Products being conducted by or on behalf of PB or its Affiliate (but not by any counterparty to a Licensing Transaction Agreement assigned to SFJ pursuant to Section 1.1(b)) as of the date of delivery of the Program Transfer Notice to PB and (y) continue to conduct such clinical studies involving Licensed Products being conducted by or on behalf of PB or an Affiliate (but not by any counterparty to a Licensing Transaction Agreement assigned to SFJ pursuant to Section 1.1(b)) as of the date of delivery of the Program Transfer Notice to PB for up to six (6) months to enable such transfer to be completed without interruption of any such clinical study, in each case ((x) and (y)), at SFJ's cost and expense; provided that SFJ shall not have any obligation to continue any clinical study for which it has elected to have control transferred to SFJ unless required by Applicable Law.

1.8 Following good faith discussions by the Parties as to which Licensed Product Agreements should be assigned to SFJ, at SFJ's written request, PB shall, and shall cause its Affiliates to, assign to SFJ or its designee any and all Licensed Product Agreements, unless, with respect to any such Licensed Product Agreement, such Licensed Product Agreement (a) expressly prohibits such assignment (in which case, PB or its Affiliate, as applicable, shall cooperate with SFJ in all reasonable respects to secure the consent of the applicable Third Party to such assignment), or (b) relates both to Licensed Products and products other than Licensed Products (in which case, at SFJ's request, PB or its Affiliate, as applicable, shall cooperate with SFJ in all reasonable respects to secure the written agreement of the applicable Third Party to a partial assignment of the applicable Licensed Product Agreement relating to the Licensed Products) and, in either case ((a) or (b)) if any such consent or agreement, as applicable, cannot be obtained with respect to a Licensed Product Agreement, at SFJ's request in order to continue to

Exploit Licensed Products following the date of delivery of the Program Transfer Notice to PB, PB shall, and shall cause its Affiliates, obtain for SFJ substantially all of the practical benefit and burden under such License Product Agreement to the extent applicable to the Licensed Products, including by entering into appropriate and reasonable alternative arrangements on terms agreeable to SFJ and subject to the consent and control of SFJ; provided that PB's obligations shall continue only for so long as is reasonably necessary for SFJ to secure alternative arrangements directly with one or more Third Parties through the exercise of commercially reasonable efforts.

1.9 At SFJ's written request, PB shall supply to SFJ the Licensed Compounds and Licensed Products then being manufactured by or on behalf of PB or its Affiliates, in such quantities as SFJ indicates in written forecasts and orders therefor from time to time; provided that (a) PB shall not be required to supply quantities that exceed PB's reasonable forecasts, if any, prepared prior to termination and not in anticipation of termination, with respect to necessary clinical or commercial quantities, as applicable, for the relevant period, (b) each forecast submitted by SFJ to PB shall be made in compliance with the requirements of PB's clinical or commercial (as applicable) supply agreement with its CMO and (c) SFJ shall provide each such forecast to PB prior to the date PB is required to deliver its corresponding forecast to the applicable CMO. PB shall supply such Licensed Compounds and Licensed Products at a supply price equal to [\*\*\*] to Manufacture such Licensed Compounds and Licensed Products, as applicable. Unless SFJ no longer desires to obtain such Licensed Compounds and Licensed Products, PB shall supply such Licensed Compounds and Licensed Products manufactured in accordance with GMP and the then current CMC Information included in the IND or BLA (as applicable) submitted to the applicable Regulatory Authority in adequate quantities to meet SFJ's forecasted requirements of Licensed Compound and Licensed Product made in accordance with the preceding provisions of this Section 1.9 until the earlier of (i) such time as SFJ has established an alternate, validated source of supply for the Licensed Compounds and Licensed Products and SFJ is receiving supply from such alternative source and (ii) (x) if such termination occurs prior to the First Commercial Sale of Licensed Product, the first (1st) anniversary of the date of delivery of the Program Transfer Notice to PB or (y) if such termination occurs after the First Commercial Sale of Licensed Product, the second (2nd) anniversary of the date of delivery of the Program Transfer Notice to PB.

It is the intention of the Parties that following Program Transfer, SFJ shall have all rights necessary from PB to Develop and Commercialize the Product. Accordingly PB agrees on behalf of itself and its Affiliates to take such actions and to reasonably cooperate with SFJ as may be necessary to enable SFJ and its sublicensees to Develop and Commercialize the Product.

2. Effect of Termination of Co-Development Agreement. For clarity, and notwithstanding any other provision of the Co-Development Agreement or this Agreement to the contrary, SFJ's right to exercise its right to obtain a Program Transfer pursuant to Section 3.20 of the Co-Development Agreement and SFJ's right to exercise any right to terminate the Co-Development Agreement pursuant to Section 14.2 thereof shall not be mutually exclusive, provided that if SFJ exercises its right to obtain a Program Transfer pursuant to Section 3.20 of the Co-Development Agreement prior to termination of the Co-Development Agreement, all amounts PB is required to pay with respect to Development Costs (or a percentage or multiple thereof, as applicable) upon termination of the Co-Development Agreement pursuant to Section 14.2 of the Co-Development Agreement as set forth in the applicable subsection thereof, and does pay ("**Termination Payments**"), shall be factored in to the amounts SFJ is entitled to recover pursuant to Section 3.1 as set forth in Sections 3.2(a) and 3.2(b).

### 3. Payments.

3.1 In the event of a Program Transfer, all further payment obligations of SFJ under Article 4 of the Co-Development Agreement shall terminate and be of no further force or effect; provided, however, from and after such time following the Program Transfer (if ever) as SFJ's and its Affiliates' total Program Net Profits (defined below) from the Commercialization and (sub)licensing of Licensed Compounds and Licensed Products equal the 3x Return (defined below) and provided that PB has fulfilled all of its obligations pursuant to Section 1 hereof and subject to Section 13.2.1 of the Co-Development Agreement, SFJ shall pay to PB royalties equal to:

(a) with respect to sales of Licensed Products in the US and the European Countries by SFJ, its Affiliates or by Third Party (sub)licensee(s) of SFJ or its Affiliates (and such (sub)licensee's(s') further sublicensees), [\*\*\*] of aggregate Net Sales of Licensed Products in the US and the European Countries; and

(b) with respect to sales of Licensed Products in the ROW by SFJ, its Affiliates or by Third Party (sub)licensee(s) of SFJ or its Affiliates (and such (sub)licensee's(s') further sublicensees), only from and after such time following the Program Transfer (if ever) as SFJ's and its Affiliates' total Program Net Profits (defined below) from the Commercialization and (sub)licensing of Licensed Compounds and Licensed Products equal the 5x Return (defined below), [\*\*\*] of aggregate Net Sales of Licensed Products in the ROW.

#### 3.2 For purposes of this Section 3:

(a) "**3x Return**" means (i) 300% of SFJ Total Costs (defined below), less (ii) the sum of (x) the total amount of Approval Payments (if any) paid by PB before or after the Program Transfer and (y) the amount of any Termination Payments paid by PB upon or after any termination of the Co-Development Agreement.

(b) "**5x Return**" means (i) 500% of SFJ Total Costs (defined below), less (ii) the sum of (x) the total amount of Approval Payments (if any) paid by PB before or after the Program Transfer and (y) the amount of any Termination Payments paid by PB upon or after any termination of this Agreement.

(c) "**European Countries**" means [\*\*\*].

(d) "**Manufacture**" has the meaning ascribed to such term in the AZ License.

(e) "**Net Sales**" has the meaning ascribed to such term in the AZ License, *mutatis mutandis*.

(f) "**Program**" means all activities by SFJ, PB, or Third Parties associated with the Development, Commercialization and Manufacture of the Licensed Product.

(g) "**Program Net Profits**" means the cumulative amount of cash proceeds derived from the Program (net of a reasonable cash reserve for working capital and capital expenditures) which are distributed or distributable by SFJ to its constituent partners. SFJ agrees to promptly distribute such amount of cash proceeds (net of such reserves) to its constituent partners.

(h) “**Regulatory Exclusivity Period**” has the meaning ascribed to such term in the AZ License, *mutatis mutandis*.

(i) “**ROW**” means all countries of the world outside of the United States and the European Countries.

(j) “**Royalty Term**” means, with respect to the Licensed Product in the United States and each of the European Countries, the period beginning on the date that SFJ first becomes obligated to pay royalties to PB pursuant to Section 3.1 and ending on the latest to occur of (i) the tenth (10th) anniversary of the First Commercial Sale of the Licensed Product in such country, (ii) the expiration of the last-to-expire Licensed Patent covering the manufacture, use or sale of the Licensed Product in such country, and (c) the expiration of Regulatory Exclusivity Period, if any, for the Licensed Product in such country.

(k) “**SFJ Total Costs**” means all capital invested by SFJ in the Program.

3.3 Royalty Term. SFJ shall have no obligation to pay any royalty with respect to Net Sales in any country with respect to any period after the Royalty Term in such country has expired, and any Net Sales in any country with respect to any period after the Royalty Term in such country has expired shall be excluded for purposes of calculating royalties due under Section 3.1.

3.4 Reductions. In the event that SFJ assumes from PB pursuant to Section 1.1, or enters into any agreement with a Third Party (including MedImmune or its Affiliates) in order to obtain or maintain a license to a Patent of such Third Party (including a Licensed Patent) that is necessary for the Manufacture, use or sale of a Licensed Product in any country (a “**Third Party Patent Right**”), under which agreement SFJ is obligated to pay [\*\*\*], SFJ shall be entitled to deduct from royalties payable hereunder in a given Calendar Quarter in such country [\*\*\*] actually paid to such Third Party with respect to such Calendar Quarter under such agreement, solely to the extent that: (i) such [\*\*\*] (a) are triggered by sales of the Licensed Products that would, absent such agreement, infringe such a Third Party Patent Right that is licensed in such country in such Calendar Quarter under such agreement, (b) are otherwise exclusively attributable to such Third Party Patent Right, and (c) exceed [\*\*\*] of Net Sales of Licensed Products in such country in such Calendar Quarter; and (ii) SFJ does not deduct such [\*\*\*] paid to such Third Party from the royalties payable by SFJ to another Third Party licensee of a different Third Party Patent Right. SFJ, upon request by PB, shall provide reasonable evidence, including a copy of any applicable agreement, of such [\*\*\*] actually paid to such Third Party with respect to such Third Party Patent Right. Examples of the calculation of the foregoing deduction [\*\*\*] are set forth in Exhibit A hereto. If the amount of such [\*\*\*] which SFJ shall be entitled to deduct with respect to a country in a particular Calendar Quarter shall exceed the royalties payable to PB with respect to Net Sales of Licensed Products in such country in such Calendar Quarter, SFJ shall be entitled to deduct the balance of the total amount of such deduction from the royalties payable to PB with respect to Net Sales of Licensed Products in such country in subsequent Calendar Quarters, and in no event shall PB be obligated to pay any “negative royalty” to SFJ under this Agreement. Notwithstanding the foregoing, Third Party Patent Rights shall not include any Patent of a Third Party that is not necessary for the Manufacture, use or sale of Licensed Products (1) in the form(s) and formulation(s) being clinically developed or Commercialized by or on behalf of PB as of the date of delivery of the Program Transfer Notice, and (2) manufactured using the manufacturing processes and manufacturing technologies being used by or on behalf of PB in the manufacture of Licensed Products for clinical development or Commercialization as of the date of

delivery of the Program Transfer Notice, and any [\*\*\*] payable by SFJ to any Third Party with respect to Licensed Products for a license of a Patent to any formulation, delivery or manufacturing technology that is not being used by PB for Licensed Products as of the date of delivery of the Program Transfer Notice shall be the sole responsibility of SFJ. [\*\*\*].

3.5 On a quarterly basis following a Program Transfer until SFJ becomes obligated to, and does, deliver its first royalty report to PB as set forth in Section 3.6, SFJ shall provide written reports to PB within [\*\*\*] after the end of each Calendar Quarter setting forth:

- (a) capital invested by SFJ in the Program during such Calendar Quarter;
- (b) SFJ Total Costs since the date of the Program Transfer; and
- (c) as applicable:

(i) in the case of any country in which SFJ or any of its Affiliates is directly Commercializing Licensed Products, Net Sales of Licensed Products in all such countries in such Calendar Quarter, including, on a Licensed Product-by-Licensed Product and country-by-country basis, the number and type of each Licensed Product sold, gross sales, Net Sales, itemized deductions by major cost category as set forth in the definition of Net Sales, and the exchange rates used; and/or

(ii) (A) in the case of any country in which a Third Party (sub)licensee of SFJ or its Affiliate is Commercializing Licensed Products, all royalties received by SFJ or its Affiliate with respect to sales of Licensed Products by such (sub)licensee and its further sublicensees in all such countries, and (B) all other (sub)license revenue received by SFJ or its Affiliate from such Third Party (sub)licensee and its further (sub)licensees in consideration of the grant of Commercialization rights with respect to Licensed Products, including upfront fees, license maintenance fees and milestone payments, in each case, in such Calendar Quarter; and

(d) the exchange rates used to convert any of the amounts paid, incurred, invoiced or received (as applicable) under Sections 3.5(a), 3.5(b) and 3.5(c) in a currency other than U.S. dollars into U.S. dollars.

3.6 Royalties payable to PB under this Section 3 shall be calculated and reported for each Calendar Quarter and shall be paid (i) within [\*\*\*] of the end of the Calendar Quarter with respect to Net Sales of Licensed Products by SFJ and its Affiliates, and (ii) within [\*\*\*] after SFJ receives its royalty payment from a third-party licensee with respect to Net Sales of Licensed Products by such third-party licensee. Each payment of royalties paid to PB shall be accompanied or preceded by a report of royalties payable, in sufficient detail to permit confirmation of the accuracy of the payment made, including: (a) the information described in Sections 3.5(a) and 3.5(b); (b) on a Licensed Product-by-Licensed Product and country-by-country basis, the information described in Section 3.5(c)(i) and clause (A) of Section 3.5(c)(ii); (c) on a Third Party (sub)licensee-by-Third Party (sub)licensee basis, the information described in clause (B) of Section 3.5(c)(ii); and (d) the information described in Section 3.5(d). All royalty payments by SFJ to PB under this Section 3 shall be paid in U.S. dollars. If any currency conversion shall be required in connection with the calculation of royalty payments payable hereunder, such conversion shall be calculated at the rate of exchange for such currency used throughout SFJ's accounting system in conformity with GAAP for the Calendar Quarter for which payment is due, or the actual rate of exchange used by a third-party licensee for payment of a royalty to SFJ, on a country-

by-country basis. All royalty payments shall be made by wire transfer to a bank and account designated in writing by PB, unless otherwise specified in writing by PB.

3.7 SFJ shall, and shall cause its Affiliates and its and their (sub)licensees to, keep complete and accurate financial books and records pertaining to the Commercialization of Licensed Products hereunder, including books and records of the information described in Sections 3.5 and 3.6, in sufficient detail to calculate and verify all amounts payable hereunder. SFJ shall, and shall cause its Affiliates and its and their (sub)licensees to, retain such books and records for [\*\*\*] after the end of the Calendar Year to which such books and records pertain.

3.8 At the request of PB, no more than once each Calendar Year, SFJ shall, and shall cause its Affiliates and its and their (sub)licensees to, permit an independent certified public accounting firm of international standing designated by PB and reasonably acceptable to SFJ (the “**Auditor**”), at reasonable times and upon at least [\*\*\*] prior written notice, to audit the books and records maintained pursuant to Section 3.7 in the location where such books and records are maintained, solely to confirm payments due from SFJ under Section 3 for a period covering not more than the preceding three (3) Calendar Years. No Calendar Year shall be subject to audit under this Section 3.8 more than once, provided that if such records of SFJ, its Affiliates, and its and their (sub)licensees for a given Calendar Year have already been audited pursuant to the AZ License and SFJ has provided a true and complete copy of the report from such audit to PB, then PB shall only be entitled to audit SFJ’s books and records with regard to items not covered by such audit report, and provided further that [\*\*\*]. If MedImmune conducts any audit of the books and records of SFJ, its Affiliates, and its and their (sub)licensees pursuant to the AZ Agreement, SFJ shall provide a true and complete copy of the report from such audit to PB within [\*\*\*] after SFJ receives such report. PB and SFJ shall reasonably cooperate to minimize the burden to SFJ and the expense of conducting any such audit. The Auditor will execute a reasonable written confidentiality agreement with SFJ and will disclose to PB only such information as is reasonably necessary to provide PB with information regarding any actual or potential discrepancies between amounts reported and actually paid and amounts payable under this Agreement. The Auditor will send a copy of the report to SFJ at the same time it is sent to PB. The report sent to both Parties will include the methodology and calculations used to determine the results. PB shall bear the full cost of such audit, unless the audit reveals an underreporting or underpayment by SFJ by more than the greater of (i) [\*\*\*] or (ii) [\*\*\*] of the amount due for any Calendar Year, in which case SFJ shall bear the cost of the audit. If such audit concludes that (a) additional amounts were owed by SFJ, SFJ shall pay the additional amounts, with interest from the date originally due at the rate of [\*\*\*], or (b) excess payments were made by SFJ, PB shall reimburse such excess payments, in either case ((a) or (b)), within [\*\*\*] after the date on which the Auditor’s report is delivered to SFJ.

#### 4. Miscellaneous.

4.1 Complete Agreement. This Agreement together with the Co-Development Agreement, as the same may be amended from time to time, constitutes the entire agreement between the parties hereto regarding the subject matter of this Agreement and supersedes and preempts any prior understandings, agreements or representations, written or oral, which may have related to the subject matter hereof.

4.2 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same agreement.

4.3 Miscellaneous Provisions. Sections 15.1, 15.3, 15.4, 15.6, 15.7, 15.9, 15.10, 15.11, 15.12, 15.13, 15.14, 15.15, 15.17, 15.18 and 15.21 of the Co-Development Agreement shall apply, *mutatis mutandis*, to this Agreement.

\* \* \* \*



IN WITNESS WHEREOF, the parties have executed this Agreement on the day and year first above written.

PB:

**PhaseBio Pharmaceuticals, Inc.**

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

SFJ:

**SFJ Pharmaceuticals X, Ltd.**

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

**Exhibit A**

**“Third-Party Royalties”** means, [\*\*\*].

[\*\*\*]

Certain information has been excluded from this agreement (indicated by “[\*\*\*]”) because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

**CONFIDENTIAL  
EXECUTION COPY**

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**ASSET PURCHASE AGREEMENT**

by and among

**PHASEBIO PHARMACEUTICALS, INC.,**

**SELENITY THERAPEUTICS (BERMUDA), LTD.**

and

**VIAMET PHARMACEUTICALS HOLDINGS, LLC**

Dated as of January 13, 2020

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## ASSET PURCHASE AGREEMENT

**THIS ASSET PURCHASE AGREEMENT** (as may be amended from time to time, this “**Agreement**”) is entered into as of January 13, 2020 (the “**Effective Date**”), by and among **PHASEBIO PHARMACEUTICALS, INC.**, a Delaware corporation having a place of business at 1 Great Valley Parkway, Suite 30, Malvern, Pennsylvania 19355 (“**Purchaser**”), **SELENITY THERAPEUTICS (BERMUDA), LTD.**, a Bermuda exempted company having a place of business at Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda (“**Selenity**”), and **VIAMET PHARMACEUTICALS HOLDINGS, LLC**, a limited liability company organized under the laws of Delaware having a place of business at c/o Verdolino & Lowey, 124 Washington St., Foxborough, MA 02035 (“**VPH**” and, together with Selenity, the “**Sellers**” and each, a “**Seller**”). Sellers and Purchaser are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

### RECITALS

**WHEREAS**, Sellers own certain assets including intellectual property rights related to the compound known as SE-6440 and other CYP11B2 inhibitor compounds;

**WHEREAS**, Sellers desire to sell, transfer, and convey to Purchaser, and Purchaser desires to purchase from Sellers, the Acquired Assets (as defined below) (the “**Acquisition**”), all on the terms and subject to the conditions set forth in this Agreement;

**NOW, THEREFORE**, in consideration of the mutual representations, warranties, and covenants herein contained, and on the terms and subject to the conditions set forth herein, the Parties hereto hereby agree as follows:

### AGREEMENT

#### 1. DEFINITIONS

**1.1 “Acceptance for Filing”** shall mean, with respect to an IND filed for a Product: (a) in the United States, the date the IND goes into effect in accordance with 21 C.F.R. §312.40(b) (or its successor regulation); or (b) in any other Major Market Country or group of Major Market Countries, after filing of an IND with the applicable Regulatory Authority for such country or group of countries, the date upon which enrollment of the first subject in the applicable clinical trial of such Product may legally occur in such country or group of countries.

**1.2 “Accounting Standards”** shall mean (a) U.S. generally accepted accounting principles or (b) International Financial Reporting Standards; in each case, as applicable, consistently applied throughout the organization of a particular entity and its Affiliates.

**1.3 “Acquired Assets”** shall have the meaning provided in Section 2.1.

**1.4 “Acquisition”** shall have the meaning provided in the Recitals.

**1.5 “Actual Combination Product Net Sales”** shall have the meaning provided in Section 1.59.

**1.6 “Affiliate”** shall mean with respect to any Person, any other Person controlling, controlled by, or within common control with such Person, but for only so long as such control exists, and where “control”, for the purpose of this definition, means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance, or (b) direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such entity.

**1.7 “Agreed Amount”** shall have the meaning provided in Section 7.6(b).

**1.8 “Agreement”** shall have the meaning provided in the preamble to this Agreement.

**1.9 “Anti-Corruption Laws”** shall mean the Foreign Corrupt Practices Act of 1977, as amended, the Anti-Kickback Act of 1986 or any applicable laws of similar effect, and the related regulations and published interpretations thereunder.

**1.10 “Apportioned Obligations”** shall have the meaning provided in Section 6.11(d).

**1.11 “Assignment and Assumption Agreement”** shall mean the Assignment and Assumption Agreement among Purchaser and Sellers to be entered into at the Closing, the form of which is attached hereto as **Exhibit A**.

**1.12 “Assumed Liabilities”** shall have the meaning provided in Section 2.3.

**1.13 “Breach”** there shall be deemed to be a “Breach” of a representation, warranty, covenant, obligation or other provision if there is or has been any inaccuracy in or breach (including any inadvertent or innocent breach) of, or any failure (including any inadvertent failure) to comply with or perform, such representation, warranty, covenant, obligation or other provision.

**1.14 “Claim Notice”** shall have the meaning provided in Section 7.6(a).

**1.15 “Claimed Amount”** shall have the meaning provided in Section 7.6(a).

**1.16 “Closing”** shall have the meaning provided in Section 2.10.

**1.17 “Closing Date”** shall have the meaning provided in Section 2.10.

**1.18 “Closing Payment”** shall have the meaning provided in Section 2.5(a).

**1.19 “Combination Product”** shall mean a Product comprising a fixed-dose combination of Compound and at least one Other Active.

**1.20 “Compound”** shall mean (a) Sellers’ proprietary CYP11B2 Inhibitor compound known, or formerly known, as SE-6440 or VT-6440 (the “**Lead Compound**”), or (b) any other

compound that is within the scope of the Listed Patents, including, for clarity, any CYP11B2 Inhibitor formerly owned or Controlled by Selenity.

**1.21 “Confidentiality Agreement”** shall have the meaning provided in Section 6.5.

**1.22 “Consent”** shall mean any approval, consent, ratification, permission, waiver, authorization, filing, registration or notification (including any Governmental Authorization).

**1.23 “Contested Amount”** shall have the meaning provided in Section 7.6(b).

**1.24 “Contract”** shall mean any written, oral, implied or other agreement, contract, understanding, arrangement, instrument, note, guaranty, indemnity, representation, warranty, deed, assignment, power of attorney, certificate, purchase order, work order, insurance policy, benefit plan, commitment, covenant, assurance or undertaking of any nature.

**1.25 “Control” or “Controlled”** means the possession by a Party (whether by ownership, license or otherwise) of, (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to transfer or provide such tangible Know-How to the other Party on the terms and conditions set forth herein, or (b) with respect to Patents, intangible Know-How or other Intellectual Property Rights, the legal authority or right to provide, sell, grant a license, sublicense, access or right to use (as applicable) under such Patents, intangible Know-How or other Intellectual Property Rights to the other Party on the terms and conditions set forth herein, in each case of (a) and (b), without breaching the terms of any agreement with a Third Party.

**1.1 “Conveyance Taxes”** shall mean all sales, use, VAT, transfer, stamp, recording, registration, documentary, filing, and similar Taxes, fees or charges (together with any interest, penalties or additions in respect thereof) imposed by any Governmental Body in respect of the Acquired Assets or Assumed Liabilities that become payable by reason of the Transactions.

**1.2 “Cover” or “Covered”** shall mean, with respect to a particular subject matter at issue and a relevant Patent Right, that, in the absence of ownership of or a license under such Patent Right, the manufacture, use, sale, offer for sale, or importation of such subject matter would infringe one or more Valid Claims of such Patent Right.

**1.3 “CYP11B2 Inhibitor”** shall mean an inhibitor of enzymic activity of aldosterone synthase (Enzyme Commission number 1.14.15.4).

**1.4 “Damages”** shall mean any loss, damage, injury, diminution in value, Liability, claim, demand, settlement, judgment, award, fine, penalty, Tax, fee (including any legal fee, expert fee, accounting fee or advisory fee), charge, cost (including any cost of investigation) or expense of any nature.

**1.5 “Effective Date”** shall have the meaning provided in the preamble to this Agreement.

**1.6 “Encumbrance”** shall mean any lien, pledge, hypothecation, charge, mortgage, security interest, encumbrance, equity, trust, claim, preference, right of possession, encroachment, right of first refusal, preemptive right, community property interest, conditional and sales or other title retention device (including any restriction on the transfer of any asset or any restriction on the

receipt of any income derived from any asset), provided, however, notwithstanding the foregoing, the following shall not be considered “Encumbrances” for purposes of this Agreement (a) liens for current Taxes not yet due and payable and statutory liens incurred in the Ordinary Course of Business and consistent with past practices for obligations not past due, and (b) such imperfections of title and non-monetary encumbrances as do not and will not detract from or interfere with the use of the properties subject thereto or affected thereby, or otherwise impair business operations involving such properties.

**1.7 “Entity”** shall mean any corporation (including any non-profit corporation), general partnership, limited partnership, limited liability partnership, joint venture, estate, trust, cooperative, foundation, society, union, company (including any limited liability company or joint stock company), firm or other enterprise, association, organization, or entity.

**1.8 “Excluded Assets”** shall have the meaning provided in Section 2.2.

**1.9 “Excluded Taxes”** shall mean (i) all Taxes of the Sellers or any of their Affiliates, or for which Sellers or any of their Affiliates are liable, for any taxable period, (ii) all Taxes related to the Excluded Assets or Retained Liabilities for any taxable period, (iii) all Taxes relating to the Acquired Assets or the Assumed Liabilities for any taxable period that ends on or before the Closing Date and, with respect to any taxable period beginning before and ending after the Closing Date, for the portion of such taxable period ending on the Closing Date as determined under Section 6.11(d), and (iv) all Conveyance Taxes.

**1.10 “FDA”** shall mean the United States Food and Drug Administration or any successor agency thereto.

**1.11 “First Commercial Sale”** shall mean, on a Product-by-Product basis, the first sale by Purchaser or any of its Affiliates or Licensees to a Third Party for end use of such Product in a country or jurisdiction after Regulatory Approval has been granted with respect to such Product in such country or jurisdiction.

**1.12 “Generic Version”** shall mean, with respect to Product that has received Regulatory Approval in a country and is being marketed and sold by Purchaser or any of its Affiliates or Licensees in such country, any pharmaceutical product that: (a) is sold in such jurisdiction by a Third Party that is not a Licensee of Purchaser or its Affiliates and did not purchase or acquire such product in a chain of distribution that included Purchaser or any of its Affiliates or Licensees; and (b) has received Regulatory Approval in such jurisdiction, for at least one of the same indications as such Product, as a “generic drug,” “generic medicinal product,” “bioequivalent” or similar designation of interchangeability by the applicable Regulatory Authority in such jurisdiction, pursuant to an expedited or abbreviated approval process in accordance with the then-current rules and regulations in such jurisdiction, where (i) such Product is the “reference medicinal product,” “reference listed product” or similar designation in such jurisdiction, and (ii) such approval referred to or relied on (x) the approved NDA for such Product held by Purchaser, its Affiliate or a Licensee in such jurisdiction or (y) the data contained or incorporated by reference in such approved NDA for such Product in such jurisdiction.

**1.13 “Government Official”** shall mean (a) any officer or employee of any Governmental Body, (b) any person acting in an official capacity on behalf of a Governmental Body, (c) any officer or employee of a Person that is majority or wholly owned by a Governmental Body, (d) any officer or employee of a public international organization, such as the World Bank or the United Nations, (e) any officer or employee of a political party or any person acting in an official capacity on behalf of a political party, or (f) any candidate for political office.

**1.14 “Governmental Body”** shall mean any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature, (b) federal, state, local, municipal, foreign or other government, (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or Entity and any court or other tribunal), (d) multi-national organization or body, or (e) individual, Entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

**1.15 “Governmental Authorization”** shall mean any: (a) permit, license, certificate, franchise, concession, approval, consent, ratification, permission, clearance, confirmation, endorsement, waiver, certification, designation, rating, registration, qualification or authorization issued, granted, given or otherwise made available by or under the authority of any Governmental Body or pursuant to any Legal Requirement; or (b) right under any Contract with any Governmental Body.

**1.16 “IND”** shall mean an investigational new drug application, clinical study application, clinical trial exemption, or similar application or submission filed with or submitted to a Regulatory Authority in a jurisdiction that is necessary to commence human clinical trials in such jurisdiction, including an Investigational New Drug Application filed with the FDA pursuant to 21 C.F.R. Part 312 (or its successor regulation).

**1.17 “Indemnitees”** shall mean Seller Indemnitees and Purchaser Indemnitees, as the case may be.

**1.18 “Indemnitor”** shall mean each of the Sellers and Purchaser, as the case may be.

**1.19 “Initial Resolution Period”** shall have the meaning provided in Section 7.6(b).

**1.20 “Initiation”** shall mean with respect to a clinical trial, the first dosing of the first (1<sup>st</sup>) human subject in such clinical trial.

**1.21 “Intellectual Property”** shall mean copyrights, Know-How, Patent Rights, and Trade Secrets.

**1.22 “Intellectual Property Rights”** shall mean and include all past, present, and future rights of the following types, which may exist or be created under the laws of any jurisdiction in the world: (a) rights associated with works of authorship, including exclusive exploitation rights, copyrights, moral rights, and mask works; (b) trademark, trade name and service mark rights and similar rights; (c) trade secret rights; (d) patents and industrial property rights; (e) other proprietary rights in Intellectual Property of every kind and nature; and (f) rights in or relating to registrations,



renewals, extensions, combinations, divisions, and reissues of, and applications for, any of the rights referred to in subsections (a) through (e) above.

**1.23 “Know-How”** shall mean any and all data, technical information, know-how, processes, procedures, compositions, devices, methods, assays, formulas, protocols, techniques, designs, specifications, chemical and biological materials, test data (including pharmacological, toxicological, pre-clinical and clinical information and test data), analytical and quality control data (including drug stability data), and manufacturing technology and data (including formulation data).

**1.24 “Knowledge”** An individual shall be deemed to have “Knowledge” of a particular fact or other matter if (a) such individual is actually aware of such fact or other matter or (b) a prudent individual could be expected to discover or otherwise become aware of such fact or other matter in the course of conducting a reasonably diligent investigation concerning the truth or existence of such fact or other matter, including, as reasonably possible, consultations with outside legal counsel directly involved in such matter. Sellers shall be deemed to have “Knowledge” of a particular fact or other matter if [\*\*\*] has Knowledge of such fact or other matter.

**1.25 “Lead Compound”** shall have the meaning provided in Section 1.20.

**1.26 “Legal Requirement”** shall mean any federal, state, local, municipal, foreign, or other law, statute, legislation, constitution, principle of common law, resolution, ordinance, code, edict, decree, proclamation, treaty, convention, rule, regulation, ruling, directive, pronouncement, requirement, specification, determination, decision, opinion, or interpretation issued, enacted, adopted, passed, approved, promulgated, made, implemented, or otherwise put into effect by or under the authority of any Governmental Body.

**1.27 “Liability”** shall mean any debt, obligation, duty, or liability of any nature (including any unknown, undisclosed, unmatured, unaccrued, unasserted, contingent, indirect, conditional, implied, vicarious, derivative, joint, several, or secondary liability), regardless of whether such debt, obligation, duty, or liability would be required to be disclosed on a balance sheet prepared in accordance with Accounting Standards and regardless of whether such debt, obligation, duty, or liability is immediately due and payable.

**1.28 “Licensee”** shall mean a Third Party to whom Purchaser grants a license to develop, use, import, promote, offer for sale, sell, have sold, or otherwise commercialize any Product, beyond the mere right to purchase Products from Purchaser and its Affiliates, and excluding wholesalers and distributors that do not promote the sale of such Product, and other similar physical distributors.

**1.29 “Listed Patents”** shall have the meaning provided in Section 1.84.

**1.30 “Major Market Country”** shall mean any of the [\*\*\*].

**1.31 “Milestone Event”** shall have the meaning provided in Section 2.6(a).

**1.32 “Milestone Payment”** shall have the meaning provided in Section 2.6(a).

**1.33** “NDA” shall mean: (a) a New Drug Application, as more fully defined in 21 C.F.R. 314.5 et seq. (or any successor regulation thereto); or (b) the equivalent application filed with any equivalent Regulatory Authority outside the U.S.; including, in each case, all amendments and supplements thereto.

**1.34** “Net Sales” shall mean the gross amounts invoiced by Purchaser, its Affiliates and Licensees (in each case, a “Selling Party”) for sales or other dispositions of Products to Third Parties (excluding Licensees), less the following amounts to the extent attributable to Products and actually incurred, allowed, paid or accrued, or otherwise specifically allocated to Products by the Selling Party (if not previously deducted in calculating the amount invoiced):

- (a) [\*\*\*];
- (b) [\*\*\*];
- (c) [\*\*\*];
- (d) [\*\*\*];
- (e) [\*\*\*]; and
- (f) [\*\*\*];

*provided* that, in each case ((a) through (f)), (1) each such deduction is calculated in a manner that is consistent with the Selling Party’s customary practice for pharmaceutical products and with biopharmaceutical industry practices, and in accordance with Accounting Standards, consistently applied by the Selling Party, (2) each such deduction is directly allocable to Product, or apportioned on a good faith, fair and equitable basis to Product and other products of the Selling Party and its Affiliates such that Product does not bear a disproportionate portion of such deductions, and (3) no particular amount identified above shall be deducted more than once in calculating Net Sales (*i.e.*, no “double counting” of deductions).

For clarification, sale or other disposition of Product by a Selling Party to another Selling Party for resale by such other Selling Party to a Third Party (other than a Selling Party) shall not be deemed a sale for purposes of this definition of “Net Sales,” provided that the subsequent resale is included in the computation of Net Sales. In the event of any sale or other disposition of Product for any consideration other than exclusively monetary consideration on *bona fide* arm’s-length terms (including any sale or other disposition of Product by a Selling Party to another Selling Party for end use by such other Selling Party), then for purposes of calculating Net Sales under this Agreement, such Product shall be deemed to have been sold exclusively for cash at the weighted (by sales volume) average sale price of such Product in *bona fide* arm’s-length transactions (when sold alone, and not with other products) in the applicable country in which such sale or other disposition occurred during the applicable accounting period. Transfers or dispositions of Product for charitable, research and development, clinical or humanitarian purposes, in all cases without consideration, shall be disregarded in determining Net Sales.

On a country-by-country basis, if a Product is sold in a country as part of a Combination Product in a calendar quarter, Net Sales of such Product in such country during such calendar quarter for the purpose of determining Royalties and commercialization milestone payments due hereunder shall be calculated as follows:

(i) In the event that both (x) a Single-Agent Product is sold separately in finished form in such country during such calendar quarter and (y) the Other Active(s) in such Combination Product are sold separately in finished form in such country during such calendar quarter, then Net Sales of such Product shall be determined by multiplying the actual Net Sales of the Combination Product calculated pursuant to the preceding provisions of this Section 1.59 (“**Actual Combination Product Net Sales**”) in such country during such calendar quarter [\*\*\*].

(ii) In the event that a Single-Agent Product is sold separately in finished form in such country during such calendar quarter, but the Other Active(s) in such Combination Product are not sold separately in finished form in such country during such calendar quarter, then Net Sales of such Product shall be calculated by multiplying the Actual Combination Product Net Sales of the Combination Product in such country during such calendar quarter by [\*\*\*].

(iii) In the event that no Single-Agent Product is sold separately in finished form in such country during such calendar quarter, but the Other Active(s) in such Combination Product are sold separately in finished form in such country during such calendar quarter, Net Sales of such Product shall be calculated by [\*\*\*].

(iv) In the event that neither any Single-Agent Product is sold separately in finished form in such country during such calendar quarter, nor the Other Active(s) in such Combination Product are sold separately in finished form in such country during such calendar quarter, then the methodology for determining Net Sales of such Product in such country shall be [\*\*\*].

**1.35 “Non-Transferred Assets”** shall have the meaning provided in Section 6.10.

**1.36 “Order”** shall mean any: (a) order, judgment, injunction, edict, decree, ruling, pronouncement, determination, decision, opinion, verdict, sentence, subpoena, writ or award issued, made, entered, rendered or otherwise put into effect by or under the authority of any court, administrative agency or other Governmental Body or any arbitrator or arbitration panel; or (b) Contract with any Governmental Body entered into in connection with any Proceeding.

**1.37 “Ordinary Course of Business”** shall mean an action taken by or on behalf of Sellers shall not be deemed to have been taken in the “Ordinary Course of Business” unless such action is recurring in nature, is consistent with the past practices of Sellers in the conduct of the Program and is taken in the ordinary course of the normal day-to-day operations of the Program; such action is taken in accordance with sound and prudent business practices and such action is not required to be authorized by the board of directors of a Seller, the managers or board of directors of a Seller or any committee of the board of directors or managers of a Seller and does not require any other separate or special authorization of any nature.

**1.38 “Organizational Documents”** shall mean (a) the articles or certificate of incorporation, association or formation of an Entity; (b) any charter or similar document adopted or filed in connection with the creation, formation, or organization of an Entity; (c) the operating agreement or bylaws of an Entity and (d) any amendment to any of the foregoing.

**1.39 “Other Active”** shall mean any active pharmaceutical ingredient other than Compound.

**1.40 “Party” or “Parties”** shall have the meaning provided in the preamble to this Agreement.

**1.41 “Patent Assignment”** shall have the meaning provided in Section 6.3.

**1.42 “Patent Rights”** shall mean: (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)); and (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

**1.43 “Person”** shall mean any individual, Entity, or Governmental Body.

**1.44 “Phase 1 Clinical Trial”** shall mean a human clinical trial of a Product that satisfies the requirements for a Phase 1 study as defined in 21 CFR § 312.21(a) (or any amended or successor regulations), regardless of where such clinical trial is conducted.

**1.45 “Phase 2 Clinical Trial”** shall mean a human clinical trial of a Product that satisfies the requirements for a Phase 2 study as defined in 21 CFR § 312.21(b) (or any amended or successor regulations), regardless of where such clinical trial is conducted; provided that any Phase 1/2 clinical trial of a Product shall not be considered a Phase 2 Clinical Trial until the first dosing of the first human subject in the Phase 2 arm of such clinical trial and such arm has been acknowledged as such in writing by the FDA (or using such other method of acknowledgement as may be used in the future by the FDA) as satisfying the criteria of 21 CFR § 312.21(b).

**1.46 “Phase 3 Clinical Trial”** shall mean a human clinical trial of a Product that satisfies the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations), regardless of where such clinical trial is conducted.

**1.47 “Post-Closing Apportioned Period”** shall have the meaning provided in Section 6.11(d).

**1.48 “Pre-Closing Apportioned Period”** shall have the meaning provided in Section 6.11(d).

**1.49 “Pricing Approval”** shall mean such governmental approval, agreement, determination or decision establishing prices for a Product that can be charged and/or reimbursed in regulatory jurisdictions where the applicable Regulatory Authorities approve or determine the price and/or reimbursement of pharmaceutical products.

**1.50 “Proceeding”** shall mean any claim, action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding and any informal proceeding), prosecution, contest, hearing, inquiry, inquest, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Body or any arbitrator or arbitration panel.

**1.51 “Product”** shall mean any product that contains a Compound, whether alone or in combination with other active ingredients, in any dosage strength, form, or formulation, and for any mode of administration.

**1.52 “Product Rights”** shall mean a license or other right to develop, market or sell a Compound or Product.

**1.53 “Program”** shall mean any program of research and development directed to CYP11B2 Inhibitors the rights to which are owned or controlled by a Seller, including any program presently conducted, or presently proposed to be conducted, by or on behalf of a Seller or any of its Affiliates (including activities conducted or proposed to be conducted by any Third Party on behalf of a Seller or any of its Affiliates), and specifically including, for clarity, any program of research and development directed to selective CYP11B2 Inhibitors undertaken by or on behalf of Selenity the rights to which are owned or controlled by a Seller.

**1.54 “Program Books and Records”** shall mean all books, ledgers, files, reports, plans, records, manuals and other materials, including books of account, records, files, invoices, correspondence and memoranda, scientific records and files (including laboratory notebooks and invention disclosures), supplier lists, data, specifications, operating history information and inventory records (in any form or medium) in the possession or Control of a Seller or any of its Affiliates that, in each case, relate to the Acquired Assets and/or the Program, but excluding human resources files.

**1.55 “Program Contracts”** shall have the meaning provided in Section 2.1(c).

**1.56 “Program Know-How”** shall mean all Know-How owned or Controlled by a Seller or any of its Affiliates as of the Closing Date that (a) was generated, used, or contemplated as of the Closing Date for use, in connection with the research, development, or manufacture of any Compound or Product or the conduct of the Program, or (b) is necessary for the research, development, manufacture, or commercialization of any Compound or Product.

**1.57 “Program Material”** shall mean the quantities of Compound active pharmaceutical ingredient or other materials specifically related to the manufacture of any Compound, in either

case, in the possession or Control of a Seller or its Affiliates, including the material set forth on **Schedule 1.82**.

**1.58 “Program Patent Files”** shall mean: (a) the complete file histories for the Program Patents in the possession of a Seller or any of its Affiliates; and (b) all files relating to the Program Patents that are held or maintained on a Seller’s or its Affiliate’s behalf by a Seller’s or its Affiliate’s outside patent counsel, including all contents of such files.

**1.59 “Program Patents”** shall mean:

(a) All Patent Rights Controlled by a Seller that cover Compounds, including the composition or formulation of, or any method of making or using, any Compound or any product containing any Compound, including all of the Patent Rights listed on **Schedule 1.84** (the “**Listed Patents**”); and

(b) any and all Patent Rights corresponding to the Listed Patents, throughout the world, whether now existing or hereafter filed or issued.

**1.60 “Program Regulatory Materials”** shall mean all U.S. and foreign regulatory applications, submissions and approvals (including all INDs and NDAs, and foreign counterparts thereof, and all Regulatory Approvals) for any Compound or Product, and all correspondence with the FDA and any other Regulatory Authority relating to any Compound or Product or any of the foregoing regulatory applications, submissions and approvals; that, in each case, are in the possession of or Controlled by, or held by or for, Seller or any of its Affiliates at the Closing Date, whether generated, filed or held by or for Seller or its Affiliates or any of their licensees.

**1.61 “Program Technology”** shall mean the Program Know-How and Program Patents.

**1.62 “Purchaser”** shall have the meaning provided in the preamble to this Agreement.

**1.63 “Purchaser Confidential Information”** shall have the meaning provided in Section 6.5.

**1.64 “Purchaser Indemnitees”** shall mean the following Persons: (a) Purchaser; (b) Purchaser’s current and future Affiliates; (c) the respective Representatives of the Persons referred to in clauses (a) and (b) above; and (d) the respective successors and permitted assigns of the Persons referred to in clauses (a), (b), and (c) above.

**1.65 “Registered IP”** shall mean all Intellectual Property Rights that are registered, filed, or issued under the authority of any Governmental Body, including all patents, registered copyrights, registered mask works, and registered trademarks and all applications for any of the foregoing.

**1.66 “Regulatory Approval”** shall mean, with respect to a pharmaceutical product in a particular jurisdiction, all approvals or other permissions from the applicable Regulatory Authority in such jurisdiction necessary to market and sell such product in such jurisdiction, including pricing and reimbursement approvals if required for marketing or sale of such product in such jurisdiction.

**1.67 “Regulatory Authority”** shall mean any regulatory agency, ministry, department or other Governmental Body having the administrative authority to regulate the development or marketing of pharmaceutical products in any country or other jurisdiction, including the pricing and reimbursement of such products, and other market access activities.

**1.68 “Regulatory Filing”** shall mean all applications, filings, submissions, approvals, licenses, registrations, permits, notifications, and authorizations (or waivers) with respect to the testing, development, manufacture, or commercialization of any Product made to or received from any Regulatory Authority in a given country or jurisdiction.

**1.69 “Representatives”** shall mean officers, directors, employees, consultants, agents, attorneys, accountants, advisors, and representatives.

**1.70 “Response Notice”** shall have the meaning provided in Section 7.6(b).

**1.71 “Retained Liabilities”** shall have the meaning provided in Section 2.4.

**1.72 “Royalties”** shall have the meaning provided in Section 2.7(a).

**1.73 “Royalty Term”** shall have the meaning provided in Section 2.7(b).

**1.74 “Seller Contract”** shall mean any Contract relating to the Program or any Compound or Product: (a) to which a Seller is a party; (b) by which a Seller or any of its assets is or may become bound or under which a Seller has, or may become subject to, any obligation; or (c) under which a Seller has or may acquire any right or interest.

**1.75 “Seller CDMO”** shall mean any Third Party contract development and manufacturing organization engaged by a Seller or any of its Affiliates to perform process development, manufacturing or storage services with respect to any Compound or Product.

**1.76 “Sellers’ Disclosure Schedule”** shall mean the schedule delivered to Purchaser on behalf of Sellers.

**1.77 “Seller Indemnitees”** shall mean the following Persons: (a) Sellers; (b) the respective Representatives of Sellers; and (c) the respective successors and permitted assigns of the Persons referred to in clauses (a) and (b) above.

**1.78 “Single-Agent Product”** shall mean a Product containing Compound as its sole active pharmaceutical ingredient.

**1.79 “Tax”** shall mean any tax (including any income tax, franchise tax, capital gains tax, estimated tax, gross receipts tax, value-added tax, surtax, excise tax, ad valorem tax, transfer tax, stamp tax, sales tax, use tax, property tax, business tax, occupation tax, inventory tax, occupancy tax, withholding tax or payroll tax), levy, assessment, tariff, impost, imposition, toll, duty (including any customs duty), deficiency or fee, and any related charge or amount (including any fine, penalty or interest), that is, has been or may in the future be (a) imposed, assessed or collected by or under the authority of any Governmental Body, or (b) any Liability for the payment of any amounts of the type described above in this sentence as a result of being a transferee of or successor to any

Person or as a result of any express or implied obligation to assume such Tax or to indemnify any other Person for Tax.

**1.80 “Tax Return”** shall mean any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document or information that is, has been or may in the future be filed with or submitted to, or required to be filed with or submitted to, any Governmental Body in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Legal Requirement relating to any Tax.

**1.81 “Third Party”** shall mean any Person other than Purchaser or Sellers or an Affiliate of any of Purchaser or Sellers.

**1.82 “Third Party Licenses”** shall have the meaning provided in Section 2.7(c).

**1.83 “Trade Secrets”** shall mean confidential ideas and information, trade secrets, know-how, inventions, concepts, methods, processes, formulae, reports, data, research and development results, and other proprietary information.

**1.84 “Trademark”** shall mean any word, name, symbol, color, product shape, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, product configuration, logo or business symbol, whether or not registered.

**1.85 “Transaction Documents”** shall mean, collectively, this Agreement, the Assignment and Assumption Agreement and the Patent Assignment.

**1.86 “Transactions”** shall mean (a) the execution and delivery of the respective Transaction Documents, and (b) all of the transactions contemplated by the respective Transaction Documents, including: (i) the sale of the Acquired Assets by Sellers to Purchaser in accordance with this Agreement; (ii) the assumption of the Assumed Liabilities by Purchaser; and (iii) the performance by the Sellers and Purchaser of their respective obligations under the Transaction Documents, and the exercise by the Sellers and Purchaser of their respective rights under the Transaction Documents.

**1.87 “Update Report”** shall have the meaning provided in Section 2.6(e).

**1.88 “Valid Claim”** shall mean (a) a claim of an issued and unexpired patent that has not been revoked or held unenforceable, unpatentable, or invalid by a decision of a court or other Governmental Body of competent jurisdiction that is not appealable or has not been appealed within the time allowed for appeal, and that has not been abandoned, disclaimed, denied, or admitted to be invalid or unenforceable through reissue, re-examination, disclaimer, or otherwise, or (b) a claim of a pending patent application that (i) has not been cancelled, withdrawn, abandoned, or finally rejected by an administrative agency action from which no appeal can be taken, in such patent application, and (ii) has not been pending for more than seven years from the date of first examination on the merits of such patent application.



## 2. SALE AND TRANSFER OF ASSETS

**2.1 Acquired Assets.** Subject to the terms and conditions of this Agreement, at the Closing, Sellers shall sell, convey, transfer, assign and deliver to Purchaser, and Purchaser shall purchase and acquire from Sellers, free and clear of all Encumbrances other than the Assumed Liabilities, all of each Seller's and its Affiliates' right, title and interest in and to all of the following (collectively, the "**Acquired Assets**"):

(a) all Program Technology and all related goodwill of each Seller and its Affiliates, and all rights to sue for or assert claims or remedies against or for past, present or future infringements, misappropriation or unauthorized use or disclosure, of any or all of the foregoing and rights of priority and protection of interests therein and to retain any and all amounts therefrom.

(b) the Program Material;

(c) all Contracts listed on **Schedule 2.1(c)**, excluding (i) all rights, claims, or causes of action (including warranty claims) of or against Seller or any of its Affiliates thereunder related to Excluded Assets and (ii) all Retained Liabilities (such listed Contracts, the "**Program Contracts**");

(d) all Program Books and Records;

(e) all Program Patent Files;

(f) all causes of action (regardless of whether or not such claims and causes of action have been asserted by Sellers or any of their Affiliates), lawsuits, judgments, claims and demands of any nature available to or being pursued by Sellers or any of their Affiliates to the extent related to any Compound or Product or the Program, or any of the items identified in subparagraphs (a) through (e) or subparagraph (h) of this Section 2.1, or the ownership, use, function or value of any Compound or Product or of the Program, in each case, whether arising by way of counterclaim or otherwise, whether choate or inchoate, known or unknown, contingent or noncontingent;

(g) all credits, prepaid expenses, deferred charges, advance payments (other than advance payments to cover filing fees or other support to be rendered pursuant to Section 6.8 that are, in each case, to be reimbursed to a Seller by Purchaser), security or other deposits, prepaid items, duties, and right to offset, to the extent related to any Compound or Product or to the Program, or to any of the items identified in subparagraphs (a) through (e) or subparagraph (h) of this Section 2.1; and

(h) all guaranties, warranties, indemnities and similar rights in favor of Sellers or any of their Affiliates to the extent related to any Compound or Product, or to the Program, or to any of the items identified in subparagraphs (a) through (g) of this Section 2.1.

To the extent the Acquired Assets are in a physical form, delivery thereof shall be made in Malvern, Pennsylvania, USA, at such place as designated in writing by Purchaser. Title to all Acquired Assets transferred by Selenity, including without limitation the Program Technology and other Acquired Assets described in Section 2.1(a), shall pass at Hamilton, Bermuda, which is the present situs of such assets.

**2.2 Excluded Assets.** All assets of Sellers not specifically described in Section 2.1 (collectively, the “**Excluded Assets**”) shall not be part of the sale and purchase contemplated hereunder, are excluded from the Acquired Assets, and shall remain the property of Sellers after the Closing.

**2.3 Assumed Liabilities.** Except for the Assumed Liabilities, Purchaser shall not, by virtue of its purchase of the Acquired Assets, assume or become responsible for any Liabilities of Sellers, any of its Affiliates or any other Person in connection with this Agreement other than pursuant to Section 7.3. Upon and subject to the terms, conditions, representations and warranties of Sellers contained herein, and subject to Section 2.4, effective upon the Closing, Purchaser hereby assumes and agrees to pay, perform, and discharge in a timely manner when due any Liabilities of Sellers relating to the prosecution, ownership, operation, maintenance, sale, lease or use of Acquired Assets by Purchaser but only to the extent that they arise after the Closing (collectively, the “**Assumed Liabilities**”).

**2.4 Retained Liabilities.** Except for the Assumed Liabilities and the obligations of Purchaser pursuant to Section 7.3 hereof, Purchaser shall not assume, and shall have no Liability for, any Liabilities of a Seller or any of its Affiliates of any kind, character or description, whether accrued, absolute, contingent or otherwise, it being understood that Purchaser is expressly disclaiming any express or implied assumption of any Liabilities other than the Assumed Liabilities (collectively, the “**Retained Liabilities**”).

### **2.5 Purchase Price; Consideration; Closing Payment.**

(a) The aggregate consideration for the Acquired Assets shall be: (i) the sum of one hundred thousand U.S. dollars (\$100,000) (the “**Closing Payment**”); (ii) the assumption of the Assumed Liabilities; and (iii) all Milestone Payments and Royalties that become due pursuant to Section 2.6 and Section 2.7, respectively.

(b) The Closing Payment shall be paid by Purchaser at the Closing, and such payment shall be made via wire transfer of immediately available funds from Purchaser to an account specified by VPH.

(c) Not later than [\*\*\*] after the Closing, the Sellers shall prepare and deliver to Purchaser a schedule allocating the purchase price for the Acquired Assets (including the Closing Payment, the maximum amount of any Milestone Payments and Royalty Payments, and any Assumed Liabilities and other capitalizable costs to the extent properly taken into account under the Code) among the Acquired Assets in accordance with Section 1060 of the Code and the Treasury Regulations thereunder. Purchaser shall be permitted to review and comment on the allocation, and the Sellers and Purchaser shall use good faith efforts to resolve any dispute regarding the preparation of the allocation. The allocation as finally agreed to by the Sellers and Purchaser (the “**Allocation**”) shall be binding on the Parties and the Sellers and Purchaser shall file all Tax Returns (including Internal Revenue Service Form 8594) consistent with the Allocation. Neither the Sellers nor Purchaser shall take any Tax position inconsistent with such Allocation, except to the extent otherwise required by law.

## 2.6 Milestone Payments.

(a) **Milestones.** Subject to the remainder of this Section 2.6 and Purchaser’s right of set-off as set forth in Section 7.6(c), upon the first achievement of each of the events set forth in the table below by a Product (each, a “**Milestone Event**”), whether achieved by Purchaser, or any of its Affiliates or Licensees, Purchaser shall pay to VPH the amount in cash set forth opposite such Milestone Event in the table below (each such payment, a “**Milestone Payment**”). Each of the Milestone Payments set forth below shall be payable only one time, for the first achievement of the corresponding Milestone Event, regardless of how many times such Milestone Event is achieved.

Milestone Event	Milestone Payment
<b>A. IP Validation Milestone Event</b>	
[***]	[***]
<b>B. Development and Approval Milestone Events</b>	
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
<b>C. Net Sales Milestone Events</b>	
First calendar year in which aggregate annual Net Sales of Products exceeds [***]	[***]
First calendar year in which aggregate annual Net Sales of Products exceeds [***]	[***]
First calendar year in which aggregate annual Net Sales of Products exceeds [***]	[***]
First calendar year in which aggregate annual Net Sales of Products exceeds [***]	[***]

(b) **Notice and Payment.** Within [\*\*\*] after the first achievement of each Milestone Event in part A (IP Validation Milestone Event) or part B (Development and Approval Milestone Events) of the table in Section 2.6(a), and within [\*\*\*] each Milestone Event in part C (Net Sales Milestone Events) of the table above is first achieved, Purchaser shall: (i) provide written notice to VPH of the occurrence of such Milestone Event; and (ii) pay the corresponding Milestone Payment by wire transfer of immediately available funds to an account specified by VPH.

(c) **Purchaser Obligations.** Purchaser shall use commercially reasonable efforts (as defined below) to achieve the Milestone Events in part A (IP Validation Milestone Event) and part B (Development and Approval Milestone Events) of the table in Section 2.6(a). For purposes of this Section 2.6(c), “commercially reasonable efforts” shall mean, with respect to Purchaser’s efforts, the level of efforts consistent with the efforts and resources a similarly situated biotechnology company, in the exercise of its reasonable business judgment, would typically devote to product candidates of similar market potential and at a similar stage in development or product

lifecycle, based on conditions then prevailing and taking into account safety and efficacy, product profile, cost of goods, the competitiveness of the marketplace, Purchaser’s patent position with respect to such product (including Purchaser’s ability to obtain or enforce, or have obtained or enforced, such patent rights), the Third Party patent landscape relevant to the product, the regulatory structure involved, the likelihood of approval by a Regulatory Authority of competent jurisdiction, the anticipated or actual profitability of the applicable product, and other technical, legal, scientific and medical considerations. Sellers acknowledge that Purchaser may need to raise additional capital in order to pursue the Program. Nothing in this Agreement shall be construed to require Purchaser to pursue the Program in priority to any of Purchaser’s other programs and product candidates.

**(d) Sole Discretion.** Subject to Section 2.6(c), Purchaser shall have sole decision-making authority over the development, registration and commercialization of Compounds and Products.

**(e) Reports.** Until First Commercial Sale of a Product in any Major Market Country, Purchaser shall send to VPH a written report summarizing the status of development, regulatory and commercialization activities toward achieving the Milestone Events, [\*\*\*] (each such report, an “**Update Report**”), with the first such Update Report due in [\*\*\*]. Within [\*\*\*] after receipt of an Update Report, if VPH requests a telephonic meeting with representatives of Purchaser to discuss such report, Purchaser shall make available for such telephonic meeting employees with responsibility for or appropriate knowledge of the activities set forth in the Update Report, provided that Purchaser shall not be obligated to participate in such a meeting more than [\*\*\*]. The obligations of Purchaser under Section 2.6(b) and Section 2.6(c) shall terminate and be of no further effect upon the earliest of: [\*\*\*].

## 2.7 Royalty Payments.

**(a) Royalties; Royalty Rates.** In addition to the Milestone Payments, and subject to Sections 2.7(c), 2.7(d), 2.7(e) and 2.7(f), Purchaser shall pay royalties to VPH on worldwide aggregate annual Net Sales of each Product by Purchaser and its Affiliates and Licensees (“**Royalties**”) in each calendar year at the applicable rate(s) set forth in the table below.

[***]	[***]
[***]	[***]
[***]	[***]

**(b) Royalty Term.** Royalties shall be payable on a Product-by-Product and country-by-country basis, from First Commercial Sale of a Product in a country until the later of: (i) 10 years from the First Commercial Sale of such Product in such country and (ii) the expiration of the last-to-expire Valid Claim of the Program Patents that Covers the manufacture, use, sale, offer for sale, or import of such Product in such country (the “**Royalty Term**”).

**(c) Credit for Third Party Royalties.** Subject to Section 2.7(f), if Purchaser or any of its Affiliates or Licensees obtains one or more licenses under Patent Rights of Third Parties that it determines in good faith are reasonably necessary for the manufacture, use, sale, offer for sale or import of a Product in a given country (hereinafter “**Third Party Licenses**”), [\*\*\*]% of [\*\*\*] actually paid by Purchaser or its Affiliate or Licensee to such Third Party under such Third

Party License with respect to [\*\*\*]; *provided, however*, that in no event will the Royalties payable by Purchaser to Seller hereunder with respect to Net Sales of such Product in such country for such calendar quarter be reduced by more than [\*\*\*].

**(d) No Valid Claim.** Subject to Section 2.7(f), during any portion of the Royalty Term for a particular Product in a particular country when no Valid Claim of the Program Patents Covers the manufacture, use, sale, offer for sale or import of such Product in a such country, the Royalties payable with respect to Net Sales of such Product in such country shall be reduced to [\*\*\*].

**(e) Generic Competition.** Subject to Section 2.7(f), on a Product-by-Product and country-by-country basis, if, during the Royalty Term for a Product in a country, unit sales of one or more Generic Versions of such Product in such country account for more than [\*\*\*]% of combined unit sales of (i) such Product and (ii) such Generic Version(s) in such country, as determined by reference to applicable sales data obtained from IQVIA or from such other independent source for such sales data as may be agreed upon by Purchaser and VPH (provided that such other source, if any, shall be generally recognized as a reliable source for pharmaceutical sales data among major pharmaceutical companies), in [\*\*\*], then for the remainder of the Royalty Term for such Product in such country, Purchaser's royalty payment obligations with respect to Net Sales of such Product in such country shall be reduced by [\*\*\*]%.

**(f) Royalty Floor.** In no event shall the effective royalty rate applicable to Net Sales of Products under this Section 2.7 be reduced to less than [\*\*\*] as a result of any and all applicable credits and reductions pursuant to Sections 2.7(c), 2.7(d), and 2.7(e), in the aggregate.

**(g) Royalty Reporting.** Within [\*\*\*], Purchaser shall deliver to VPH a written report of Net Sales of Products by Purchaser and its Affiliates and Licensees in such [\*\*\*] in sufficient detail to permit confirmation of the accuracy of the Royalties paid, including gross sales and Net Sales of Products, the deductions from gross sales (itemized by major category as set forth in the definition of Net Sales), details of the calculation of any reduction made pursuant to Sections 2.7(c), 2.7(d), and/or 2.7(e), the Royalties payable, and the exchange rates used. Royalties due to VPH for any [\*\*\*] shall be paid no later than [\*\*\*].

## **2.8 Payments; Audits.**

**(a) Currency; Exchange.** All payments hereunder shall be payable in U.S. dollars. Whenever conversion of amounts paid or reported to Purchaser or any of its Affiliates or Licensees in any foreign currency to U.S. dollars is required, such conversion shall be made at the rate of exchange used throughout the accounting system of Purchaser and its Affiliates for the applicable period. All payments owed under this Agreement shall be made by wire transfer to a bank and account designated in writing by VPH, unless otherwise specified in writing by VPH.

**(b) Survival of Obligations.** In the case that Purchaser consolidates with or merges into any other Person or assigns, conveys, or transfers (excluding any grant of Product Rights) substantially all the Acquired Assets to any Person, (i) if Purchaser is the surviving entity in such transaction, Purchaser shall remain responsible for payment and other obligations of Purchaser under this Agreement or (ii) if a Person other than Purchaser is the surviving entity in

such consolidation or merger or the party to whom Acquired Assets are assigned, conveyed or transferred, such Person shall assume responsibility for all payment and other obligations of Purchaser under this Agreement arising from and after the date that such transaction is consummated.

**(c) Audit Rights.** Until [\*\*\*], Purchaser shall keep complete and accurate records pertaining to the sale or other disposition of Products by Purchaser, its Affiliates and Licensees in sufficient detail to permit VPH to confirm the accuracy of the Royalties and Net Sales Milestone Payments due hereunder. VPH shall have the right to cause an independent, certified public accountant reasonably acceptable to Purchaser to audit such records to confirm Net Sales and Royalties for a period covering not more than the preceding [\*\*\*]. Purchaser may require such accountant to execute a reasonable confidentiality agreement with Purchaser prior to commencing the audit. Such audits may be conducted during normal business hours upon reasonable prior written notice to Purchaser, but no more than frequently than once per year. No accounting period of Purchaser shall be subject to audit more than one time. Prompt adjustments (including remittances of underpayments or overpayments disclosed by such audit) shall be made by the parties to reflect the results of such audit. VPH shall bear the full cost of such audit unless such audit discloses an underpayment by Purchaser of [\*\*\*] of the amount of Royalties due under this Agreement, in which case Purchaser shall bear the full cost of such audit.

**2.9 Allocation.** Within [\*\*\*] after the Closing Date, Purchaser shall deliver to VPH a statement setting forth Purchaser's good faith determination of the manner in which the consideration payable pursuant to Section 2.5 is to be allocated among the Acquired Assets. The allocation prescribed by such statement shall be conclusive and binding upon Sellers for all applicable Tax purposes. Sellers shall file all Tax Returns in a manner consistent with such allocation and shall not take any Tax position that is inconsistent with such allocation, including in any audit or examination by any Governmental Body.

**2.10 Closing.** The consummation of the purchase and sale of the Acquired Assets and the assumption of the Assumed Liabilities in accordance with this Agreement (the "**Closing**") shall take place at the offices of Cooley LLP, 4401 Eastgate Mall, San Diego, CA 92121, USA, concurrently with the execution and delivery of this Agreement by all of the parties hereto, or at such other time and place as may be mutually agreed by the parties, and shall be contingent upon the satisfaction or waiver of all of the conditions to Closing set forth in Article 4. The date of the Closing shall be referred to as the "**Closing Date**." The parties hereby agree to deliver at the Closing such documents, certificates of officers and other instruments as are set forth in Article 4 hereof and as may reasonably be required to effect the transfer by Sellers of the Acquired Assets pursuant to and as contemplated by this Agreement and to consummate the Acquisition. All events which shall occur at the Closing shall be deemed to occur simultaneously.

**2.11 Withholding.** Purchaser shall be entitled to deduct and withhold from any payments to VPH (or its permitted designees) made pursuant to this Agreement such amounts as may be required to be deducted and withheld with respect to such payments under the Internal Revenue Code of 1986, as it may be amended from time to time, and any successor thereto, or any other applicable Legal Requirement. To the extent that amounts so withheld by Purchaser are paid to the appropriate Governmental Body, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to VPH. [\*\*\*].

**2.12 Set-off.** Purchaser shall have the set-off rights set forth in Section 7.6(c) in respect of the Milestone Payments and Royalties that become due pursuant to Section 2.6 and Section 2.7, respectively.

### **3. REPRESENTATIONS AND WARRANTIES OF SELLERS**

Except as set forth in the disclosure schedules delivered by Seller on the Closing Date (the “**Sellers’ Disclosure Schedule**”), Sellers jointly and severally represent and warrant to Purchaser as of the Closing Date (except to the extent such representations and warranties speak expressly as of a different date, and then, as of such date) that:

**3.1 Due Organization.** Part 3.1 of the Sellers’ Disclosure Schedule lists a complete description of each Seller’s name, its form of organization, its jurisdiction of organization and each other jurisdiction in which it is authorized to do business. Selenity is an entity duly organized, validly existing, and in good standing under the laws of Bermuda. VPH is an entity duly organized, validly existing, and in good standing under the laws of Delaware. Each Seller has all requisite corporate power and authority to conduct its business as it is now being conducted and to own or use the properties and assets that it purports to own or use.

**3.2 Organizational Documents.** Sellers have delivered to Purchaser accurate and complete copies of the Organizational Documents of Sellers. There has not been any violation of any of the provisions of a Seller’s Organizational Documents or of any resolution adopted by a Seller’s board of directors or managers or any committee of its board of directors or managers; and no event has occurred, and no condition or circumstance exists, that might (with or without notice or lapse of time) constitute or result directly or indirectly in such a violation.

**3.3 Authority; Binding Nature of Agreements.** Each Seller has the absolute and unrestricted right, power, and authority to enter into and to perform its obligations under each of the Transaction Documents; and the execution, delivery, and performance by each Seller of the Transaction Documents has been duly authorized by all necessary corporate action on the part of such Seller. Each Transaction Document constitutes the legal, valid, and binding obligation of such Seller, enforceable against such Seller in accordance with its terms. Each Seller has approved the sale of the Acquired Assets, and no further approvals are required. Each Seller has agreed not to revoke any such approval.

**3.4 Non-Contravention; Consents.** Except as set forth in Part 3.4 of the Sellers’ Disclosure Schedule, neither the execution and delivery of any of the Transaction Documents, nor the consummation or performance of any of the Transactions by Sellers, will directly or indirectly (with or without notice or lapse of time):

(a) contravene, conflict with, or result in a violation of, or give any Governmental Body or other Person the right to challenge any of the Transactions or to exercise any remedy or obtain any relief under, any Legal Requirement or any Order to which a Seller or any Affiliate of a Seller, or any of the Acquired Assets, is subject;

(b) cause any of the Acquired Assets to be reassessed or revalued by any taxing authority or other Governmental Body;

(c) contravene, conflict with, or result in a violation of (i) any of the provisions of the Organizational Documents of a Seller or (ii) any resolution adopted by the board of directors or managers, or any committee of the board of directors or managers, of a Seller;

(d) contravene, conflict with, or result in a violation or breach of, or result in a default under: (i) any provision of any Program Contract; or (ii) any other Contract of a Seller, in the case of this clause (ii), solely to the extent such contravention, violation, or breach could reasonably be expected to prevent, enjoin, alter, or delay the transactions contemplated by any of the Transaction Documents;

(e) give any Person the right to (i) declare a default or exercise any remedy under any Program Contract, (ii) accelerate the maturity or performance of any Program Contract or (iii) cancel, terminate, or modify any Program Contract; or

(f) result in the imposition or creation of any Encumbrance upon or with respect to any of the Acquired Assets.

Except as listed in Part 3.4 of the Sellers' Disclosure Schedule, no Consent to or from any Person is or will be required in connection with the execution and delivery of any of the Transaction Documents by Sellers or the consummation or performance of any of the Transactions by Sellers.

### **3.5 Absence of Changes.** Since June 1, 2019:

(a) there has not been any adverse change in, and no event has occurred that would reasonably be expected to have an adverse effect on the Program or Assumed Liabilities;

(b) there has not been any loss, damage, or destruction to, or any interruption in the use of, any of the assets used in the Program (whether or not covered by insurance);

(c) Sellers have not sold or otherwise transferred, or leased or licensed, any portion of the assets used in the Program to any other Person;

(d) no Program Contract has been amended or terminated;

(e) Sellers have not materially changed any methods of accounting or accounting practices in any respect; and

(f) except for the Transactions contemplated hereby, Sellers have not agreed, committed or offered (in writing or otherwise) to take any of the actions referred to in subsections (c) or (d) above.

### **3.6 Title to Assets; Existence of Assets.**

(a) None of the Acquired Assets is subject to any Encumbrances (including Tax-related Encumbrances). Sellers have good and marketable title to all Acquired Assets, free and clear of any Encumbrances. No Affiliate of a Seller has title or other rights to any of the Acquired



Assets. The Acquired Assets constitute all of the assets, properties, rights, and goodwill necessary to carry on the Program as conducted by Sellers and as proposed to be conducted.

**(b)** (i) There are no Program Regulatory Materials or Governmental Authorizations held by or for Sellers (or either of them) or any of their respective Affiliates or licensees, in relation to the Program or any Compound or Product, and (ii) there have been no Regulatory Filings, including any regulatory applications, submissions and approvals (including all INDs and NDAs, and foreign counterparts thereof, and all Regulatory Approvals), or correspondence with the FDA or any other Regulatory Authority, in relation to the Program or any Compound or Product, whether generated, filed or held by or for a Seller or any of its Affiliates or licensees.

**(c)** There are no Trademarks owned by Sellers (or either of them) or any of their respective Affiliates that have been used or are held for use in connection with the Program or the research, development, manufacture or commercialization of any Compound or Product.

### **3.7 Intellectual Property.**

**(a)** Part 3.7(a) of the Sellers' Disclosure Schedule lists (i) each item of Registered IP (A) which is included in the Acquired Assets or (B) in which either Seller has or purports to have an interest of any nature (whether by ownership or license, exclusively, jointly, with another Person, or otherwise) and which is related to the Program, (ii) the jurisdiction in which such item of Registered IP has been registered or filed and the applicable registration or serial number, and (iii) any other Person that has or purports to have an ownership interest in such item of Registered IP and the nature of such ownership interest. Sellers have made available to Purchaser copies of all applications and all other correspondence and other documents related to each such item of Registered IP. Except as set forth in Part 3.7(a) of the Sellers' Disclosure Schedule, there are no actions that are required to be taken within [\*\*\*] of the Effective Date with respect to the Program Patents existing as of the Effective Date, including the payment of any registration, maintenance or renewal fees or the filing of any response to the United States Patent and Trademark Office actions or foreign equivalents.

**(b)** Part 3.7(b) of the Sellers' Disclosure Schedule accurately identifies: (i) each Contract pursuant to which any Intellectual Property Right or Intellectual Property included in the Program Technology or related to the Program is or has been licensed, sold, assigned or otherwise conveyed or provided to a Seller, and (ii) whether the licenses or rights granted to such Seller in each such Contract are exclusive or non-exclusive (other than licenses for commercial off-the-shelf software).

**(c)** Neither Seller is a party to or is bound by any Contract pursuant to which any Person has been granted any license under, or otherwise has received or acquired any right (whether or not currently exercisable, and including ownership rights) or interest in, any Program Technology. Neither Seller is bound by, and no Program Technology is subject to, any Contract containing any covenant or other provision that in any way limits or restricts the ability of Sellers to use, exploit, assert, or enforce any Program Technology anywhere in the world.

**(d)** The Sellers exclusively own all right, title, and interest to and in the Program Technology free and clear of any Encumbrances. Without limiting the generality of the foregoing:

**(i)** Each Person who is or was a member, employee, consultant or contractor of either Seller, or, to Sellers' Knowledge, any other Third Party from whom either Seller acquired rights related to the Program, and who is or was involved in the creation or development

of any Intellectual Property Rights related to the Program or any Compound or Product has signed a valid, enforceable agreement containing an assignment of such Intellectual Property Rights to such Seller (directly or indirectly through the other Seller or such other Third Party) and confidentiality provisions protecting Intellectual Property Rights. No current or former member, employee, consultant or contractor of a Seller, or, to Sellers' Knowledge, any other Third Party from whom a Seller acquired rights related to the Program, has any claim, right (whether or not currently exercisable), or interest to or in any Intellectual Property Rights related to the Program or any Compound or Product.

**(ii)** Each Seller, and to Sellers' Knowledge, any Third Party from whom a Seller acquired rights related to the Program, has taken all reasonable steps to maintain the confidentiality of and otherwise protect and enforce their rights in all Program Technology.

**(iii)** No Seller and, to Sellers' Knowledge, no Third Party from whom either Seller acquired rights related to the Program, is in any case now or ever was a member or promoter of, or a contributor to, any industry standards body or similar organization that could require or obligate Sellers (or such Third Party) to grant or offer to any other Person any license or right to any Program Technology.

**(iv)** No Third Party has any ownership or other interest in any of the Program Technology or Program Materials and no Seller or any Seller Affiliate has previously entered into any Contract with respect to or otherwise assigned, transferred, licensed, conveyed or otherwise encumbered its right, title or interest in or to any Intellectual Property Rights, or Compound (including any materials specifically related to the manufacture of any Compound), that would be within the Program Technology or Program Materials but for such Contract, assignment, transfer, license, conveyance or encumbrance.

**(e)** To Sellers' Knowledge, no Person has infringed, misappropriated, or otherwise violated, and no Person is currently infringing, misappropriating, or otherwise violating, any Program Technology. Part 3.7(e) of the Sellers' Disclosure Schedule accurately identifies (and Sellers have provided to Purchaser a complete and accurate copy of) each letter or other written or electronic communication or correspondence that has been sent or otherwise delivered by or to Sellers or any Representative of Sellers, or any Third Party from whom Sellers acquired rights related to the Program, regarding any actual, alleged, or suspected infringement or misappropriation of any Program Technology, and provides a brief description of the current status of the matter referred to in such letter, communication, or correspondence.

**(f)** No Seller and, to Sellers' Knowledge, no Third Party from whom a Seller acquired rights related to the Program, has infringed, misappropriated, or otherwise violated or made unlawful use of the Intellectual Property Rights of any other Person in the performance of the Program, and if Sellers were to commercialize any Product, the manufacturing, production, sale, distribution, or other exploitation of such Product in any indication or territory in the world would not infringe, misappropriate, or otherwise violate or make unlawful use of the Intellectual Property Rights of any other Person. No Seller has ever received and, to Sellers' Knowledge, no Third Party from whom a Seller acquired rights related to the Program has ever received, any notice or other communication (in writing or otherwise) relating to any actual, alleged, or suspected infringement, misappropriation, or violation by a Seller or any of its Representatives (or any such Third Party) of

any Intellectual Property Right of another Person in connection with performance of the Program or the research, development, manufacture or commercialization of any Compound or Product.

**(g)** The Sellers are not bound by any Contract to indemnify, defend, hold harmless, or reimburse any other Person with respect to, or otherwise assumed or agreed to discharge or otherwise take responsibility for, any existing or potential intellectual property infringement, misappropriation, or similar claim in connection with performance of the Program or the research, development, manufacture or commercialization of any Compound or Product.

**(h)** To Sellers' Knowledge, there are no issues or information related to the Program Technology or Program, which in Sellers' reasonable opinion, are reasonably likely to have a material impact on the research, development, manufacture or commercialization of any Product that have not been fully disclosed to Purchaser.

**(i)** With respect to the Program Technology, no Proceeding is pending or, to the Knowledge of Sellers, is threatened that challenges the validity, enforceability, inventorship, patentability, claim construction, use or ownership of or Sellers' right to grant a license or other right to the item and, to the Knowledge of Sellers, no valid basis exists for such a challenge.

**(j)** Except as set forth in Section 3.7(j) of the Sellers' Disclosure Schedule, no Program Technology rights have been abandoned, and the Listed Patents have been and continue to be timely prosecuted in accordance with applicable Legal Requirements (including duties of disclosure, candor and good faith), all necessary maintenance fees, annuities and renewals have been timely paid to continue all such rights in effect, and none of the Listed Patents have expired, lapsed, been declared invalid (in whole or in part), or been declared unenforceable by any Governmental Body.

**(k)** No funding, facilities, or personnel of any Governmental Body or any university, college, research institute, or other educational institution has been or is being used, directly or indirectly, to create, in whole or in part, Intellectual Property Rights related to the Program or any Compound or Product, except for any such funding or use of facilities or personnel that does not result in such Governmental Body or institution obtaining ownership rights or any other similar right, title or interest (including any "march in" rights) in or to such Intellectual Property Rights (including any claim or option to any of the foregoing).

### **3.8 Contracts.**

**(a)** Part 3.8 of the Sellers' Disclosure Schedule lists each Seller Contract. Sellers have delivered or made available to Purchaser accurate and complete copies of all Seller Contracts, including all amendments and material correspondence thereto.

**(b)** Each Program Contract is valid and, except as set forth on Part 3.8 of Sellers' Disclosure Schedule, is in full force and effect and is enforceable in accordance with its terms. No Person has violated or breached, or declared or committed any default under, any Program Contract; and no event has occurred and, to the Sellers' Knowledge, no circumstance or condition exists, that might (with or without notice or lapse of time) (i) result in a violation or breach of any of the provisions of any Program Contract, (ii) give any Person the right to declare a default or exercise any remedy under any Program Contract, (iii) give any Person the right to accelerate the maturity or performance of any Program Contract, or (iv) give any Person the right to cancel, terminate, or modify any Program Contract. Sellers have not received any notice or other communication (in

writing or otherwise) regarding any actual, alleged, possible, or potential violation or breach of, or default under, any Program Contract, and Seller has not waived any right under any Program Contract. No Consents are necessary for the effective assignment to and assumption by the Purchaser of any of the Program Contracts or the transactions contemplated hereby.

(c) There is no basis upon which any party to any Program Contract may object to (i) the assignment to Purchaser of any right under such Program Contract or (ii) the delegation to or performance by Purchaser of any obligation under such Program Contract.

(d) The Program Contracts collectively constitute all of the Contracts necessary to enable Purchaser to conduct the Program in the manner in which it is currently being conducted and upon consummation of the transactions contemplated in this Agreement, Purchaser will be permitted to exercise all of the rights a Seller had under the Program Contracts without the payment of any additional amounts or consideration other than ongoing fees, royalties or payments which a Seller would otherwise be required to pay had the transactions contemplated by this Agreement not occurred.

(e) Sellers have timely made all payments owed or owing to any Third Party under each Program Contract as of the Effective Date, and there are no amounts required to be paid to any Third Party pursuant to any Program Contract for any activity or Service performed under any such Program Contract prior to the Effective Date, as applicable.

**3.9 Bankruptcy; Solvency.** Neither Seller is entering into this Agreement with the intent to hinder, delay or defraud any Person to which it is, or may become, indebted. Neither Seller will be insolvent after the consummation of the transactions contemplated by this Agreement. As used in this section, “insolvent” means the debts and other probable Liabilities of a Seller exceed the sum of the present fair saleable value of such Seller. Immediately after giving effect to the consummation of the transactions contemplated by this Agreement: (a) each Seller will be able to pay its Liabilities as they become due in the usual course of business; and (b) each Seller will have assets (calculated at fair market value) that exceed its Liabilities.

**3.10 Compliance with Legal Requirements.** Sellers and, to Sellers’ Knowledge, any Third Party from whom Sellers acquired rights related to the Program, is in full compliance, and has been in full compliance at all times, with each Legal Requirement that is applicable to the conduct of the Program or the ownership or use of any of the Acquired Assets. No event has occurred, and no condition or circumstance exists, that could (with or without notice or lapse of time) constitute or result directly or indirectly in a violation by Sellers of, or a failure on the part of Sellers to comply with, any such Legal Requirement. Sellers have not received, and to Sellers’ Knowledge, no Third Party from whom Sellers acquired rights related to the Program has received, at any time, any notice or other communication (written or otherwise) from any Governmental Body or any other Person regarding (a) any actual, alleged, possible, or potential violation of, or failure to comply with, any such Legal Requirement or (b) any actual, alleged, possible or potential obligation on the part of Sellers to undertake, or to bear all or any portion of the cost of, any cleanup or any remedial, corrective or response action of any nature.

**3.11 Tax Matters.** Each Seller (a) has timely paid all material Taxes required to be paid that relate to the Acquired Assets or the Assumed Liabilities to the appropriate Governmental Body (whether or not shown on any Tax Return) and no such Taxes are delinquent and (b) has timely filed all material Tax Returns required to be filed that relate in whole or in part to the Acquired

Assets or the Assumed Liabilities. There are no liens for Taxes on any of the Acquired Assets except for Taxes not yet due and payable. There is no material audit, examination, contest, litigation, or other proceeding relating to Taxes pending or threatened in writing with respect to any of the Acquired Assets or Assumed Liabilities.

**3.12 Affiliate Transactions.** No Affiliate of a Seller (a) has had any direct or indirect interest of any nature in any of the Acquired Assets, (b) has entered into, or has any direct or indirect financial interest in any Program Contract or other any transaction or business dealing of any nature involving the Program, (c) is competing, or has at any time competed, directly or indirectly, with the Program, or (d) has any claim or right against the Program. No event has occurred, and no condition or circumstance exists, that with or without notice or lapse of time directly or indirectly give rise to or serve as a basis for any claim or right in favor of any Affiliate of a Seller against the Program.

**3.13 Proceedings; Orders.** There is no pending Proceeding, and no Person has threatened to commence any Proceeding (a) that involves a Seller or any Third Party from whom a Seller acquired rights related to the Program, that in any case could reasonably be expected to affect the Program, any of the Acquired Assets, or the obligations of a Seller under this Agreement or any of the Transaction Documents, or (b) that challenges, or that may have the effect of preventing, delaying, making illegal, or otherwise interfering with, any of the Transactions. No event has occurred, and no claim or dispute or other condition or circumstance exists, that could directly or indirectly give rise to or serve as a basis for the commencement of any such Proceeding. There is no Order to which the Program or any of the Acquired Assets is subject, and neither of the Sellers and none of their respective Affiliates are subject to any Order that relates to the Program or the Acquired Assets.

**3.14 Certain Business Practices.** Each Seller, and to Sellers' Knowledge, each Seller's employees or other representatives (a) has not used and is not using any funds for any unlawful contributions, unlawful gifts, unlawful entertainment or other unlawful expenses; (b) has not made any direct or indirect unlawful payments to any foreign or domestic Government Official; (c) has not violated and is not violating any Anti-Corruption Laws; (d) has not established or maintained, and is not maintaining, any unlawful or unrecorded fund of monies or other properties; (e) has not made, and is not making, any false or fictitious entries on its accounting books and records; (f) has not made, and is not making, any bribe, rebate, payoff, influence payment, kickback or other unlawful payment of any nature, and has not paid, and is not paying, any fee, commission or other payment that has not been properly recorded on its accounting books and records as required by the Anti-Corruption Laws; and (g) has not otherwise given or received anything of value to or from a Government Official, an intermediary for payment to any individual including Government Officials, any political party or customer for the purpose of obtaining or retaining business.

**3.15 Bulk Transfer Laws.** Sellers have satisfied all obligations pursuant to any bulk transfer law or similar legal requirement in connection with any of the Transactions.

**3.16 Brokers.** No broker, finder or other third party has any right to a commission or other fee as the result of action by or on behalf of Sellers in connection with this Agreement or any of the Transactions.

#### 4. Closing Deliverables.

**4.1 Closing Deliverables of Purchaser.** At the Closing, in addition to the Closing Payment, Purchaser shall deliver to Sellers the following:

- (a) A duly executed copy of this Agreement; and
- (b) Duly executed copies of each other Transaction Document to be executed and delivered by the Purchaser.

**4.2 Closing Deliverables of Sellers.** At the Closing, each of the Sellers shall deliver to Purchaser, at Sellers' expense, the following:

(a) Evidences of transfer or assignment of all of the Acquired Assets from Sellers to Purchaser free and clear of all Encumbrances (except Assumed Liabilities) reasonably satisfactory to Purchaser and its counsel;

(b) A certificate, dated the Closing Date, executed on behalf of each Seller by the Chief Executive Officer of such Seller and certifying that the representations and warranties of such Seller in this Agreement are true and correct in all material respects (without giving double effect to any materiality qualifications) as of the Closing;

(c) A duly executed copy of this Agreement;

(d) An Assignment and Assumption Agreement in the form attached hereto as **Exhibit A** executed by each Seller;

(e) The Patent Assignment in the form attached hereto as **Exhibit B** executed by Selenity; and

(f) such other documents as Purchaser may reasonably request for the purpose of (i) evidencing the accuracy of any representation or warranty made by Sellers, (ii) evidencing the compliance by each Seller or the performance by such Seller of, any covenant or obligation set forth in this Agreement or (iii) otherwise facilitating the consummation or performance of any of the Transactions.

#### 5. REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser represents and warrants to Sellers as of the Closing Date that:

**5.1 Due Organization.** Purchaser is a corporation duly organized, validly existing, and in good standing under the laws of Delaware.

**5.2 Authority; Binding Nature of Agreements.** Purchaser has the corporate power and authority to enter into and perform its obligations under each of the Transaction Documents, and the execution and delivery and performance by Purchaser of each Transaction Document has been duly authorized by all necessary corporate action on the part of Purchaser (including any required shareholder approvals). Each Transaction Document constitutes the legal, valid, and

binding obligation of Purchaser, enforceable against it in accordance with its terms, subject to any applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance or similar laws now or hereinafter in effect relating to creditors' rights generally or to general principles of equity.

**5.3 Governmental and Other Authorizations.** The execution, delivery, and performance by Purchaser of the Transaction Documents, and the consummation by it of the transactions contemplated hereby and thereby, require no approval of any Governmental Body on the part of Purchaser or any material Consent of any other Person on the part of Purchaser, except where the failure to obtain such Consents or to make such filings or give such notice would not have a material adverse effect on Purchaser's ability to consummate the Transactions.

**5.4 Brokers.** No broker, finder or other third party has any right to a commission or other fee as the result of action by or on behalf of Purchaser in connection with this Agreement or any of the Transactions.

**5.5 Litigation.** There is no pending Proceeding to which Purchaser is a party, and Purchaser has not received any written threat by any Person to commence any Proceeding against Purchaser, that challenges, or that may have the effect of preventing, delaying, making illegal, or otherwise interfering with, any of the Transactions.

## **6. ADDITIONAL COVENANTS**

**6.1 Further Assurances.** Each Seller hereby agrees and without further consideration, to execute and deliver following the Closing such assignments and other instruments of transfer and take such other actions as Purchaser or its counsel may reasonably request in order to put Purchaser in possession of, and to vest in Purchaser, good, valid and unencumbered title to the Acquired Assets in accordance with this Agreement. In addition to the foregoing, each Seller shall execute and deliver, and shall cause its Affiliates to execute and deliver as applicable, to Purchaser such documentation as shall be reasonably requested and approved by Purchaser, including assignments in form and substance acceptable to Purchaser, in order to transfer to Purchaser, and put Purchaser in possession of and to vest in Purchaser, good, valid and unencumbered title to the Program Patents in any jurisdiction.

**6.2 Sellers' Non-Compete.** Each Seller agrees that for the period [\*\*\*], neither such Seller nor any of its Affiliates shall engage, either directly or indirectly, alone or with others, in the development or commercialization of any compound that is within the scope of the Listed Patents or any CYP11B2 Inhibitor. Sellers acknowledge that any violation of this Section 6.2 may result in an irreparable injury to Purchaser and that damages at law may not be reasonable or adequate compensation to Purchaser for violation of this Section 6.2 and that, in addition to any other available remedies, Purchaser shall be entitled to seek to have the provisions of this Section 6.2 specifically enforced by preliminary and permanent injunctive relief without the necessity of proving actual damages or posting a bond or other security to an equitable accounting of all earnings, profits and other benefits arising out of any violation of this Section 6.2. In the event that the provision of this Section 6.2 shall ever be deemed to exceed the time, geographic scope or other limitations permitted

by applicable Legal Requirement, then the provisions shall be deemed reformed to the maximum extent permitted by applicable Legal Requirement.

**6.3 Patent Assignment.** Purchaser shall promptly following the Closing file patent assignments substantially in the form attached hereto as **Exhibit B** with the U.S. Patent and Trademark Office and any other applicable Government Body to record the assignment of the Listed Patents (the “**Patent Assignments**”).

**6.4 Public Announcements.** The parties agree to issue the press release attached here to as **Exhibit C** (the “**Press Release**”) at a time on or after the Closing Date chosen by Purchaser. From and after the date of this Agreement, except for the Press Release, Sellers agree not to make any public announcement or other disclosure concerning this Agreement or the transactions contemplated herein without obtaining the prior written consent of Purchaser as to form, content and timing. Notwithstanding the foregoing, the Parties acknowledge that either or both Parties may be obligated to file under applicable laws or rules or regulations promulgated by Governmental Body or applicable securities exchanges a copy of this Agreement with the U.S. Securities and Exchange Commission or other Governmental Body. In the event that a Party determines based on advice of outside counsel that such a filing is required, such Party shall request confidential treatment of all confidential information herein, including the sensitive commercial, financial and technical terms hereof, to the extent such confidential treatment may be reasonably available to such Party. In the event of any such filing, the filing Party shall provide the other Party with a copy of this Agreement marked to show provisions for which such filing Party intends to seek confidential treatment within a reasonable amount of time prior to filing and shall use good faith efforts to incorporate the other Party’s reasonable comments thereon to the extent consistent with applicable laws or rules or regulations promulgated by Governmental Body or applicable securities exchanges. Each Party shall be responsible for its own legal and other external costs in connection with any such filing.

**6.5 Confidentiality.** All obligations of Purchaser with respect to the Acquired Assets under that certain Confidentiality Agreement, effective as of May 15, 2019, by and between Purchaser and VPH (the “**Confidentiality Agreement**”) shall terminate simultaneously with the Closing. From and after the Closing, except as expressly provided herein, each Seller shall, and shall cause its Affiliates and its and their respective Representatives to, treat as strictly confidential and safeguard all nonpublic, confidential or proprietary information concerning the Program and the Acquired Assets (the “**Purchaser Confidential Information**”), provided that the foregoing obligation shall not apply to any information which was in, or comes into, the public domain through no breach of this Agreement by Sellers. In addition, each Seller shall not be prohibited from disclosing any portion of the Purchaser Confidential Information that such Seller is required to disclose by judicial or administrative process or, in the opinion of legal counsel, by other requirements of law, provided that such Seller shall, except where impracticable, give reasonable advance notice to Purchaser of such disclosure and shall cooperate with Purchaser’s efforts to contest or limit such disclosure and/or to seek a protective order or other confidential treatment of the Purchaser Confidential Information required to be disclosed by appropriate legal means. In the event of a Seller’s breach of its obligations under this Section 6.5, Purchaser, in addition to all other available remedies, will be entitled to injunctive relief to enforce the provisions of this Section 6.5 in any court of competent jurisdiction.



**6.1 Transfer of Files.** With respect to devices, records, data, notes, reports, proposals, lists, correspondence, specifications, drawings, blueprints, sketches, laboratory notebooks, flow charts, materials, equipment, other documents or property, or copies or reproductions of any aforementioned items, whether in tangible or electronic format (including but not limited to any of the foregoing in the possession of members, consultants and employees of Sellers) constituting Acquired Assets, Sellers shall transfer and deliver to Purchaser, at no cost to Purchaser, all of the aforementioned items, on the Closing Date or thereafter on such date or dates as may be requested by Purchaser, to the locations, and in accordance with the instructions, specified by Purchaser. In the event that any of the abovementioned items reside in digital or electronic format on any equipment that is not included in the Acquired Assets, then the hard drive or other medium shall be imaged and provided to Purchaser in a reasonably accessible format.

**6.2 Program Material.** The Program Material shall be stored by Sellers for the period [\*\*\*]. During the period that any Program Material is being stored by Sellers on behalf of Purchaser, Sellers shall supply and transfer to Purchaser (or its designee), upon Purchaser's request at any time during that period, the Program Material. In the event Purchaser does not request such supply and transfer prior to the expiration of such period, Sellers shall promptly destroy the remaining Program Material. Without limiting the foregoing, as soon as practicable following the Closing Date, Sellers shall deliver written authorization to the applicable Seller CDMO(s) to deliver the Program Material (or, if requested by Purchaser, to take instruction from Purchaser as to the continued storage thereof) and to deliver all associated documentation generated by such Seller CDMO(s) and deliverable by such Seller CDMO(s) to a Seller with respect to the Program Material (including, without limitation, and if applicable, a copy of the executed batch manufacturing record and a certificate of analysis for each batch of Compound active pharmaceutical ingredient in the Program Material) to Purchaser in accordance with Purchaser's delivery instructions. Upon Purchaser's request from time to time during the [\*\*\*], Sellers shall provide Purchaser with an introduction to any Seller CDMO specified by Purchaser and shall deliver to such Seller CDMO, (A) written authorization (1) to contract with Purchaser for development and manufacturing services with respect to Compounds and Products or for the manufacture and supply of Compounds and Products, (2) to manufacture Compounds and Products on behalf of Purchaser, and (3) to disclose and transfer to Purchaser or its designee any Program Know-How in the possession of such Seller CDMO(s) as is necessary or useful for Purchaser to develop, manufacture or have manufactured, and obtain and maintain Regulatory Approvals for, Compounds and Products, and (B) to the extent reasonably requested by Purchaser, written notice of any assignment to Purchaser of any Program Contract with such Seller CDMO.

**6.3 Patent Matters.** Sellers shall be responsible for and shall cover all costs of transferring the Program Patents to Purchaser. Within [\*\*\*], Sellers shall inform in writing any outside patent counsel and all local patent representatives used by a Seller or any of its Affiliates to prosecute and maintain any Program Patent, that (i) the Program Patents have been assigned to Purchaser and (ii) a copy of all future correspondence regarding the Program Patents should be sent to Purchaser, and Sellers shall forward copies of any correspondence it or any of its Affiliates receives from any such outside patent counsel or local patent representative or any Governmental Authorities regarding the Program Patents to Purchaser. Promptly after the Closing Date, Sellers shall provide Purchaser or shall instruct outside patent counsel to provide Purchaser with complete copies of the Program Patent Files. Except as otherwise provided in this Agreement, Purchaser or

its agents or designees will be responsible for the prosecution and maintenance of the Program Patents after the Closing Date. Upon Purchaser's written request, for a period of up to [\*\*\*], Sellers will be responsible for prosecuting and/or maintaining the Program Patents on Purchaser's behalf at Purchaser's cost. Further, in the event that the assignment recording process has not been completed for any Program Patent within such period, Sellers shall, upon Purchaser's reasonable written request and at Purchaser's cost, continue to be responsible for prosecuting and/or maintaining the Program Patent on Purchaser's behalf until the assignment record process for such Program Patent has been completed and for a [\*\*\*]. For a period of [\*\*\*], at Purchaser's reasonable request, Sellers will, subject to reimbursement of costs, cooperate with and reasonably assist and provide support to Purchaser in relation to the prosecution and maintenance of the Program Patents.

**6.4 Transition Support.** As reasonably requested by Purchaser, during the [\*\*\*] following the Closing Date, Sellers shall make [\*\*\*] available to Purchaser [\*\*\*] to provide reasonable technical consultation and assistance with respect to the use of the Program Technology or the development or manufacture of any Compound or Product.

**6.5 Post-Closing Transfers.** Following the Closing, the parties shall cooperate with each other to identify any assets that were not transferred as part of the Acquired Assets at the Closing but that, pursuant to the provisions of this Agreement, were required to be transferred (the "**Non-Transferred Assets**"). To the extent any Non-Transferred Assets are identified and Sellers are legally and contractually permitted to transfer such assets, Sellers shall, at no cost to Purchaser, promptly take all actions to transfer such Non-Transferred Assets to Purchaser. In the event a Seller is required to obtain the consent or approval of any Person prior to the transfer of any Non-Transferred Asset, then such Seller shall, at its own expense, use its commercially reasonable efforts to promptly obtain such approval or consent, and upon obtaining such approval or consent, shall promptly transfer such Non-Transferred Asset to Purchaser. In the event a Seller is unable to obtain such approval or consent, then such Seller and Purchaser shall discuss in good faith an appropriate resolution for the transfer of the economic benefit of such Non-Transferred Asset to Purchaser.

#### **6.6 Tax Matters.**

**(a) Tax Cooperation and Exchange of Information.** Sellers and Purchaser will cooperate in good faith in connection with the filing of any Tax Returns, audit, or Proceeding with respect to Taxes and in connection with any other Proceeding, in each case relating to the Acquired Assets, as and to the extent reasonably requested by Purchaser or Sellers. Such cooperation shall include furnishing or causing to be furnished to the Purchaser, upon request and as promptly as practicable, such information and assistance relating to the Acquired Assets (including access to books and records) as is necessary for the filing of all Tax Returns, the making of any election related to any Tax, the preparation for any audit by any taxing authority, and the prosecution or defense of any claim or proceeding relating to any Tax Return.

**(b) Conveyance Taxes.** Each of [\*\*\*]. Purchaser and Sellers agree to cooperate in the execution and delivery of all instruments and certificates reasonably necessary to minimize the amount of any Conveyance Taxes and to enable the Parties to comply with any pre-closing filing requirements.

(c) **Tax Deficiencies.** Sellers shall not permit to exist any Tax deficiencies (including penalties and interest) assessed against or relating to Sellers with respect to taxable periods ending on or before, or including, the Closing Date of a character or nature that could reasonably be expected to result in liens or claims on any of the Acquired Assets or on Purchaser's title or use of the Acquired Assets following the Closing Date or that would reasonably be expected to result in any claim against Purchaser.

(d) **Tax Apportionment.** All personal property Taxes and similar ad valorem obligations levied with respect to the Acquired Assets for a taxable period that includes (but does not end on) the Closing Date (collectively, the "**Apportioned Obligations**") shall be apportioned between Sellers and Purchaser as of the Closing Date based on the number of days of such taxable period ending on and including the Closing Date ("**Pre-Closing Apportioned Period**") and the number of days of such taxable period beginning the day after the Closing Date through the end of such taxable period (the "**Post-Closing Apportioned Period**"). Sellers shall be liable for the proportionate amount of Apportioned Obligations that is attributable to the Pre-Closing Apportioned Period. Purchaser shall be liable for the proportionate amount of the Apportioned Obligations that is attributable to the Post-Closing Apportioned Period.

(e) **Tax Treatment of Payments.** The Parties intend that all payments to VPH under this Agreement constitute, for Tax purposes, proceeds paid for the purchase and sale of the Acquired Assets. The Parties shall report such payments in a manner consistent with the preceding sentence on all Tax returns to which such treatment is relevant, except to the extent that a different treatment is required by the applicable Governmental Body after audit or examination.

## 7. INDEMNIFICATION

### 7.1 Survival of Representations and Warranties.

(a) The representations and warranties of each Party under this Agreement shall survive the Closing Date for a period of [\*\*\*]; provided, however, that (i) the representations and warranties contained in Section 3.1, Section 3.2, Section 3.3, Section 3.6, Section 3.7 and Section 3.16 (collectively, the "**Seller Fundamental Representations**") shall survive the Closing Date for a period of [\*\*\*], and (ii) the representations and warranties contained in Section 3.11 shall survive the Closing until the date that is [\*\*\*].

(b) The representations and warranties of Sellers and the rights and remedies that may be exercised by Purchaser Indemnitees with respect thereto shall not be limited or otherwise affected by or as a result of any information furnished to, or any investigation made by or any knowledge of, any of Purchaser Indemnitees or any of their Representatives. The representations and warranties of Purchaser and the rights and remedies that may be exercised by Seller Indemnitees with respect thereto shall not be limited or otherwise affected by or as a result of any information furnished to, or any investigation made by or any knowledge of, any of Seller Indemnitees or any of Representative thereof.

## 7.2 Indemnification by Sellers.

(a) Sellers shall jointly and severally hold harmless and indemnify each Purchaser Indemnitee from and against, and shall compensate and reimburse each of Purchaser Indemnitees for, any Damages that are directly or indirectly suffered or incurred by any Purchaser Indemnitee or to which any Purchaser Indemnitee may otherwise become subject at any time (regardless of whether or not such Damages relate to any Third Party claim) and that arise directly or indirectly from or as a direct or indirect result of, or are directly or indirectly connected with:

(i) any Breach of any representation or warranty made by Sellers in this Agreement or in any other Transaction Document, it being understood that for the purposes of determining the amount of any Losses hereunder but not for determining whether such Breach has occurred, such representations and warranties shall be interpreted without giving effect to any qualifications regarding “materiality” or other terms of similar import or effect (as if such standard or qualification were deleted from such representation or warranty);

(ii) any Breach of any covenant or obligation of Sellers contained in any of the Transaction Documents;

(iii) any Liabilities (other than the Assumed Liabilities) of Sellers; and

(iv) any Proceeding relating directly or indirectly to any Breach, alleged Breach, Liabilities, or matter of the type referred to in any of the foregoing subsection (i), (ii), or (iii) above (including any Proceeding commenced by any Purchaser Indemnitee for the purpose of enforcing any of its rights under this Section 7.2).

## 7.3 Indemnification by Purchaser.

(a) Purchaser shall hold harmless and indemnify Seller Indemnitees from and against, and shall compensate and reimburse Seller Indemnitees for, any Damages that are directly or indirectly suffered or incurred by Seller Indemnitees or to which Seller Indemnitees may otherwise become subject at any time (regardless of whether or not such Damages relate to any Third Party claim) and that arise directly or indirectly from or as a direct or indirect result of, or are directly or indirectly connected with:

(i) any Breach of any representation or warranty made by Purchaser in this Agreement or in any other Transaction Document, it being understood that for the purposes of determining the amount of any Losses hereunder but not for determining whether such Breach has occurred, such representations and warranties shall be interpreted without giving effect to any qualifications regarding “materiality” or other terms of similar import or effect (as if such standard or qualification were deleted from such representation or warranty);

(ii) any Breach of any covenant or obligation of Purchaser contained in any of the Transaction Documents; and

(iii) any Proceeding relating directly or indirectly to any Breach, alleged Breach, Liabilities or matter of the type referred to in the foregoing subsections (i) or (ii) above

(including any Proceeding commenced by any Seller Indemnitee for the purpose of enforcing its rights under this Section 7.3).

#### **7.4 Defense of Third Party Claims.**

**(a)** In the event of the assertion or commencement by any Person of any claim or Proceeding (whether against Purchaser or a Seller, against any other Indemnitee or against any other Person) with respect to which a Seller, on one hand, and Purchaser, on the other hand, may become obligated to indemnify, hold harmless, compensate, or reimburse any Indemnitee pursuant to this Article 7, the Indemnitee shall have the right, at its election, to designate the Indemnitor to assume the defense of such claim or Proceeding at the sole expense of the Indemnitor. If the Indemnitee so elects to designate the Indemnitor to assume the defense of any such claim or Proceeding:

**(i)** the Indemnitor shall proceed to defend such claim or Proceeding in a diligent manner with counsel satisfactory to the Indemnitee;

**(ii)** the Indemnitee shall make available to the Indemnitor any non-privileged documents and materials in the possession of the Indemnitee or any Affiliate of the Indemnitee that may be necessary to the defense of such claim or Proceeding;

**(iii)** the Indemnitor shall keep the Indemnitee informed of all material developments and events relating to such claim or Proceeding;

**(iv)** the Indemnitee shall have the right to participate in the defense of such claim or Proceeding;

**(v)** the Indemnitor shall not settle, adjust, or compromise such claim or Proceeding without the prior written consent of the Indemnitee; provided, however, that the Indemnitee shall not unreasonably withhold such consent; and

**(vi)** the Indemnitee may at any time (notwithstanding the prior designation of the Indemnitor to assume the defense of such claim or Proceeding) assume the defense of such claim or Proceeding.

**(b)** If the Indemnitee does not elect to designate the Indemnitor to assume the defense of any such claim or Proceeding (or if, after initially designating the Indemnitor to assume such defense, the Indemnitee elects to assume such defense), the Indemnitee may proceed with the defense of such claim or Proceeding on its own. If the Indemnitee so proceeds with the defense of any such claim or Proceeding on its own:

**(i)** all reasonable expenses relating to the defense of such claim or Proceeding (whether or not incurred by the Indemnitee) shall be considered Damages hereunder and shall be borne and paid exclusively by the Indemnitor;

(ii) the Indemnitor shall make available to the Indemnitee any non-privileged documents and materials in the possession or control of either of the Indemnitor or any Affiliate of the Indemnitor that may be necessary to the defense of such claim or Proceeding;

(iii) the Indemnitee shall keep the Indemnitor informed of all material developments and events relating to such claim or Proceeding; and

(iv) the Indemnitee shall have the right to settle, adjust, or compromise such claim or Proceeding with the consent of the Indemnitor; provided, however, that the Indemnitor shall not unreasonably withhold such consent.

**7.5 Exercise of Remedies by Indemnitees Other Than Parties to This Agreement.** No Indemnitee (other than the Parties to this Agreement or any successor thereto or permitted assignee thereof) shall be permitted to assert any indemnification claim or exercise any other remedy under this Agreement unless the respective Party to this Agreement entitled to indemnification (or any successor thereto or permitted assignee thereof) has consented to the assertion of such indemnification claim or the exercise of such other remedy.

#### **7.6 Indemnification Claims.**

(a) **Delivery of Claim Notice.** If any Indemnitee has or claims to have incurred or suffered Damages for which it is or may be entitled to indemnification, compensation, or reimbursement under Article 7 of this Agreement, such Indemnitee is required to deliver a claim notice (a “**Claim Notice**”) to the Indemnitor. Each Claim Notice shall state that such Indemnitee believes that there is or has been a breach of a representation, warranty, or covenant contained in this Agreement or that such Indemnitee is otherwise entitled to indemnification, compensation, or reimbursement under Article 7 of this Agreement, and contain a brief description of the circumstances supporting such Indemnitee’s belief that there is or has been such a breach or that such Indemnitee is so entitled to indemnification, compensation, or reimbursement and shall, to the extent possible, contain a good faith, non-binding, preliminary estimate of the amount of Damages such Indemnitee claims to have so incurred or suffered (the “**Claimed Amount**”).

(b) **Response Notice; Uncontested Claims.** Within [\*\*\*] after receipt by the Indemnitor of a Claim Notice, the Indemnitor may deliver to the Indemnitee who delivered the Claim Notice a written response (the “**Response Notice**”) in which the Indemnitor: (i) agrees that the Indemnitee is entitled to the full Claimed Amount; (ii) agrees that the Indemnitee is entitled to part, but not all, of the Claimed Amount (the “**Agreed Amount**”); or (iii) indicates that the Indemnitor disputes the entire Claimed Amount. Any part of the Claimed Amount that is not agreed to pursuant to the Response Notice shall be the “**Contested Amount**”. If a Response Notice is not received by the Indemnitee within such [\*\*\*] period, then the Indemnitor shall be conclusively deemed to have agreed that the Indemnitee is entitled to the full Claimed Amount. If the Indemnitor and the Indemnitee are unable to resolve the dispute relating to any Contested Amount within [\*\*\*] after the delivery of the Claim Notice (“**Initial Resolution Period**”), then the Parties shall follow the procedures set forth in Section 8.6(b) hereof.

(c) **Set-Off.** The Purchaser Indemnitees shall be entitled to, and shall seek payment of, indemnification obligations pursuant to this Article 7 by set-off against any Milestone Payment under Section 2.6 or any payment of Royalties under Section 2.7 of this Agreement that has become payable but has not yet been paid or that later becomes payable.

**7.7 Limitations on Indemnification Obligations.** The rights of the Purchaser Indemnitees to indemnification pursuant to the provisions of Section 7.2 and of the Seller Indemnitees to indemnification pursuant to the provisions of Section 7.3 are subject to the following limitations:

(a) The amount of any and all Damages will be determined [net of any amounts actually recovered by the Indemnitees under insurance policies or similar arrangements with third parties with respect to such Damages (less expenses incurred by such Indemnitee in procuring such recovery, including the costs, if any, resulting from premium adjustments with respect to such insurance policies). If the amount to be netted hereunder from any payment required under Sections 7.2 or 7.3 is determined after payment of any amount otherwise required to be paid to an Indemnitee under this Article 7, the Indemnitee shall repay to the Indemnitors, promptly after such determination, any amount that the Indemnitors would not have had to pay pursuant to this Article 7 had such determination been made at the time of such payment].

(b) The Purchaser Indemnitees shall not be entitled to recover for any particular Damages or series of related Damages pursuant to Section 7.2(a)(i) unless the amount of such Damages or series of related Damages equals or exceeds [\*\*\*] dollars (\$[\*\*\*]), and then for all such Damages from and including the first dollar of any Damages; provided, however, that this Section 7.7(b) shall not apply in respect of any claim (i) for any breach of any of the Seller Fundamental Representations, or (ii) of fraud or willful Breach.

(c) The maximum aggregate obligation of Sellers under Section 7.2(a)(i) and Section 7.2(a)(iv) (with respect to Section 7.2(a)(i)) (except in respect of any claim (i) for any breach of any of the Seller Fundamental Representations, or (ii) of fraud or willful Breach) for any Damages in the aggregate shall not exceed [\*\*\*].

(d) In no event, shall the total amount of Damages for which Sellers shall be liable under this Article 7 [\*\*\*] (except in respect of any claim of fraud or willful Breach).

**7.8 Exclusive Remedy.** After the Closing Date, the provisions of this Article 7 shall provide the sole and exclusive remedy of any Party hereto with respect to the matters set forth in Section 7.2 and Section 7.3 of this Agreement by the other Parties, and shall preclude the assertion of any other right or remedy by such Party in connection therewith; *provided, however*, that this Section 7.8 shall not preclude or otherwise limit the assertion of (a) any right or remedy for fraud or willful Breach by any Person, or (b) any right or remedy for specific performance or other equitable relief, including specific performance of the covenants contained in Article 6 of this Agreement.

## 8. MISCELLANEOUS PROVISIONS

**8.1 Further Assurances.** Each Party hereto shall execute and/or cause to be delivered to each other Party hereto such instruments and other documents, and shall take such other actions, as such other Party may reasonably request (at or after the Closing) for the purpose of carrying out or evidencing any of the Transactions.

**8.2 Fees and Expenses.** Each Party to this Agreement shall bear and pay all fees, costs, and expenses, including all legal fees and expenses, that have been incurred or that are in the future incurred by, on behalf of or for the benefit of such Party in connection with: (a) the negotiation, preparation and review of any letter of intent or similar document relating to any of the Transactions, (b) the investigation and review conducted by such Party and its Representatives with respect to the Transactions, (c) the negotiation, preparation, and review of this Agreement, the other Transaction Documents and all assignments, certificates, and other instruments and documents delivered or to be delivered in connection with the Transactions, (d) the preparation and submission of any filing or notice required to be made or given in connection with any of the Transactions, and the obtaining of any Consent required to be obtained in connection with any of the Transactions, and (e) the consummation and performance of the Transactions.

**8.3 Notices.** Any notice or other communication required or permitted to be delivered to any Party under this Agreement shall be in writing and shall be deemed delivered, given, and received when delivered (by hand, by registered mail, by courier or express delivery service, or by email) to the physical address or email address set forth beneath the name of such Party below (or to such other physical address or email address as such Party shall have specified in a written notice given to the other Parties hereto):

if to Selenity:

c/o Verdolino & Lowey  
124 Washington St.  
Foxborough, MA 02035  
Attention: Robert Schotzinger  
Email: rschotzinger@selenitytx.com

if to VPH:

c/o Verdolino & Lowey  
124 Washington St.  
Foxborough, MA 02035  
Attention: Robert Schotzinger  
Email: rschotzinger@selenitytx.com

with a copy (which shall not constitute notice) to:

Wilmer Cutler Pickering Hale and Dorr LLP  
60 State Street  
Boston, MA 02109  
Attention: Rosemary Reilly, Esq.



Email: [rosemary.reilly@wilmerhale.com](mailto:rosemary.reilly@wilmerhale.com)

if to Purchaser:

PhaseBio Pharmaceuticals, Inc.  
1 Great Valley Parkway, Suite 30  
Malvern, PA 19355  
Attention: Legal Department  
Email: [notices@phasebio.com](mailto:notices@phasebio.com)

with a copies (which shall not constitute notice) to:

PhaseBio Pharmaceuticals, Inc.  
11260 El Camino Real, Suite 100  
San Diego, CA 92130  
Attention: Kristopher Hanson  
Email: [kris.hanson@phasebio.com](mailto:kris.hanson@phasebio.com)

and

Cooley LLP  
4401 Eastgate Mall  
San Diego, CA 92121-1909  
Attn: Jane K. Adams

**8.4 Headings.** The bold headings contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

**8.5 Counterparts.** This Agreement may be executed in counterparts and by electronic (i.e., pdf) or facsimile transmission, each of which shall constitute an original and all of which, when taken together, shall constitute one agreement.

**8.6 Governing Law; Dispute Resolution.**

**(a) Governing Law.** This Agreement shall be governed in all respects by the laws of the State of New York, without reference to choice of law doctrines or statutes with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law. The United Nations Convention of International Contracts on the Sale of Goods does not apply to this Agreement and is expressly and entirely excluded.

**(b) Dispute Resolution.**

**(i) General.** Unless otherwise set forth in this Agreement, in the event of any dispute in connection with this Agreement, such dispute shall first be referred to the executive officers of the Parties designated below or their designees, who shall confer in good faith on the resolution of the issue. If the executive officers are not able to agree on the resolution of any such issue within 30 days (or such other period of time as mutually agreed by the executive officers) after such issue was first referred to them, then, if a Party wishes to pursue further resolution of

such dispute, such Party may initiate litigation proceedings in accordance with Section 8.6(b)(ii). The designated executive officers are as follows:

For Sellers: Robert Schotzinger

For Purchaser: Jonathan Mow

**(ii) Litigation.** Except as otherwise expressly provided in this Agreement, any suit, action or proceeding seeking to enforce any provision of this Agreement, or any matter arising out of or in connection with, arising under, related to, associated with, or arising in connection with, this Agreement or the Transaction shall be brought in the United States District Court for the Southern District of New York, or any other court of the State of New York, and each of the parties hereto hereby consents to the jurisdiction of such courts (and of the appropriate appellate courts therefrom) in any such suit, action or proceeding and irrevocably waives, to the fullest extent permitted by law, any objection which it may now or hereafter have to the laying of the venue of any such suit, action or proceeding in any such court or that any such suit, action or proceeding which is brought in any such court has been brought in an inconvenient forum. Process in any such suit, action or proceeding may be served on any party anywhere in the world, whether within or without the jurisdiction of any such court. Without limiting the foregoing, each party agrees that service of process on such party as provided in Section 8.3 shall be deemed effective service of process on such party.

**8.7 Waiver of Jury Trial.** EACH OF PURCHASER AND SELLERS HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING, OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT, OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE ACTIONS OF PURCHASER OR SELLERS IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE, AND ENFORCEMENT HEREOF.

**8.8 Successors and Assigns; Parties in Interest.**

**(a)** This Agreement shall be binding upon each Seller and its successors and assigns (if any) and Purchaser and its successors and assigns (if any). This Agreement shall inure to the benefit of Sellers, Purchaser, the other Indemnitees (subject to Section 7.5) and the respective successors and assigns (if any) of the foregoing.

**(b)** Purchaser may freely assign any or all of its rights or delegate any or all of its obligations under this Agreement (including its indemnification rights under Article 7), in whole or in part, to any other Person without obtaining the consent or approval of any other Person, and, in connection with any such delegation of obligations, the Parties acknowledge and agree that Purchaser shall not retain any obligation to continue to satisfy or perform such obligations. A Seller shall not be permitted to assign any of its rights or delegate any of its obligations under this Agreement without Purchaser's prior written consent.

**(c)** Except for the provisions of Article 7, none of the provisions of this Agreement is intended to provide any rights or remedies to any Person other than the Parties to this

Agreement and their respective successors and assigns (if any). Without limiting the generality of the foregoing, no creditor of or other claim holder against Sellers shall have any rights under this Agreement or any of the other Transaction Documents.

**8.9 Remedies Cumulative.** Subject to Section 7.8, the rights and remedies of the Parties hereto shall be cumulative and not alternative.

**8.10 Injunctive Relief; Specific Performance.** The Parties hereto hereby acknowledge that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise Breached and that the Parties hereto would not have any adequate remedy at law. Accordingly, the Parties hereto shall be entitled to an injunction or injunctions to prevent Breaches or threatened Breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement, in each case, without prejudice to any other right or remedy under this Agreement or any right or remedy that may be available at law or in equity.

**8.11 Waiver.**

(a) No failure on the part of any Person to exercise any power, right, privilege, or remedy under this Agreement, and no delay on the part of any Person in exercising any power, right, privilege, or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege, or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

(b) No Person shall be deemed to have waived any condition or claim arising out of this Agreement, or any power, right, privilege, or remedy under this Agreement, unless the waiver of such condition, claim, power, right, privilege, or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such Person; and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

**8.12 Amendments.** This Agreement may not be amended, modified, altered, or supplemented other than by means of a written instrument duly executed and delivered on behalf of Purchaser and each Seller.

**8.13 Severability.** In the event that any provision of this Agreement, or the application of such provision to any Person or set of circumstances, shall be determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to Persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, will not be affected and will continue to be valid and enforceable to the fullest extent permitted by law. In lieu of such invalid, unlawful, void or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such invalid, unlawful, void or unenforceable provision as may be possible and reasonably acceptable to the Parties.

**8.14 Entire Agreement.** The Transaction Documents set forth the entire understanding of the Parties relating to the subject matter thereof and supersede all prior agreements and understandings among or between any of the Parties relating to the subject matter thereof.

**8.15 Interpretation.** The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. The term “including” or “includes” as used in this Agreement means including, without limiting the generality of any description preceding such term, and the word “or” has the inclusive meaning represented by the phrase “and/or.” Unless otherwise specified, references in this Agreement to any section shall include all subsections and paragraphs in such Section and references in this Agreement to any subsection shall include all paragraphs in such subsection. All references to days in this Agreement shall mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either party, irrespective of which party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the parties regarding this Agreement shall be in the English language.

**8.16 Sellers’ Disclosure Schedule.** The Sellers’ Disclosure Schedule has been arranged, for purposes of convenience only, as separate Parts corresponding to the subsections of Article 3 of this Agreement. The representations and warranties contained in Article 3 of this Agreement are subject to (a) the exceptions and disclosures set forth in the part of the Sellers’ Disclosure Schedule corresponding to the particular subsection of Article 3 in which such representation and warranty appears and Parts of the Sellers’ Disclosure Schedule referenced herein are a part of this Agreement as if fully set forth herein; (b) any exceptions or disclosures explicitly cross-referenced in such part of the Sellers’ Disclosure Schedule by reference to another part of the Sellers’ Disclosure Schedule; and (c) any exception or disclosure set forth in any other part of the Sellers’ Disclosure Schedule to the extent it is reasonably apparent on the face of such disclosure that such exception or disclosure is intended to qualify another part of the Sellers’ Disclosure Schedule. No reference to or disclosure of any item or other matter in the Sellers’ Disclosure Schedule shall be construed as an admission or indication that such item or other matter is material (nor shall it establish a standard of materiality for any purpose whatsoever) or that such item or other matter is required to be referred to or disclosed in the Sellers’ Disclosure Schedule. The information set forth in the Sellers’ Disclosure Schedule is disclosed solely for the purposes of this Agreement, and no information set forth therein shall be deemed to be an admission by any Party to any third party of any matter whatsoever, including of any violation of Legal Requirement or breach of any agreement. The Sellers’ Disclosure Schedule and the information and disclosures contained therein are intended only to qualify and limit the representations, warranties and covenants of Sellers contained in this Agreement.

{Remainder of Page Intentionally Left Blank}

IN WITNESS WHEREOF, the Parties hereto have caused this Asset Purchase Agreement to be executed and delivered as of the Effective Date.

**PURCHASER:**

**PHASEBIO PHARMACEUTICALS, INC.**

By: /s/ Jonathan Mow

Name: Jonathan Mow

Title: Chief Executive Officer

**SELENITY:**

**SELENITY THERAPEUTICS (BERMUDA), LTD.**

By: /s/ Robert J. Schotzinger

Name: Robert J. Schotzinger

Title: President

**VPH:**

**VIAMET PHARMACEUTICALS HOLDINGS, LLC**

By: /s/ Robert J. Schotzinger

Name: Robert J. Schotzinger

Title: President

**EXHIBIT A**  
**FORM OF ASSIGNMENT AND ASSUMPTION AGREEMENT**

**FINAL FORM**

**ASSIGNMENT AND ASSUMPTION AGREEMENT**

**THIS ASSIGNMENT AND ASSUMPTION AGREEMENT** (this “**Agreement**”) is made on January 13, 2020, by and among **PhaseBio Pharmaceuticals, Inc.**, a Delaware corporation having a place of business at 1 Great Valley Parkway, Suite 30, Malvern, Pennsylvania 19355 (“**Assignee**”), **Selenity Therapeutics (Bermuda), Ltd.**, a Bermuda exempted company having a place of business at Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda (“**Selenity**”), and **Viamet Pharmaceuticals Holdings, LLC**, a limited liability company organized under the laws of Delaware having a place of business at c/o Verdolino & Lowey, 124 Washington St., Foxborough, MA 02035 (“**VPH**” and, together with Selenity, the “**Assignors**” and each, an “**Assignor**”).

**RECITALS**

**WHEREAS**, Assignee and Assignors, have entered into that certain Asset Purchase Agreement (the “**Asset Purchase Agreement**”) dated January 13, 2020, whereby Assignee agreed to purchase, acquire and accept the Acquired Assets (as defined in the Asset Purchase Agreement) and Assignee agreed to assume and accept the Assumed Liabilities (as defined in the Asset Purchase Agreement), all on the terms and subject to the conditions set forth therein;

**WHEREAS**, this Agreement is being executed to evidence the sale, assignment, conveyance, transfer and delivery of all of each Assignor’s right, title and interest in and to the Acquired Assets and the acceptance and assumption by Assignee of the Assumed Liabilities; and

**WHEREAS**, pursuant to the Asset Purchase Agreement, the execution and delivery of this Agreement is a condition precedent to the closing of the transactions contemplated by the Asset Purchase Agreement.

**AGREEMENTS**

**NOW, THEREFORE**, pursuant to the terms of the Asset Purchase Agreement and in consideration for the mutual promises it contains, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignee and each Assignor each further agree as follows:

- 1. Defined Terms.** Capitalized terms used herein but not otherwise defined in this Agreement shall have the meanings ascribed to such terms in the Asset Purchase Agreement.
- 2. Assignment.** Each Assignor does hereby sell, assign, convey, transfer and deliver unto Assignee, and Assignee hereby assumes, all of the rights, titles and interests of each Assignor in and to each and all of the Acquired Assets.
- 3. Assumption of Liabilities.** Assignee hereby assumes and agrees to discharge and perform when due, in accordance with the terms of the Asset Purchase Agreement, each of the Assumed Liabilities.
- 4. Further Assurances.** Each Assignor will take all further actions and execute and deliver all further documents after the Closing that are necessary to transfer and convey the Program Contracts to Assignee

and the Assumed Liabilities on the terms herein contained. The Program Contracts are expressly set forth on Schedule 2.1(c) of the Asset Purchase Agreement.

**5. Excluded Assets and Retained Liabilities.** Notwithstanding anything in this Agreement to the contrary, Assignors are retaining all Excluded Assets and Retained Liabilities, all as set forth in the Asset Purchase Agreement.

**6. Asset Purchase Agreement Controls.** This Agreement is executed and delivered pursuant to, is in accordance with, and is subject to, all of the representations, warranties, covenants, indemnities and miscellaneous provisions set forth in the Asset Purchase Agreement; all of which shall survive the consummation of the transactions contemplated hereby on the basis and to the extent set forth in the Asset Purchase Agreement. In the event that any provision of this Agreement shall be construed to conflict with a provision in the Asset Purchase Agreement, the provision in the Asset Purchase Agreement shall control.

**7. Governing Law.** This Agreement will be governed and construed in accordance with the laws of the New York, to the exclusion of both its principles and rules on conflicts of laws.

**8. Binding Effect; Benefit.** This Agreement will inure to the benefit of and bind the Parties and their respective successors and permitted assigns. Nothing in this Agreement, express or implied, may be construed to give any Person other than the Parties and their respective successors and permitted assigns any right, remedy, claim, obligation or liability arising from or related to this Agreement. This Agreement and all of its provisions and conditions are for the sole and exclusive benefit of the Parties and their respective successors and permitted assigns.

**9. Counterparts.** This Agreement may be executed by facsimile or electronic (.pdf) delivery of original signatures, and in counterparts, both of which shall be considered one and the same agreement, and shall become effective when such counterparts have been signed by each party and delivered, including by facsimile or other electronic means, to the other party. No Party may raise (a) the use of a facsimile or email transmission to deliver a signature or (b) the fact that any signature, agreement or instrument was signed and subsequently transmitted or communicated through the use of a facsimile or email transmission as a defense to the formation or enforceability of a contract, and each Party forever waives any such defense.

**10. Amendment.** This Agreement may not be amended or modified except by an instrument in writing signed by or on behalf of each of the Parties hereto.

**11. Notice.** Any notice given pursuant to this Agreement shall be given in the same manner as stated in Section 8.3 of the Asset Purchase Agreement.

*[Signature Page Follows]*

**IN WITNESS WHEREOF**, the Parties have caused this Assignment and Assumption Agreement to be duly executed and delivered as of the date first set forth above.

**Assignor:**

**SELENTY THERAPEUTICS (BERMUDA), LTD.**

**BY:** /s/ Robert J. Schotzinger

**NAME:** Robert J. Schotzinger

**TITLE:** President



**IN WITNESS WHEREOF**, the Parties have caused this Assignment and Assumption Agreement to be duly executed and delivered as of the date first set forth above.

**Assignor:**

**VIAMET PHARMACEUTICALS HOLDINGS, LLC**

**BY:** /s/ Robert J. Schotzinger

**NAME:** Robert J. Schotzinger

**TITLE:** President

**IN WITNESS WHEREOF**, the Parties have caused this Assignment and Assumption Agreement to be duly executed and delivered as of the date first set forth above.

**Assignee:**

**PHASEBIO PHARMACEUTICALS, INC.**

**BY:** /s/ Jonathan Mow

**NAME:** Jonathan Mow

**TITLE:** CEO

**EXHIBIT B**  
**FORM OF PATENT ASSIGNMENT**

Certain information has been excluded from this agreement (indicated by “[\*\*\*]”) because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

Final Form  
Page 1 of 5

**CONFIRMATORY ASSIGNMENT OF PATENT RIGHTS**

WHEREAS, **SELENITY THERAPEUTICS (BERMUDA), LTD.**, a corporation having its principal place of business at 2 Church Street, Clarendon House, Hamilton Bermuda HM 11 (herein referred to as “**Assignor**”) has rights in the following patent applications and the invention(s) set forth in applications for patent of the United States and elsewhere, and which are laid out in **Schedule A**:

WHEREAS, **PHASEBIO PHARMACEUTICALS, INC.**, a corporation having its principal place of business at One Great Valley Parkway, Suite 30, Malvern PA 19355 its successors, legal representatives and assigns, (the “**Assignee**”), is desirous of acquiring Assignor’s entire right, title and interest in and to said patent applications and the invention(s) disclosed therein; and in and to any letters patent(s) that claim the priority benefit of said patent applications in the United States and in any and all foreign countries; the right to file applications for patent of the United States or other countries on the invention(s) disclosed therein; any application for patent of the United States or other countries claiming priority to these applications; any provisional or other right to recover damages, including royalties, for prior infringements of these applications; and any patent of the United States or other countries that may be granted therefor or thereon.

NOW, THEREFORE, for good and sufficient consideration, the receipt of which is hereby acknowledged, the Assignor has sold, assigned, transferred, and set over, and by these presents does sell, assign, transfer, and set over, unto the Assignee, its successors, legal representatives, and assigns Assignor’s entire right, title, and interest in and to said invention(s), said application(s), and said patent(s), the right to file applications on said invention(s), Assignor’s entire right, title and interest in and to any applications for Letters Patent of the United States or other countries claiming priority to said application(s), including divisions, continuations, reissue and reexamined patents, patents or patent applications filed or modified during any post-grant or inter partes review proceeding, and continuations-in-part of said application(s), the right to recover any and all past, present, and future damages, including provisional or other royalties, for any and all past, present, and future infringements of said application(s) and said patent(s), Assignor’s entire right, title and interest in and to any and all Letters Patent or Patents, United States or foreign, to be obtained for said invention(s) and said application(s), entire right, title and interest in and to any and all reissues and extensions of said patent(s), and all rights under the Hague Convention, the Paris Convention for the Protection of Industrial Property, and under the Patent Cooperation Treaty, the same to be held and enjoyed by the Assignee, for its own use and behalf and the use and behalf of its successors, legal representatives, and assigns, to the full end of the term or terms for which Letters Patent or Patents may be granted as fully and entirely as the same would have been held and enjoyed by the Assignor had this sale and assignment not been made;

AND for the same consideration, the Assignor hereby covenants and agrees to and with the Assignee, its successors, legal representatives, and assigns, that, at the time of execution and delivery of these presents, the Assignor is the sole and lawful owner of Assignor’s entire right, title, and interest in and to said invention(s), said application(s), and said patent(s), and that the Assignor has good and full right and lawful authority to sell and convey the same in the manner herein set forth;

AND for the same consideration, the Assignor hereby covenants and agrees to and with the Assignee, its successors, legal representatives, and assigns that the Assignor will, whenever counsel of the Assignee, or the counsel of its successors, legal representatives, and assigns, shall advise that any proceeding in connection with said invention(s), said application(s), said patent(s), any application claiming priority to said application(s), any reissue or extension of said patent(s), and any United States or foreign Letters Patent or Patents for said invention(s) or said application(s), including interference and derivation proceedings, and any post-grant proceedings (e.g., opposition proceedings, post-grant reviews, *Inter partes* reviews, supplemental examinations, etc.), is lawful and desirable, sign all papers and documents, take all lawful oaths, and do all acts necessary or required to be done for the procurement, maintenance, enforcement and defense of Letters Patent or Patents for said invention(s), without charge to the Assignee, its successors, legal representatives, and assigns, but at the cost and expense of the Assignee, its successors, legal representatives, and assigns;

AND the Assignor hereby requests the Commissioner of Patents to issue any and all aforementioned patent(s) of the United States to the Assignee, as the Assignee of said invention(s) and the Letters Patent to be issued thereon for the sole use and behalf of the Assignee, its successors, legal representatives, and assigns.

Date: January 10, 2010\_\_ By: /s/ Robert J. Schotzinger\_\_

Name: Robert J. Schotzinger\_\_

Title: President\_\_

Company: **Selenity Therapeutics (Bermuda), Ltd.**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of North Carolina )  
 ) ss.  
County of Durham )

On 1/10/2020, before me, Sara Drake, Notary Public, personally appeared Robert J. Schotzinger, who proved to me on the basis of satisfactory evidence, to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

/s/ Sara Drake

Signature of Notary Public

Place Notary Seal Above

My Commission Expires: 4-21-2020



## SCHEDULE A

<b>Application No. Filing Date</b>	<b>Title</b>
[**]	[**]

**EXHIBIT C**  
**PRESS RELEASE**

*(See attached.)*



**SCHEDULE 1.82**  
**PROGRAM MATERIAL**

<b>Selenity ID/Sample Description</b>	<b>Net Weight (mg)</b>
[***]	[***]

**SCHEDULE 1.84  
PROGRAM PATENTS**



**SCHEDULE 2.1(C)**  
**PROGRAM CONTRACTS**

1. [\*\*\*].
2. [\*\*\*].
3. [\*\*\*].
4. [\*\*\*].
5. [\*\*\*].



**Consent of Independent Registered Public Accounting Firm**

The Board of Directors  
PhaseBio Pharmaceuticals, Inc.:

We consent to the incorporation by reference in the registration statements (No. 333-227935 and No. 333-230504) on Form S-8 and in the registration statement (No. 333-235735) on Form S-3 of PhaseBio Pharmaceuticals, Inc. of our report dated March 30, 2020, with respect to the balance sheets of PhaseBio Pharmaceuticals, Inc. as of December 31, 2019 and 2018, the related statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively, the financial statements), which report appears in the December 31, 2019 annual report on Form 10-K of PhaseBio Pharmaceuticals, Inc. Our report refers to a change in the accounting for leases in the year ended December 31, 2019.

/s/ KPMG LLP

Philadelphia, Pennsylvania  
March 30, 2020

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jonathan P. Mow, certify that

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2019 of PhaseBio Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2020

By: /s/ Jonathan P. Mow

Jonathan P. Mow  
Chief Executive Officer



**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John Sharp, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2019 of PhaseBio Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2020

By: /s/ John Sharp

John Sharp  
Chief Financial Officer

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

In connection with the Annual Report on Form 10-K of PhaseBio Pharmaceuticals, Inc. (“the Company”) for the period ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 30, 2020

By: /s/ Jonathan P. Mow

Jonathan P. Mow  
Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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

In connection with the Annual Report on Form 10-K of PhaseBio Pharmaceuticals, Inc. (the "Company") for the period ending December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of her knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 30, 2020

By: /s/ John Sharp

John Sharp  
Chief Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.