Nbgjn IN THE UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE

In re:	
PHASEBIO PHARMACEUTICALS, INC., Debtor. ¹	Chapter 11 Case No. 22-10995 (LSS)
PHASEBIO PHARMACEUTICALS, INC.,	
Plaintiff,	
v.	Adv. Proc. No. 22 (LSS)
SFJ PHARMACEUTICALS X, LTD.,	

Defendant.

COMPLAINT FOR RECHARACERIZATION AND DECLARATORY RELIEF

Plaintiff, PhaseBio Pharmaceuticals, Inc. ("PhaseBio," or the "Plaintiff"), by and through its undersigned counsel, hereby files, on behalf of the above-captioned debtor and debtor-in-possession (the "Debtor") and the Debtor's estate, this Complaint for Recharacterization and Declaratory Relief (the "Complaint") against SFJ Pharmaceuticals X, Ltd. (the "Defendant" or "SFJ"), and respectfully alleges as follows:

NATURE OF THE ACTION

1. The Debtor brings this adversary proceeding to, *inter alia*, properly characterize the purported obligations of the Debtor under a Co-Development Agreement ("CDA") between the Debtor and SFJ, as the equity investment it is and was intended to be, and for declaratory relief to confirm the Debtor's ownership of the clinical trial and related data associated with its bentracimab

The last four digits of the debtor's federal tax identification number are 5697. The debtor's principal office is located at 1 Great Valley Parkway, Suite 30, Malvern, Pennsylvania 19355.

drug program. Determining these issues is central to the Debtor's efforts to sell its bentracimab program assets and maximize recoveries for its actual creditors and stakeholders. To implement a successful sale process, and to provide potential bidders with certainty as to what is being transferred, the Debtor's ownership of its trial data package must be reaffirmed. A copy of the CDA as filed by the Debtor with the Securities and Exchange Commission is attached hereto as Exhibit A.

- 2. Under the CDA, SFJ has the right to invest up to \$120 million of fully at-risk equity capital with the Debtor with the intention of receiving potentially substantial future equity return-on-investment payments of up to \$600 million—representing a five-times (5x) return on investment—but if and only if the Debtor succeeded with its business and obtained regulatory approval of its principal drug candidate, bentracimab. Importantly, and consistent with the risk capital nature of the investment, SFJ receives nothing if regulatory approval is not obtained. To date, the Debtor has not obtained regulatory approval of bentracimab anywhere in the world and, accordingly, it owes SFJ nothing as of the Petition Date (defined below).
- 3. SFJ did not invest its capital with the Debtor expecting to be repaid no matter the Debtor's fortunes. Instead, under the CDA, SFJ's ability to recover its investment, or to earn any upside returns, is entirely dependent on whether the Debtor obtains regulatory approval of bentracimab. The fully risk capital nature of SFJ's investment under the CDA makes SFJ the very essence of an equity investor. SFJ therefore is no "creditor" at all, and its attempt to "secure" its contingent equity returns with a security interest in the Debtor's assets must be set aside. Once the CDA is properly characterized as equity, SFJ's purported secured claim must be disallowed in its entirety, and its lien and security interest held void and preserved for the benefit of the Debtor's estate.

- 4. Despite the fundamental nature of the equity arrangement, SFJ insisted on creating an overreaching and legally unsupportable agreement, attempting to protect its potential downside risk by inserting provisions more appropriate for a secured lending arrangement into an equity arrangement. For example, SFJ insisted on receiving a security interest encumbering all the Debtor's assets to secure the contingent equity returns. SFJ then required inclusion of an unenforceable ipso facto provision—that purports to force the Debtor to transfer the entire bentracimab program to SFJ—if the Debtor's financial condition placed in doubt the Debtor's ability to pay its obligations as they came due. These provisions do not alter the inescapable conclusion that the CDA is not (and was not intended to be) a debt instrument.
- 5. Reaching to attain the most advantageous tax treatment it could as a foreign entity, SFJ also insisted on being designated as the purported "owner" of the clinical trial data that the Debtor creates, maintains, controls, and uses for its bentracimab regulatory filings; this tax structure fiction required the Debtor to later "buy" the trial data package so that SFJ could take advantage of a "sale of property" exception to withholding taxes for the contingent return-on-investment payments.
- 6. SFJ, however, has no actual ownership interest in the trial data package. Instead, in virtually all circumstances under the CDA, the Debtor is required to "purchase" its own trial data package from SFJ for the return-on-investment payments plus an additional, token consideration payment. The legal fiction of SFJ's "ownership" of the trial data package was created only for SFJ's tax purposes as a foreign entity and does not change the reality that the clinical trial data always was and still is owned by the Debtor.
- 7. This never-before-tested co-development arrangement, which purports to combine a pure risk capital investment with a host of unenforceable provisions and legal fictions, is, in fact,

just an equity investment vehicle. Here, SFJ and the Debtor intended SFJ's investment to be fully at risk, entirely contingent on regulatory approvals, with SFJ receiving zero recovery should the Debtor be unsuccessful in obtaining those approvals. The rest of SFJ's creation—the security interest, the ipso facto handover provision, and the fictional trial data package tax structure—are all inconsistent with the economic realities of (1) the parties' intent in creating an equity investment through the CDA and (2) the Debtor's actual ownership of the clinical trial data package. The CDA's deeply flawed provisions, which make the CDA far different from other, true codevelopment agreements used in the life sciences industry, cannot be enforced and instead must be recharacterized as equity, the security interest declared void, and the Debtor held to be the true owner of its own bentracimab trial data package.

JURISDICTION AND VENUE

- 8. On October 23, 2022 (the "**Petition Date**"), the Debtor filed a voluntary petition for relief under chapter 11 of title 11 of the United States Code (as amended, the "**Bankruptcy Code**"). The Debtor continues to operate its business and manage its property as a debtor-in-possession pursuant to Sections 1107(a) and 1108 of the Bankruptcy Code.
- 9. This is an adversary proceeding pursuant to Rule 7001 of the Federal Rules of Bankruptcy Procedure.
- 10. The Court has jurisdiction over this adversary proceeding pursuant to 28 U.S.C. §§ 1334(b) and (c). This adversary proceeding is a "core" proceeding pursuant to 28 U.S.C. § 157(b). Plaintiff consents to the entry of final orders or judgment by this Court.
- 11. Pursuant to 28 U.S.C. §§ 157(a) and 157(b)(1) and the district court's reference of proceedings to the bankruptcy court, this Court may exercise subject matter jurisdiction over this adversary proceeding. Venue in this district is proper in accordance with 28 U.S.C. §§ 1408 and

1409(a).

12. This Court has personal jurisdiction over the Defendant pursuant to Rule 7004 of the Federal Rules of Bankruptcy Procedure.

THE PARTIES

- 13. The Debtor is the Plaintiff in this adversary proceeding. Founded in 2002, PhaseBio is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiovascular diseases. The Debtor has no subsidiaries and as of the Petition Date, its common stock was publicly traded and listed on the Nasdaq Global Market under the symbol "PHAS".
- 14. Upon information and belief, SFJ is an SFJ Pharmaceuticals Group company and a corporation organized and existing under the laws of the Cayman Islands, with its principal place of business at SIX, 2nd Floor, Cricket Square PO Box 2681, Grand Cayman, KY1-1111 Cayman Islands, and maintains an office at 5000 Hopyard Road, Suite 330, Pleasanton, California 94588.
- 15. SFJ's website describes its business model as making investments that are "risk capital," and states that its "Sole Mission" is "Providing Risk Capital, Expertise, Resources and Global Reach for Accelerated Clinical Development." SFJ's website further states that SFJ "Assumes 100% of clinical development risk" and that "SFJ assumes 100% of the development & approval risk." On its website, SFJ publicizes the CDA with the Debtor as a featured example of its risk capital agreements.

FACTUAL BACKGROUND

A. Overview of the Debtor's Business

16. PhaseBio's business strategy is to identify, develop and commercialize novel therapies for cardiovascular diseases. Its portfolio of products includes a number of clinical and

pre-clinical candidates that are currently in varying stages of development, none of which has received regulatory approval to date.

- 17. The U.S. Food and Drug Administration ("FDA") and other regulatory authorities at the 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 the Debtor is developing. The process required by the FDA before biologic product candidates may be marketed in the United States is lengthy and complex, and generally involves the following steps:
 - completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's "Good Laboratory Practices" regulations;
 - submission of a request for authorization from the FDA to administer an investigational new drug product to humans (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 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 biologics license application (a "BLA") after completion of all pivotal clinical trials;²

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

- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA that the applicant may file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the proposed product is produced to assess compliance with the FDA's "commercial Good Manufacturing Practices" regulations 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 the FDA's "Good Clinical Practices" regulations; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

B. Intellectual Property Rights

- 18. The Debtor's commercial success depends in part upon its ability to: (a) obtain and maintain proprietary protection for its current and future product candidates, its elastin-like polypeptides technology, and related discoveries; (b) operate without infringing on or otherwise violating the proprietary rights of others; and (c) prevent others from infringing or otherwise violating its proprietary rights. The Debtor's intellectual property strategy relies on a combination of patent, trade secret and trademark laws in the United States and other jurisdictions and on license and confidentiality agreements to protect its proprietary technology and brand.
- 19. As of the Petition Date, the Debtor held in-licenses to or owned at least 22 patent families, including 29 U.S. patents, 14 U.S. patent applications, 161 foreign patents and 87 foreign patent applications.

C. The Debtor's Bentracimab Product

20. The Debtor has been pursuing development of its lead product candidate,

intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

bentracimab (also known as PB2452), since November 2017.³ Bentracimab is a novel reversal agent for the antiplatelet drug ticagrelor. Ticagrelor is marketed and sold by AstraZeneca under the brand name "Brilinta," and is widely prescribed to reduce the rates of death, heart attack and stroke in patients with acute coronary syndrome, or who have previously experienced a heart attack. 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. Upon approval, bentracimab would be the only therapeutic agent available for specific reversal of ticagrelor. The availability of bentracimab 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.

21. In March 2020, PhaseBio commenced a global, multi-center, non-randomized, open-label Phase 3 trial for bentracimab (the "REVERSE-IT Trial"), in which it planned to enroll a total of 200 ticagrelor patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. In November 2021, PhaseBio published REVERSE-IT Trial results for patients requiring urgent surgery or an invasive procedure, which demonstrated that bentracimab immediately and sustainably reversed the antiplatelet effects of ticagrelor and was generally well tolerated by patients, with only five drug-related non-serious adverse events reported in three individuals. The cohort of patients requiring urgent surgery or an invasive

The Debtor acquired worldwide rights to develop and commercialize bentracimab pursuant to a license agreement the Debtor entered into with MedImmune Limited (a subsidiary of AstraZeneca) on November 21, 2017.

procedure has been fully enrolled, and trial sites have since shifted focus to enrolling patients with uncontrolled major or life-threatening bleeding events.

- 22. Based on feedback from the FDA, the Debtor intends to seek approval of bentracimab in the United States through an accelerated approval process to treat patients who present with uncontrolled bleeding or require surgery. The Debtor is currently targeting submission of a BLA to the FDA for bentracimab in mid-2023.
- 23. To date, the Debtor estimates that it has invested approximately \$192.9 million in pursuing the development and intended commercialization of bentracimab (which amount is separate and apart from any investment made by SFJ).

B. The SFJ Co-Development Agreement

- 24. The development of new pharmaceutical products is a lengthy, capital intensive, and uncertain process. Investing in pre-commercial companies like the Debtor is generally a high risk, high reward proposition, and debt financing at the scale required to finance clinical trials is not typically available. Instead, such companies rely on various risk capital investment vehicles (primarily equity capital) to meet their funding needs. As of December 31, 2019, the Debtor reported a net loss of \$39,247,000, and stated in its Form 10-K that it expected to continue to incur significant expenses and operating losses for the foreseeable future. The Debtor also lacked the cash required to fund Phase 3 clinical trials for bentracimab and was unable to borrow from a lender the amounts needed to fund such Phase 3 clinical trials.
- 25. Prior to executing the CDA with SFJ, the Debtor sought debt financing of approximately \$100 million from multiple lenders. Each lender rejected the Debtor's request for such debt financing, and the Debtor was unable to borrow an amount of that size from any lender.
- 26. Unable to obtain debt financing, on January 9, 2020, the Debtor entered into the CDA with SFJ to obtain the investment funds needed to support the global development of the

Debtor's lead drug candidate, bentracimab. Pursuant to the CDA, SFJ agreed to provide up to a \$120 million investment, comprised of (a) \$90 million in initial funding, and (b) up to \$30 million in additional funding. The Debtor was eligible and elected to receive the full \$30 million in additional funding on December 15, 2021, having met certain clinical development milestones, and SFJ has invested approximately \$11.3 million of that amount to date. Accordingly, as of the Petition Date, SFJ has invested a total of approximately \$101.3 million with the Debtor pursuant to the CDA. As described in greater detail below, the CDA provides for SFJ to receive highly lucrative, return-on-investment payments of up to \$600 million—representing a five-times (5x) return on investment—but if, and only if, the Debtor receives future regulatory approvals (collectively, the "Contingent Return-On-Investment Payments").

- 27. Under the CDA, the Debtor has primary responsibility for overall clinical development strategy and regulatory activities for bentracimab, including with respect to the Phase 1 and Phase 2 studies. With respect to the Phase 3 trial, the Debtor has primary responsibility for clinical development and regulatory activities for bentracimab in the United States and the European Union, while SFJ was designated to have primary responsibility for clinical development and regulatory activities for bentracimab in China and Japan and to provide clinical trial operational support in the European Union. The Debtor and SFJ agreed to use commercially reasonable efforts to conduct and complete the REVERSE-IT Trial of bentracimab and for the Debtor to submit a BLA or its foreign equivalent within specified timelines to each of the FDA and the European Medicines Agency (the "EMA").
- 28. Although SFJ has certain limited development obligations under the CDA, the Debtor holds the bentracimab program assets, including all of the intellectual property and license rights and "know-how" required to complete the clinical development. In particular, these

program assets include the clinical trial data and research results associated with the development of bentracimab, called the "Trial Data Package," which the Debtor creates, maintains, and controls. Notwithstanding the Debtor's actual ownership and control of the Trial Data Package, SFJ insisted that the CDA include language that designated SFJ as the purported "owner" of the Trial Data Package. In light of SFJ's foreign entity status and U.S. withholding tax requirements, SFJ insisted on this designation so that it could take the most favorable tax position related to its receipt of the Contingent Return-On-Investment Payments should bentracimab obtain regulatory approval in the future.

- 29. However, it is the Debtor, not SFJ, that creates, maintains, and controls the Trial Data Package, and it is the Debtor that uses this clinical trial data in regulatory filings with FDA and other regulatory authorities as required under the CDA. Indeed, in addition to lacking possession of the information needed for clinical development of bentracimab, SFJ has limited inhouse capabilities to make use of that information in order to develop and secure regulatory approval, and has never independently pursued commercial sales of a pharmaceutical product.
- 30. The CDA also expressly provides that the Research Results, a core part of the Trial Data Package, are "Confidential Information" of the Debtor rather than that of SFJ. Furthermore, the CDA provides that, under virtually all circumstances, the Debtor—not SFJ—is to be the ultimate owner of the Trial Data Package, with "ownership" reverting back to the Debtor by "purchasing" the Trial Data Package in exchange for the Contingent Return-On-Investment Payments, plus an additional and minimal token payment.⁴
 - 31. Accordingly, the Debtor owns the Trial Data Package—just as it owns the critical

Specifically, the CDA provides that SFJ will transfer the Trial Data Package to the Debtor for the Return-On-Investment Payments, plus a minimal token payment, upon (a) termination the CDA or (b) receipt of regulatory approval of bentracimab in at least one of the jurisdictions covered under the CDA.

IND application and all other bentracimab program assets—notwithstanding the insertion of the "ownership" language as part of SFJ's tax structuring in the CDA.

- 32. As referenced above, in return for its investment of up to \$120 million with the Debtor, SFJ is to receive certain Contingent Return-On-Investment Payments if the Debtor receives regulatory approvals of bentracimab. The Debtor's obligation to make the following Contingent Return-On-Investment Payments is entirely contingent on bentracimab actually receiving approval by the FDA, EMA, and either of the applicable regulatory bodies for Japan or China, as follows:
 - upon FDA approval of a BLA for bentracimab, the CDA obligates the Debtor to pay SFJ up to \$330 million, comprised of (a) an initial payment of \$5.0 million and (b) an additional \$325.0 million payable in seven annual installments;
 - if the EMA, or the national regulatory authority in certain European countries, authorizes a marketing approval for bentracimab, the CDA obligates the Debtor to pay SFJ up to \$210 million, comprised of (a) an initial payment of \$5.0 million and (b) an additional \$205.0 million payable in seven annual installments; and
 - if either the applicable regulatory bodies for Japan or China approves a marketing application for bentracimab, the CDA obligates the Debtor to pay SFJ up to \$60 million, comprised of (a) an initial payment of \$1.0 million and (b) an additional \$59.0 million payable in eight annual installments.
- 33. In summary, if bentracimab receives broad regulatory approval, SFJ stands to receive up to \$600 million, representing over a 500% return on its total committed investment of \$120 million, but <u>nothing at all</u> if regulatory approval is not obtained. To date, none of these regulatory approvals has been received.
- 34. The Debtor estimates that only \$101.3 million of that commitment has been actually invested by SFJ to date. Under the CDA, if SFJ does not invest the full \$120 million then the amount of the Contingent Return-On-Investment Payments would be reduced in proportion to the amount SFJ actually invests.
 - 35. In an attempt to secure the Contingent Return-On-Investment Payments, the CDA

also purports to grant SFJ a security interest in all of the Debtor's assets. This security interest covers not only all assets of the Debtor that are necessary for the manufacture, use or sale of bentracimab, but also all intellectual property and other assets related to the Debtor's clinical development programs for unrelated products. Under a subordination agreement, SFJ's security interest and ability to receive the Contingent Return-On-Investment Payments are subordinated to the Debtor's senior secured debt.

- 36. The CDA also gives SFJ a number of significant operational controls over the Debtor's bentracimab program, including the following:
 - Governance Rights. The CDA provides for governance through multiple operating committees, including a Joint Commercial Committee, a Joint Development Committee, and a Joint Steering Committee ("JSC"), each with a different purview of decision making. The JSC is the most senior of the governance committees, with the parties' respective Executive Officers (as defined in the CDA), among others, serving as members. The unanimous approval of the JSC is required with respect to all matters within its decision-making authority (including, among other things approving changes to the clinical protocols). If the JSC cannot reach consensus on an issue for which it has decision-making authority following escalation of a dispute to the Executive Officers, then the Debtor has the final decision-making authority, but subject to SFJ's termination and payment rights below.
 - <u>Licensing Approval Rights</u>. The CDA also provides SFJ with significant approval rights over potential licensing transactions for bentracimab. In particular, the CDA provides that the Debtor cannot enter into a licensing transaction for bentracimab without SFJ's prior written consent, and states that SFJ may withhold its consent if it believes that such licensing transaction would have a substantial likelihood of materially adversely impacting the Debtor's ability to timely pay or satisfy its repayment obligations under the CDA. Furthermore, even if approved, any licensing transaction that includes the grant of rights to commercialize bentracimab in the United States is deemed to be a "Change of Control," which, under the CDA, entitles SFJ to various termination and payment acceleration rights.

CLAIMS FOR RELIEF

First Claim for Relief

Recharacterization of the Co-Development Agreement Pursuant to 11 U.S.C. § 105(a)

37. Plaintiff repeats and realleges each and every allegation in paragraphs 1 through 36

as if fully set forth herein.

- 38. SFJ asserts that the contingent and other obligations of the Debtor under the CDA represent claims secured by all of the Debtor's assets. Notwithstanding that assertion, as a matter of substance, the CDA is an equity investment vehicle and should be characterized as equity.
- 39. Section 6.1 of the CDA sets out the Contingent Return-On-Investment Payments (called "Approval Payments" in the CDA) that SFJ hoped to receive in return for its investment. Each of these payments would become payable only "Following Regulatory Approval" by the specified regulatory agencies. That section describes the regulatory approval required and the type of payments to be made following regulatory approval, reflecting initial payments of up to \$11 million upon approval and up to \$600 million in total.
- 40. The CDA's termination sections also make clear that SFJ's investment is fully at risk. Section 14.2.1 refers to the Contingent Return-On-Investment Payments becoming due and payable "(if ever)" and "at such time that such payments become due and payable (if ever) pursuant to ARTICLE 6." Similar "if ever" references about these Contingent Return-On-Investment Payments are found throughout Article 14, specifically including in Sections 14.2.2, 14.2.3, 14.2.4.2, 14.2.5.1, 14.2.5.2, 14.2.6, 14.2.7, 14.2.8.1, 14.2.8.2, and 14.2.10. SFJ knew full well that its ability to recover any of its up to \$120 million investment, and any of the up to 5x returns on that investment, were completely contingent and at risk.
- 41. Considering the totality of the circumstances surrounding the CDA, in particular that the parties intended for the Debtor's obligations to make the up-to \$600 million in payments to SFJ to be fully contingent on the Debtor's success, specifically including in obtaining regulatory approval of bentracimab, the CDA and all of the Debtor's obligations thereunder are, and should be recharacterized as, equity, with SFJ holding only equity interests and not a valid claim,

including, but not limited to, for the following reasons:

- To date, SFJ has invested approximately \$100 million of fully contingent risk capital with the Debtor in connection with its bentracimab drug development program;
- SFJ's own website admits that its very business model is to make investments that are "risk capital," and it touts that its "Sole Mission" is "Providing Risk Capital, Expertise, Resources and Global Reach for Accelerated Clinical Development";
- The SFJ website further states that in these agreements it "Assumes 100% of clinical development risk" and that "SFJ assumes 100% of the development & approval risk," and publicizes its agreement with the Debtor as an example of these at risk agreements;
- Consistent with SFJ's investment strategy, the CDA provides that the Debtor's obligation to make the Contingent Return-On-Investment Payments to SFJ is entirely contingent upon regulatory approval of bentracimab;
- As of the Petition Date, the Debtor owes SFJ nothing under the CDA since no regulatory approval has been obtained for bentracimab;
- If regulatory approval is not obtained, the Debtor would owe SFJ nothing, including any of the approximately \$100 million invested to date with the Debtor and any of the Contingent Return-On-Investment Payments;
- Even if regulatory approval is obtained, the Debtor's ability to actually fund the Contingent Return-On-Investment Payments would depend on its business success in the commercialization of bentracimab;
- Consistent with the contingent, equity-based nature of SFJ's investment, the CDA includes no promissory note evidencing any such amount;
- SFJ obtained special voting rights over the Debtor's principal asset, including through a joint steering committee, permitting SFJ to exert influence and control over the development of the Debtor's bentracimab program;
- SFJ even has a right under the CDA to terminate the agreement and impose a penalty payment on the Debtor based on certain unresolved disagreements with the Debtor's handling of the bentracimab program;
- The Contingent Return-On-Investment Payments have no fixed maturity date, and instead are contingent on regulatory approval as to both payment and timing;
- There is no fixed or other rate of interest applied to the Contingent Return-On-Investment Payments;
- SFJ bears the same risk as the Debtor's stockholders, who also invested risk capital with returns contingent solely on the Debtor's success in obtaining regulatory approval and commercializing bentracimab;

- At the time the CDA was executed, the Debtor was unable to obtain financing from a lender in the amount of the SFJ investment and the Debtor lacked sufficient capital, and was undercapitalized, to fund the bentracimab program and the associated Phase 3 clinical trials;
- SFJ agreed to subordinate its purported security interest under the CDA to the claims of the Debtor's senior lender, up to the amount of \$16.5 million;
- No sinking fund was established to fund the Contingent Return-On-Investment Payments;
 and
- In conjunction with its investment, SFJ also received a ten-year warrant exercisable for 2,200,000 shares of the Debtor's common stock at an exercise price per share of \$6.50.
- 42. For the reasons set forth above, the CDA, and all of SFJ's purported rights and the Debtor's purported obligations thereunder, are, and should be recharacterized as, equity pursuant to 11 U.S.C. § 105(a).
- 43. Wherefore, the Debtor respectfully requests that the Court enter judgment in favor of the Debtor recharacterizing the CDA, and all of SFJ's purported rights and the Debtor's purported obligations under the CDA, as an equity investment.

Second Claim for Relief

Declaratory Relief Pursuant to 28 U.S.C. § 2201 and 11 U.S.C. §§ 506(d) and 551 to Disallow Claims and to Determine Validity, Priority and Extent of Asserted Lien

- 44. Plaintiff repeats and realleges each and every allegation in paragraphs 1 through 43 as if fully set forth herein.
- 45. Pursuant to 28 U.S.C. § 2201, "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."
- 46. There is a real, substantial, and justiciable controversy regarding whether SFJ's rights under the CDA should be treated as equity, and whether SFJ has a valid security interest in

any of the Debtor's assets.

- 47. SFJ asserts that it holds a perfected security interest in the Debtor's assets.
- 48. For the reasons alleged in this Complaint, SFJ's rights are solely those of an equity investor and not of a creditor.
- 49. As an equity investor, SFJ's asserted secured claim, and any other claim, should be disallowed in its entirety.
- 50. Accordingly, the liens and security interests asserted by SFJ are void and should be preserved for the benefit of the Debtor's estate pursuant to 11 U.S.C. §§ 506(d) and 551.
- 51. The Debtor is entitled to a declaratory judgment that SFJ's asserted secured claim is disallowed in its entirety, that SFJ's asserted security interest and lien is void, and that such security interest and lien is preserved for the benefit of the Debtor's estate.
- 52. Wherefore, the Debtor respectfully requests that the Court enter a declaratory judgment that SFJ's asserted secured claim is disallowed in its entirety, that SFJ's asserted security interest and lien is void, and that such security interest and lien is preserved for the benefit of the Debtor's estate pursuant to 11 U.S.C. §§ 506(d) and 551.

Third Claim for Relief

Declaratory Relief Pursuant to 28 U.S.C. § 2201 and 11 U.S.C. § 541 to Determine Validity, Priority and Extent of Asserted Interest in Property

- 53. Plaintiff repeats and realleges each and every allegation in paragraphs 1 through 52 as if fully set forth herein.
- 54. Pursuant to 28 U.S.C. § 2201, "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

- 55. There is a real, substantial, and justiciable controversy regarding whether the Debtor or SFJ owns the Trial Data Package.
 - 56. SFJ asserts that it owns the Trial Data Package.
- 57. Although the CDA recognizes that the Debtor owns the bentracimab program assets and related intellectual property, SFJ insisted that the CDA include language to allow SFJ, as a foreign entity, to attempt to minimize the tax consequences of receiving the Contingent Return-On-Investment Payments, should bentracimab obtain regulatory approval in the future.
- 58. Given withholding and other tax laws appliable to foreign entities, SFJ required that the CDA designate SFJ as the "owner" of the clinical trial data and research results, called the Trial Data Package. This legal fiction further required that the Debtor is to "purchase" the Trial Data Package (which the Debtor already actually owns, creates, maintains, controls, and uses in regulatory filings), in exchange for the Contingent Return-On-Investment Payments of up to \$600 million plus an additional token consideration payment.
- 59. SFJ explained that, since it is a foreign entity, using this tax structure would put it in the best position to minimize the tax consequences of the Contingent Return-On-Investment Payments by taking advantage of a "sale of property" withholding tax exception.
- 60. SFJ's tax-structuring motivation for the legal fiction of purporting that SFJ is the "owner" of the Trial Data Package becomes even clearer when the CDA is compared to similar agreements involving SFJ's domestic affiliates that do not face foreign entity withholding tax issues.
- 61. SFJ, through its domestic affiliates, has entered into at least two other codevelopment or development funding agreements with public companies. In each of these publicly available agreements, SFJ used a Delaware entity affiliate that did not have foreign entity tax

withholding issues. Neither of these agreements contain any language purporting to make the SFJ Delaware entity the owner of clinical trial data or "Trial Data Package." Instead, in each of these publicly available agreements between an SFJ Delaware entity, on the one hand, and a different public company, on the other hand, the agreement acknowledged that the public company developing the drug was the sole and exclusive owner of all of its clinical trial data or Trial Data Package.

- 62. As in those other agreements, here, it is the Debtor, not SFJ, that creates, maintains, and controls the Trial Data Package, and it is the Debtor that uses this clinical trial data in regulatory filings with the FDA and other regulatory authorities as required under the CDA for its bentracimab program. The CDA further expressly provides that the Research Results, a core part of the Trial Data Package, are the Debtor's "Confidential Information," not that of SFJ, and the CDA provides under virtually all circumstances it is the Debtor, and not SFJ, that will be the ultimate owner of the Trial Data Package.
- 63. All indicia of actual ownership demonstrate and confirm that the Debtor owns the Trial Data Package, just as it owns the critical IND application with the FDA, all related intellectual property, and all other bentracimab program assets. Notwithstanding SFJ's insistence on the insertion of this language as part of its efforts to obtain a favorable tax structure, all bentracimab program assets, including the Trial Data Package, are in fact owned by the Debtor and all constitute property of the Debtor's estate.
- 64. The definitions of the Trial Data Package and its material components are set forth in the CDA. Section 1.1.193 of the CDA defines "Trial Data Package" as follows:

"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.

65. Section 1.1.95 defines "Information" as follows:

"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.

66. Section 1.1.162 defines "Research Results" as follows:

"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).

67. Section 1.1.194 defines "Trial Invention" as follows:

"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 PB⁵ 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.

68. To implement its desired tax structuring, SFJ required that Section 11.1.1.4 reflect the legal fiction of SFJ's initial purported "ownership" of the Trial Data Package. However, the provision makes clear that the intention of the parties was that the Debtor and only the Debtor (SFJ has no right to sell or transfer the Trial Data Package to a third party) be the eventual and ultimate owner of the Trial Data Package:

⁵ Under the CDA, the term "PB" is defined to mean PhaseBio Pharmaceuticals Inc., the Debtor.

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 [a token payment], 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.

69. Section 1.1.45, the definition of "Confidential Information," recognizes that the Research Results, a core part of the Trial Data Package, is the Confidential Information only of the Debtor, and not that of SFJ, underscoring that SFJ's purported ownership is merely a tax-driven legal fiction:

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.

- 70. Further emphasizing that the parties in fact intended the Debtor to own the Trial Data Package, each section of Article 14 governing "Term and Termination", specifically including Sections 14.2.1, 14.2.2, 14.2.3, 14.2.4.3, 14.2.5.1, 14.2.5.2, 14.2.6, 14.2.7, 14.2.8.1, 14.2.8.2, 14.2.9, and 14.2.10, provides that upon termination of the CDA, the Debtor will in all instances own the Trial Data Package, employing the tax-driven fiction that the Debtor shall "purchase" it. None of these sections calls for SFJ to own the Trial Data Package upon termination of the CDA.
- 71. SFJ's purported ownership of the Trial Data Package is a legal fiction to minimize SFJ's tax consequences as a foreign entity in the event that it received the Contingent Return-On-

Investment Payments. The Debtor, and not SFJ, in fact owns, and should be held to own, the Trial Data Package, including, but not limited to, for the following reasons:

- The language added to the CDA purporting to designate SFJ as "owner" of the Trial
 Data Package was included for tax structuring reasons given SFJ's status as a foreign
 entity;
- As a foreign entity, SFJ sought to impose the legal fiction that the Contingent Return-On-Investment Payments would be made by the Debtor to "purchase" the Trial Data Package, reducing the risk to SFJ of tax withholding and other unfavorable tax treatment;
- SFJ does not use this "ownership" and "purchase" tax structure for trial data when its domestic affiliates enter into similar agreements;
- This tax structure is inconsistent with reality, as the Debtor owns all bentracimab program assets, including the IND application that gives the Debtor the sole right to make regulatory filings with the FDA;
- All indicia of actual ownership of the Trial Data Package remain solely with the Debtor and are inconsistent with any purported ownership claim by SFJ:
 - o the Debtor creates, maintains, and controls the Trial Data Package;
 - the Debtor must use the Trial Data Package in regulatory filings required under the CDA;
 - the Research Results, a core part of the Trial Data Package, are expressly designated in Section 1.1.45 of the CDA as the Debtor's "Confidential Information" and not that of SFJ;
 - o the Debtor is party to dozens of clinical trial site agreements in the United States, Canada, and Europe, which provide that the Debtor, as owner of the bentracimab program assets and sponsor of the clinical trials, owns all of the

- clinical trial, research, and study data, the main components of the Trial Data Package;
- o under Section 3.2.1.3 of the CDA, these clinical trial site agreements were required to be substantially in the form provided by the Debtor, and SFJ was fully aware of these agreements, which specified that the Debtor, and not SFJ, is the owner of the clinical trial, research, and study data; and
- o under virtually all circumstances under the CDA, ownership of the Trial Data Package reverts to the Debtor following regulatory approval of bentracimab or any prior termination of the CDA.
- 72. Accordingly, the Debtor, not SFJ, is the actual owner of the Trial Data Package, and the Trial Data Package is property of the Debtor's estate under 11 U.S.C. § 541.
- 73. The Debtor is entitled to a declaratory judgment that the Trial Data Package is property of the Debtor's estate and that SFJ is not the owner of the Trial Data Package.
- 74. Wherefore, the Debtor respectfully requests that the Court enter a declaratory judgment that the Trial Data Package is property of the Debtor's estate and that SFJ is not the owner of the Trial Data Package.

Fourth Claim for Relief

In the Alternative, Declaratory Relief Pursuant to 28 U.S.C. § 2201 to Determine Validity, Priority and Extent of Asserted Interest in Property

- 75. Plaintiff repeats and realleges each and every allegation in paragraphs 1 through 74 as if fully set forth herein.
- 76. Pursuant to 28 U.S.C. § 2201, "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

- 77. There is a real, substantial, and justiciable controversy regarding whether the Debtor or SFJ owns the Trial Data Package.
 - 78. SFJ asserts that it owns the Trial Data Package.
- 79. The Debtor, not SFJ, is the actual owner of the Trial Data Package. In the alternative, SFJ's purported ownership of the Trial Data Package is at most merely a disguised security interest (that should also be recharacterized and declared void for the reasons alleged in this Complaint) and not an actual ownership interest in the Trial Data Package, including, but not limited to, for the following reasons:
 - Section 1-201(35) of the Delaware Uniform Commercial Code defines a security interest as "an interest in personal property or fixtures which secures payment or performance of an obligation";
 - Section 9-109(a)(1) of the Delaware Uniform Commercial Code provides that the provisions of Article 9 apply to "a transaction, regardless of its form, that creates a security interest in personal property or fixtures by contract";
 - Under virtually all circumstances under the CDA, the Debtor is to own the Trial Data
 Package upon regulatory approval or other agreement termination, but in return for
 paying the Contingent Return-On-Investment Payments (if payable), plus an additional
 minimal token payment; and
 - SFJ's purported "ownership" of the Trial Data Package, which is an asserted interest in personal property, operates to secure the Debtor's payment of the Contingent Return-On-Investment Payments to SFJ because the Debtor needs the Trial Data Package but cannot obtain title to it unless the Debtor makes those Contingent Return-On-Investment Payments that become payable.

- 80. Accordingly, and in the alternative, SFJ's purported ownership of the Trial Data Package is instead at most a disguised security interest (that should also be recharacterized and declared void), with the Debtor, not SFJ, as the actual owner of the Trial Data Package. The Trial Data Package therefore is property of the Debtor's estate under 11 U.S.C. § 541.
- 81. The Debtor is entitled to a declaratory judgment that, in the alternative, SFJ's interest in the Trial Data Package, if any, is at most a disguised security interest (that should also be recharacterized and declared void) and not ownership, and that the Trial Data Package is instead property of the Debtor's estate.
- 82. Wherefore, the Debtor respectfully requests that the Court enter a declaratory judgment that, in the alternative, SFJ's interest in the Trial Data Package, if any, is at most a security interest (that should also be recharacterized and declared void) and not ownership, and that the Trial Data Package is instead property of the Debtor's estate.

PRAYER FOR RELIEF

83. Wherefore, the Debtor respectfully requests that the Court (a) enter a declaratory judgment in favor of the Debtor (i) recharacterizing the CDA as an equity investment, (ii) disallowing any secured, contingent or other claims of SFJ in their entirety, including without limitation any claim for the Contingent Return-On-Investment Payments and all other purported obligations of the Debtor under the CDA, (iii) pursuant to 11 U.S.C. §§ 506(d) and 551, setting aside as void the purported security interest and lien in favor of SFJ and preserving the security interest and lien for the benefit of the Debtor's estate, and (iv) holding that the Trial Data Package is property of the estate under 11 U.S.C. § 541 and not owned by SFJ, (b) in the alternative, enter a declaratory judgment in favor of the Debtor holding that SFJ's asserted ownership interest in the Trial Data Package is merely a disguised security interest (that should also be recharacterized and

declared void), and that the Trial Data Package is property of the estate under 11 U.S.C. § 541 and is not owned by SFJ, and (c) granting such other and further relief as the Court deems just and proper.

Dated: October 31, 2022

Wilmington, Delaware

Respectfully submitted,

/s/ Brendan J. Schlauch

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Proposed Counsel to the Plaintiff

EXHIBIT A

Exhibit 10.21

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 ("<u>Agreement</u>"), made effective as of January 9, 2020 (the "<u>Effective Date</u>"), 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 ("<u>PB</u>"), and SFJ Pharmaceuticals X, Ltd. ("<u>SFJ</u>"), 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 "<u>Party</u>" and collectively, the "<u>Parties</u>").

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 <u>Defined Terms</u>. 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 "<u>Account</u>" 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 "<u>Affiliate</u>" 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

case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 3 of 97 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 "<u>Anti-Corruption Laws</u>" 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 FFDCA, 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.

- Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 4 of 97 1.1.15 "AstraZeneca Product References" has the meaning ascribed to such term in the AZ License.
- 1.1.16 "<u>AZ License</u>" means the License Agreement between MedImmune and PB dated November 21, 2017, a copy of which is attached hereto as <u>Exhibit L</u>, as amended by that certain First Amendment to License Agreement dated January 9, 2020, a copy of which is attached hereto as <u>Exhibit M</u>.
- 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, the (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 "<u>Calendar Year</u>" 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 "<u>Case Report Form</u>" or "<u>CRF</u>" 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 "<u>Change of Control</u>" 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 "<u>Clinical Trials</u>" 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.

- Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 6 of 97 means chemistry, manufacturing and controls.
- 1.1.38 "<u>CMC Information</u>" means the CMC information intended or required for the submission of an IND or BLA.
- 1.1.39 "<u>CMO</u>" means contract manufacturing organization or contract development and manufacturing organization.
- 1.1.40 "<u>Commercial Launch</u>" 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 "<u>Commercialization</u>" or "<u>Commercialize</u>" 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 "<u>Competing Product</u>" means any agent intended to neutralize, abrogate or reverse the antiplatelet activity of the Ticagrelor Compound.
- 1.1.44 "<u>Completion Date</u>" 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 "<u>Confidential Information</u>" of a Party means all information and materials provided and/or disclosed (including in written form, electronic form or otherwise) by,

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 7 of 97 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 "<u>Copyrights</u>" 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.

- Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 8 of 97 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 "<u>Data Room</u>" 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 "<u>Development Costs</u>" 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 "<u>Development Plan</u>" means a written plan for the Development Program, the initial version of which is attached hereto as <u>Exhibit D</u>, and which will be subject to amendment by the JDC from time to time during the Development Term.
- 1.1.59 "<u>Development Program</u>" 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 "<u>Development Term</u>" 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.

- Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 9 of 97 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 "<u>EMA</u>" means the European Medicines Agency and any successor agency thereto in the EU having substantially the same function.
- 1.1.65 "<u>EU</u>" 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 "<u>Governmental Authority</u>" 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 "<u>IDMC</u>" 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.

- "Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 12 of 97 "Indemnifying Party" has the meaning ascribed to such term in Section 12.2.1.
- 1.1.94 "<u>Indication</u>" 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 "<u>Information</u>" 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 "<u>Investigator's Brochure</u>" 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

Case 22-10995-LSS. Doc 71-1 Filed 10/31/22 Page 13 of 97 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 "<u>Licensed Product</u>" has the meaning ascribed to such term in the AZ License.
- 1.1.117 "<u>Licensing Transaction</u>" 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.

Case 22-10995-LSS. Doc 71-1 Filed 10/31/22 Page 14 of 97 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 "<u>Licensing Transaction Agreement</u>" means a definitive agreement for a Licensing Transaction between PB and a Third Party.
- 1.1.119 "<u>Losses</u>" 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 "<u>Material Anti-Corruption Law Violation</u>" 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 "<u>MedImmune</u>" means MedImmune Limited, a limited liability company formed under the laws of the United Kingdom.
- 1.1.125 "<u>MedImmune Confidential Information</u>" means (a) the terms of the AZ License; and (b) any AstraZeneca Product Know-How and any AstraZeneca Product Improvement.
- 1.1.126 "<u>MedImmune Pharmacovigilance Agreement</u>" has the meaning ascribed to the term "Pharmacovigilance Agreement" in the AZ License.

- 1.1.127 Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 15 of 97 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 "<u>Patent</u>" 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 "<u>PB2452</u>" 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 "<u>PB Confidential Information</u>" 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 "<u>PB Intellectual Property</u>" 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 "<u>PB Services</u>" 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.

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 16 of 97 1.1.140 "PB Territory" means the US and the European Clinical Trial Countries.

- 1.1.141 "<u>Permitted Third Party</u>" 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 "<u>Person</u>" 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 "<u>Personally Identifiable Information</u>" 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 "<u>Phase 3 Interim Data</u>" 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 "<u>Phase 3 Success Criteria</u>" 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 "<u>PHSA</u>" 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 "<u>PK Studies</u>" 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 "<u>Program Transfer</u>" has the meaning ascribed to such term in the form of Program Transfer Agreement attached hereto as <u>Exhibit O</u>.
 - 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 "<u>Regulatory Authority</u>" 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.

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 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 "<u>SFJ Confidential Information</u>" 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 "<u>SFJ Services</u>" 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.

- Case 22-10995-LSS, Doc 71-1. Filed 10/31/22 Page 19 of 97 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 "<u>Successful Phase 3 Interim Analysis</u>" 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 "<u>SVB Loan</u>" means, subject to Section 7.4, the \$15,000,000 term loan evidenced by the SVB Loan Agreement.
- 1.1.184 "<u>SVB Loan Agreement</u>" 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 "<u>Territory</u>" 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 "<u>Third Party Infringement</u>" 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.

2-10995-LSS Doc 71-1 for Compound means (15,25,3R,5S)-3-[7-{||TR,2S|-2-(3:4 $difluor ophenyl) cyclopropyl] amino \} -5 - (propylthio) -3H - [1,2,3] - triazolo [4,5-d] pyrimidin -3 - yl] -5 - (2-hydroxyethoxy) cyclopentane -4 - (2-hydroxyethoxyethoxy) cyclopentane -4 - (2-hydroxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxyethoxye$

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- 1.1.190 "Timeline" has the meaning ascribed to such term in Section 2.3.1.
- "Timeline Remediation Plan" has the meaning ascribed to such term in Section 2.3.2. 1.1.191
- 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 "<u>US</u>", "<u>U.S.</u>" or "<u>USA</u>" means the United States of America, its territories and possessions, including Puerto Rico.

Case 22-10995-LSS. Doc 71-1. Filed 10/31/22. Page 21 of 97 1.1.197. "US Approval Payments" has the meaning ascribed to such term in Section 6.1.

- 1.1.198 "<u>US Commercialization Rights</u>" 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 "<u>Vendor Agreement</u>" has the meaning ascribed to such term in Section 2.4.2.
- 1.2 <u>Construction</u>. 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 <u>Conflicts</u>. 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 <u>The Protocols</u>. The protocol for the Phase 3 Trial (the "<u>Phase 3 Trial Protocol</u>") 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 "<u>SFJ Territory Clinical Trial Protocol</u>") will be prepared by SFJ in consultation with PhaseBio and approved by the JDC within [***].

2.1.2 <u>Changes to the Protocols</u>.

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 <u>Protocol Approval</u>. 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 <u>Sponsorship and Responsibilities</u>. 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 <u>Exhibit G.</u>
- 2.2.2 <u>Compliance with the Protocol and Applicable Laws</u>. 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 <u>Diligence</u>. 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. Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 23 of 97

- 2.3.1 <u>The Timeline</u>. The timeline for conducting the Clinical Trials is attached as <u>Exhibit I</u> hereto (the "<u>Timeline</u>"). In conducting the Clinical Trials, the Parties will use Commercially Reasonable Efforts to complete each activity specified on the Timeline (each, a "<u>Clinical Trial Activity</u>") 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 <u>Failure to Complete a Timeline Remediation Plan</u>. 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 <u>Approved CROs and Approved Vendors</u>.

- 2.4.1 <u>Approved CROs.</u> 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 <u>Exhibit B</u> or is approved in advance by the JDC (in either case, an "<u>Approved CRO</u>"). Each Party will be required to enter into a written agreement with each Approved CRO utilized by such Party (each, a "<u>CRO Agreement</u>") 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 <u>Approved Vendors</u>. 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 <u>Exhibit C</u> or is approved in advance by the JDC (each, an "<u>Approved Vendor</u>"). Such Party will be required to enter into a written agreement with each such Person (each, a "<u>Vendor Agreement</u>") 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 <u>Responsibility</u>. 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.

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 25 of 97 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 <u>Questions Pertaining to the Phase 3 Trial Protocol</u>. 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.

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 26 of 97 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 <u>Regulatory Interactions</u>. 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 27 of 97 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 <u>Compliance</u>. 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 <u>SFJ SOPs</u>. 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 "<u>SFJ SOPs</u>") 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; <u>provided that</u> 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 <u>PB SOPs</u>. 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 "<u>PS SOPs</u>") 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. Doc 71-1 Filed 10/31/22 Page 28 of 97

3.2.1 <u>Selection of Sites and Investigators</u>.

- 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 <u>Obligations During the Clinical Trials Conduct</u>.

- 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 "<u>Clinical Investigator Meeting</u>"), 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 29 of 97 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 <u>Subject Recruitment Plan</u>. 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 "<u>Subject Recruitment Plan</u>") 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 <u>Informed Consent</u>.

- 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.

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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 <u>Investigator's Brochure</u>.

- 3.4.1 <u>Investigator's Brochure</u>. 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 <u>Parties' Responsibilities</u>. 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 <u>Data Collection and Data Management</u>.

3.5.1 <u>CRF</u>. 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 "<u>Data Management Plan</u>"). 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.

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 31 of 97 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, www.clinicalstudyresults.org, and the PHRMA Website Synopsis.
- 3.5.4 <u>Clinical Trials Master File</u>. 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 "<u>Clinical Trials Master File</u>"). 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 <u>Source Data Verification</u>. 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 <u>Statistical Analysis</u>. 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 "<u>Statistical Analysis Plan</u>").

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.

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 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 <u>Monitoring</u>. 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; <u>provided</u> 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 Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 33 of 97 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. Doc 71-1 Filed 10/31/22 Page 34 of 97

- 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 <u>Regulatory Approvals</u>. 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

Case 22-10995-LSS. Doc 71-1 Filed 10/31/22 Page 36 of 97 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 37 of 97 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 <u>Complaints Related to the Product</u>. 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.

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 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 <u>Program Transfer</u>. 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 "<u>Program Transfer Notice</u>"), 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 <u>Exhibit O</u> (the "<u>Program Transfer Agreement</u>") 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 <u>Development Costs</u>. SFJ will be obligated to pay or incur up to One Hundred Twenty Million U.S. Dollars (\$120,000,000.00) of Development Costs ("<u>Maximum Development Costs</u>") in accordance with the funding schedule set forth in Section 4.2. Any

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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 "<u>Initial Development Cost Payment</u>"), shall be payable on the date ("<u>Initial Funding Date</u>") 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").

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 41 of 97 (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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 42 of 97 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 <u>Pre-Commercialization Costs</u>. 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 "<u>Pre-Approval Commercialization Activities</u>"). 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 <u>Representatives</u>. Within [***] after the Effective Date, the Parties will establish a joint steering committee to oversee and manage the collaboration (the "<u>JSC</u>"). Each Party initially will appoint [***] to serve as representatives to the JSC (the "<u>JSC Representatives</u>"), 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 <u>Chairperson</u>. The JSC chairperson ("<u>JSC Chairperson</u>") 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 <u>Participants</u>. The JSC may invite individuals who are not JSC Representatives to participate in JSC meetings; <u>provided</u> 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 <u>Alliance Managers</u>. Each Party shall appoint an individual to act as an alliance manager for such Party (each, an "<u>Alliance Manager</u>") 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 <u>Costs</u>. 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 <u>Responsibilities (Review and Discuss)</u>. The JSC's responsibilities will include reviewing and discussing (but not approving) the following:

- Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 44 of 97 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 <u>Responsibilities (Review and Approve)</u>. 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 "<u>Approved Third Party Vendor Costs</u>") 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 <u>Limitation on Authority</u>. 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 <u>Decision-Making</u>. 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 <u>Representatives</u>. Within [***] of the Effective Date, the Parties will establish a joint development committee to oversee the conduct of the Clinical Trials (the "<u>JDC</u>"). Each Party initially will appoint [***] to serve as representatives to the JDC (the "<u>JDC Representatives</u>"), 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 <u>Chairperson</u>. The JDC chairperson ("<u>JDC Chairperson</u>") 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 <u>Timing</u>.

- (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 <u>Participants.</u> 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 <u>Costs</u>. 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 <u>Unusual or Unforeseen Events</u>. 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 <u>Urgent Safety Measures or Serious Breaches</u>. 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 <u>Regulatory Inspections</u>. 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 <u>Government Investigations</u>. 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 <u>Compliance with Laws</u>. 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 <u>Progress Reports</u>. 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 <u>Post-Development Term Notices</u>. 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 <u>Decision-Making</u>. 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 <u>Information</u>. 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 <u>Chairperson</u>. PB shall designate the JCC chairperson ("<u>JCC Chairperson</u>") 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 <u>Participants</u>. The JCC may invite individuals who are not JCC Representatives to participate in JCC meetings; <u>provided</u> 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).

- Case 22-10995-LSS. Doc 71-1 Filed 10/31/22 Page 49 of 97 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 <u>Responsibilities</u>. The JCC's responsibilities will include the following:

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5.6.1.1 [***].
5.6.1.2 [***];
5.6.1.3 [***];
5.6.1.4 [***];
5.6.1.5 [***]; and
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- 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 <u>Decision Making</u>. 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 SEJ

- 6.1 <u>Regulatory Approval</u>. 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 "<u>Initial US Payment</u>") 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 "<u>US Approval Payments</u>");
- 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 "<u>Initial EU Payment</u>") and annual payments in the amounts set forth below on or before each applicable anniversary of the date of the such

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 50 of 97 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 "<u>Initial Japan/China Payment</u>") 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 "<u>Approval Payments</u>", 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
Total	11,000,000	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	600,000,000

6.2 <u>Payment Adjustments</u>. 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 <u>Late Payments</u>. 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 <u>Taxes</u>. 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 <u>Approval Buy-Out Option</u>. 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 "<u>Approval Buy-Out Payment</u>") 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 <u>Change of Control Buy-Out Option</u>. 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 "<u>Change of Control Buy-Out Payment</u>") 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 "<u>Change of Control Buy-Out Notice</u>") 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 53 of 97 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

case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 54 of 97 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 <u>Priority of Security Interest</u>. 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 <u>ARTICLE 7</u> (the "<u>SFJ Security Interest</u>") 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 <u>Incurrence of Certain Indebtedness</u>. 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 <u>Subordinated Debt</u>. 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 <u>Distributions; Investments</u>. 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, <u>provided</u> 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 56 of 97 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 <u>Further Negative Pledges</u>. 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 57 of 97 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 constituing 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 <u>Government Compliance</u>.

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 Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 59 of 97 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 <u>ARTICLE</u> 6, all remaining unpaid Approval Payments that are based on such Regulatory Approval shall become immediately due and payable; <u>provided that</u>, 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 <u>Certain Defined Terms</u>. 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 "<u>Indebtedness</u>" 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 60 of 97 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 "<u>Investment</u>" 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 "<u>Lien</u>" 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, <u>provided</u> that no notice of any such Lien has been filed or recorded under the IRC;

- Case 22-10995-LSS. Doc 71-1 Filed 10/31/22 Page 61 of 97 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, <u>provided</u> 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;

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 62 of 97 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 "<u>Subordinated Debt</u>" 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 <u>Warrant Issuance</u>. PB shall issue to SFJ on the Effective Date a warrant ("<u>Warrant</u>") exercisable for two million two hundred thousand (2,200,000) shares of PB common stock ("<u>Stock</u>") at an exercise price per share ("<u>Exercise Price</u>") 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)

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 63 of 97 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 <u>Form of Warrant</u>. The Warrant shall in the form attached hereto as <u>Exhibit H</u>, shall have a term of ten (10) years, and shall contain "net-exercise" issuance provisions.

ARTICLE 9

RECORDS

- 9.1 <u>Accounting</u>. 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 <u>Clinical Trials-Related Records</u>. 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 <u>Confidentiality.</u> 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 "<u>Receiving Party.</u>") 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 <u>ARTICLE 9</u>, 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 "<u>Disclosing Party</u>") 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;

- Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 64 of 97 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 65 of 97 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 <u>MedImmune Confidential Information</u>. 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 66 of 97 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 <u>Use of Name</u>. 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 <u>Existing Intellectual Property</u>. 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.

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- (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 <u>Trial Data Package</u>. 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 <u>Exhibit K</u>, 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 <u>Inventorship; Further Assurances.</u> 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 <u>No Other Rights</u>. 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 70 of 97 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 <u>Patent Prosecution</u>. 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 <u>Intellectual Property Enforcement</u>.

- 11.3.1 <u>PB Intellectual Property</u>. 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 <u>Infringement of Third Party Rights</u>. 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,

Case 22-10995-LSS. Doc 71-1 Filed 10/31/22 Page 71 of 97 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.

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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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 73 of 97 SFJ Indemnified Party, or (ii) material breach of this Agreement, or, if applicable, the Program Transfer Agreement by, SFJ.

12.2 <u>Indemnification Procedure</u>.

- 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 <u>Right to Participate in Defense</u>. 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 <u>Settlement</u>. 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 Hability, Secoming 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 <u>Cooperation</u>. 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 <u>Generally.</u> 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 <u>Minimum Requirements</u>. 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 <u>Commercial General Liability</u>: [***] 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 <u>Umbrella Excess Liability</u>: [***] dollars (\$[***]) per occurrence.
- 12.3.2.3 <u>Clinical Trials Liability</u>: [***] 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 <u>Professional Liability</u>: 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 <u>Additional Insured</u>. 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 <u>Product Liability Insurance</u>. Prior to a Program Transfer, PB will be responsible for maintaining product liability insurance related to the Development and

Case 22-10995-LSS. Doc 71-1 Filed 10/31/22 Page 76 of 97 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.

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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 <u>Disclosure of Regulatory Notices and Communications</u>. 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 <u>CRO Inquiry</u>. 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 <u>Compliance</u>. 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 78 of 97 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 <u>Intellectual Property</u>. 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 <u>Outstanding Indebtedness</u>. 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 <u>Contingent Liabilities</u>. PB hereby represents and warrants that, except as reflected in PB's consolidated balance sheet for the quarter ended September 30, 2019 included 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 <u>SFJ Representation, Warranty and Covenant</u>. 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

Case 22-10995-LSS Doc 71-1. Filed 10/31/22 Page 79 of 97 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 <u>Term</u>. The term of this Agreement (the "<u>Term</u>") 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 80 of 97 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 <u>Termination by SFJ for Material Adverse Event</u>. 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), <u>provided that</u> such Approval Payments (or Buy-Out Payment, as applicable) shall also be adjusted as set forth in Section 6.2.

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 81 of 97 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 <u>Termination for Bankruptcy</u>. 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 82 of 97 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.

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 84 of 97 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 <u>Termination for JSC Decision</u>. 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 (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 <u>Certain Additional Consequences of Termination</u>. 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 <u>Accrued Rights and Obligations</u>. 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 <u>Exclusive Remedy</u>. 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 <u>Surviving Obligations</u>. 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

Case 22-10995-LSS Doc. 71-1 Filed 10/31/22 Page 87 of 97 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 <u>Relationship with Affiliates</u>. 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 <u>Prior Agreements</u>. The Parties agree on behalf of themselves and their respective Affiliates that any prior Confidentiality Agreement, by and between PB and SFJ (the "<u>Prior CDA</u>") 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 <u>ARTICLE 10</u>, with the confidentiality and non-use provisions of <u>ARTICLE 10</u> applying retroactively to such Confidential Information from the date of disclosure.
- 15.3 <u>Notices</u>. 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)

Cooley LLP 11951 Freedom Drive Reston, VA 20190 USA Attn: Christian E. Plaza

15.3.2 If to SFJ:

SFJ Pharmaceuticals X, Ltd SIX, 2nd 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 <u>Force Majeure</u>. 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 <u>Use of Names</u>. 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 <u>Assignment</u>. 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 <u>Further Assurances</u>. 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 <u>Fees and Expenses</u>. 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 <u>Governing Law.</u> 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 <u>Dispute Resolution</u>. 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 "<u>Dispute</u>") 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

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 91 of 97 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.

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 92 of 97 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 <u>Cumulative Remedies</u>. 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 <u>Independent Contractors</u>. 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,

Case 22-10995-LSS Doc 71-1 Filed 10/31/22 Page 93 of 97 representatives, or franchisees of the other Party or enter into any agreements on such Party's behalf.

- 15.13.2 <u>Direction</u>. Neither Party will be subject to the supervisory direction of the other Party in regard to the conduct of the Clinical Trials.
- 15.14 <u>No Third Party Beneficiaries</u>. 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 <u>Rights Reserved</u>. 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 <u>Nonsolicitation</u>. 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.
- 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 <u>Severability</u>. 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 <u>Entire Agreement</u>. 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 <u>Counterparts</u>. 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 <u>Construction</u>. 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]

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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: <u>/s/ Jonathan Mow</u>
Name: Jonathan Mow

Title: CEO

Date: January 9, 2020

SIGNATURE PAGE TO THE CO-DEVELOPMENT AGREEMENT

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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: <u>/s/ Robert DeBenedetto</u>
Name: Robert DeBenedetto

Title: Director

Date: <u>January 9, 2020</u>

SIGNATURE PAGE TO THE CO-DEVELOPMENT AGREEMENT

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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