# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

**FORM 10-Q/A** 

(Amendment No. 1)

(Mark C	one)					
X	QUARTERLY REPORT PUI	RSUANT TO SECTION 13 OR	15(d) OF THE SECURITIES EXCHA	NGE ACT OF 1934		
		FOR THE QUARTERLY I	PERIOD ENDED SEPTEMBER 30, 20	16		
			or			
	TRANSITION REPORT PUR	RSUANT TO SECTION 13 OR	15(d) OF THE SECURITIES EXCHA	NGE ACT OF 1934		
		FOR THE TRANSITION P	ERIOD FROM TO			
		Commission	n File Number: 001-36818			
			TRACON Pharmaceuticals, Inc. (Exact name of registrant as specified in its charter)		_	
	Delaware			34-2037594		
	(State or other jurisd	liction of		(I.R.S. Employer		
	incorporation or orga			Identification No.)		
	8910 University Center L					
	San Diego C			92122		
	(Address of principal exec	cutive offices)		(Zip Code)		
			858-550-0780 hone number, including area code)			
			e filed by Section 13 or 15(d) of the Securities (ts), and (2) has been subject to such filing requ			
pursuant t			ed on its corporate Web site, if any, every Integrating 12 months (or for such shorter period the			
		is a large accelerated filer, an accelera aller reporting company" in Rule 12b-	ated filer, a non-accelerated filer, or a smaller r-2 of the Exchange Act.	reporting company. See the defin	nitions of "large	
Large acco	elerated filer		Acceler	rated filer		
Non-accel	erated filer	heck if a smaller reporting company)	Smaller	r reporting company	X	
Indicate b	y check mark whether the registrant	is a shell company (as defined in Rule	e 12b-2 of the Exchange Act). Yes □ No	X		
The numb	er of outstanding shares of the regis	strant's common stock as of Novembe	er 4, 2016 was 13,065,971.			
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#### EXPLANATORY NOTE

TRACON Pharmaceuticals, Inc. filed its Quarterly Report on Form 10-Q for the period ended September 30, 2016, on November 9, 2016 (the "Original Filing"). TRACON is filing this Amendment No. 1 on Form 10-Q/A to refile Exhibit 10.1 thereto. This Amendment No. 1 on Form 10-Q/A does not reflect subsequent events occurring after the filing date of the Original Filing or modify or update any disclosures made in the Original Filing, except as described above.

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

#### TRACON Pharmaceuticals, Inc.

Date: February 15, 2017 By: /s/ Charles P. Theuer, M.D., Ph.D.

Charles P. Theuer, M.D., Ph.D.

President and Chief Executive Officer

(principal executive officer)

Date: February 15, 2017 By: /s/ Patricia L. Bitar, C.P.A.

Patricia L. Bitar, C.P.A.

Chief Financial Officer

(principal financial and accounting officer)

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#### INDEX TO EXHIBITS TO FORM 10-Q/A

Exhibit Number	Description of Document
10.1*	License and Option Agreement By and Between Janssen Pharmaceutica N.V. and TRACON Pharmaceuticals, Inc., dated September 27, 2016.
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
*	Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

# BY AND BETWEEN JANSSEN PHARMACEUTICA N.V. AND TRACON PHARMACEUTICALS, INC.

#### LICENSE AND OPTION AGREEMENT

This LICENSE AND OPTION AGREEMENT (this "Agreement") is made and effective as of September 27, 2016 (the "Effective Date"), by and between Janssen Pharmaceutica N.V. ("Janssen") and TRACON Pharmaceuticals, Inc., a Delaware corporation ("Licensee"). Each of Janssen and Licensee is sometimes referred to herein individually as a "Party" and collectively as the "Parties."

#### **RECITALS**

WHEREAS, Janssen has developed certain technology and owns certain intellectual property rights relating to certain preclinical development Programs (as defined below) conducted by Janssen and its Affiliates prior to the Effective Date;

WHEREAS, Licensee desires to obtain, and Janssen desires to grant to Licensee, an exclusive, worldwide license under such Janssen technology and intellectual property rights to develop, manufacture and commercialize Licensed Compounds (as defined below) and Licensed Products (as defined below) with respect to each Program;

WHEREAS, the license granted to Licensee with respect to the AR Mutant Program (as defined below) shall be subject to Janssen's exclusive option to obtain a reversion of the rights granted by Janssen to Licensee with respect to the AR Mutant Program and an exclusive license under any technology and intellectual property rights developed by Licensee in the course of conducting the AR Mutant Program, on the terms and conditions set forth in this Agreement; and

WHEREAS, the license granted to Licensee with respect to the NIK Program (as defined below) shall be subject to Janssen's right to negotiate with Licensee to obtain a reversion of the rights granted by Janssen to Licensee with respect to the NIK Program and an exclusive license under any technology and intellectual property rights developed by Licensee in the course of conducting the NIK Program, on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the various promises and covenants set forth herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

## Article 1 DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, will have the meaning set forth below or, if not listed below, the meaning designated where first used in this Agreement.

- 1.1. "Acquirer" means any Third Party that is a party to any Change of Control transaction and any of such Third Party's Affiliates.
- 1.2. "Affiliate" means, with respect to any Party, any corporation or other business entity that directly or indirectly controls, is controlled by, or is under common control with such Party at the

time at which the determination of affiliation is being made. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to any Party, means the possession of at least 50% of the voting stock or other ownership interest of the other corporation or entity, or the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint at least 50% of the members of the governing body of the corporation or other entity through the ownership of the outstanding voting securities or by contract or otherwise.

- 1.3. "Antitrust Laws" means any federal, state or foreign law, regulation or decree, including the HSR Act, designed to prohibit, restrict or regulate actions for the purpose or effect of monopolization or restraint of trade.
- 1.4. "Applicable Law" means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any governmental authority, including the FFDCA, Prescription Drug Marketing Act of 1987 (21 U.S.C. §§331, 333, 353, 381), the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335(a) et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal False Claims Act (31 U.S.C. §3729 et seq.), and the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder.
- 1.5. "AR Competing Product" means a therapeutic product, an active pharmaceutical ingredient of which [...\*\*\*...].
- 1.6. "AR Mutant Compound" means any compound that is (a) (i) described as a composition-of-matter as of the Effective Date in a claim of a Patent Right in the United States or the EPO or treaty country thereof (including such a claim of a Patent Cooperation Treaty application designating the United States or EPO) set forth on Schedule AR Mutant Program Patents of the Schedule Letter or (ii) described after the Effective Date in a claim of such a Patent Right filed within [...\*\*\*...], or (b) described in a claim of a Patent Right in the United States or the EPO or treaty country thereof (including such a claim of a Patent Cooperation Treaty application designating the United States or EPO) Controlled by a Party which also describes as a composition-of-matter a compound described in (a) above as of the [...\*\*\*...]. AR Mutant Compound includes the compound specifically set forth on Schedule AR Mutant Compound of the Schedule Letter.
- 1.7. "AR Mutant Data Package" means: (a) the AR Mutant POC Trial Data; (b) the full tables, figures and listings from any other Clinical Trial of any AR Mutant Product conducted by or on behalf of Licensee; (c) the data and results of all other Development activities conducted by or on behalf of Licensee with respect to any AR Mutant Compound or AR Mutant Product; and (d) an IP Disclosure Document for the AR Mutant Program.

1.8.

\*\*\*Confidential Treatment Requested

"AR Mutant License Agreement" means the license agreement that would become effective upon Janssen's exercise of the Option in accordance with Section 3.3.1, which is attached hereto as <u>Exhibit A</u>.

- 1.9. "AR Mutant Pre-Phase III Activities" means the activities with respect to the AR Mutant Program described on Schedule AR Mutant Pre-Phase III Activities of the Schedule Letter.
- 1.10. "AR Mutant POC Trial" means the first Clinical Trial of the AR Mutant Product containing the AR Mutant Compound set forth on Schedule AR Mutant Compound of the Schedule Letter as the only active ingredient that satisfies the following criteria: (a) such Clinical Trial has [...\*\*\*...]; and (b) such Clinical Trial has [...\*\*\*...]. For purposes of this definition, [...\*\*\*...] means that [...\*\*\*...].
- 1.11. "AR Mutant POC Trial Data" means full tables, figures and listings from the AR Mutant POC Trial.
- 1.12. "AR Mutant Product" means any pharmaceutical product in any dosage form containing an AR Mutant Compound.
- 1.13. "AR Mutant Program" means the conduct of Development, Manufacturing and Commercialization activities with respect to AR Mutant Compounds and AR Mutant Products.
- 1.14. "AR Mutant Program Know-How" means any Know-How Controlled by Janssen or any of its Affiliates on the Effective Date or during the Term (other than Janssen-Owned Development Program Know-How) that is necessary to make, have made, use, have used, import, have imported, sell, have sold, offer for sale or have offered for sale any AR Mutant Compound or AR Mutant Product, including the Know-How contained in or embodied by the items described on Schedule AR Mutant Program Know-How of the Schedule Letter; provided, however, that with regard to Know-How regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Know-How that is applied to or used to make any AR Mutant Product as such AR Mutant Product exists as of the Effective Date is included, and any other formulation or Manufacturing method Know-How is excluded. For clarification, AR Mutant Program Know-How does not include any Know-How with respect to any active ingredient(s) in any Combination Product other than an AR Mutant Compound.

1.15.

\*\*\*Confidential Treatment Requested

"AR Mutant Program Patents" means any Patent Rights Controlled by Janssen or any of its Affiliates on the Effective Date or during the Term (other than Development Program Patents) that Cover any AR Mutant Compound or AR Mutant Product, including the Patent Rights set forth on <a href="Schedule AR Mutant Program Patents">Schedule AR Mutant Program Patents</a> of the Schedule Letter and all Patent Rights arising therefrom; <a href="provided">provided</a>, <a href="however">however</a>, that with regard to Patent Rights regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Patent Rights that are applied to or used to make any AR Mutant Product as such AR Mutant Product exists as of the Effective Date is included, and any other formulation or Manufacturing method Patent Rights are excluded. AR Mutant Program Patents does not include any Patent Rights with respect to any active ingredient(s) in any Combination Product other than an AR Mutant Compound or the Patent Rights set forth on <a href="Schedule AR Mutant Diagnostic Patent">Schedule Letter</a>.

<a href="Mutant Diagnostic Patent">Mutant Diagnostic Patent</a> of the Schedule Letter.

- 1.16. "Calendar Quarter" means each of the successive three (3) month periods beginning on January 1, April 1, July 1 and October 1 of a given Calendar Year; *provided*, *however*, that the first Calendar Quarter and the last Calendar Quarter of the applicable period (such as the Royalty Term) may be partial quarters as applicable under the relevant Calendar Year.
- 1.17. "Calendar Year" means the twelve (12) month period beginning on January 1 and ending on December 31; *provided*, *however*, that the first Calendar Year and the last Calendar Year of the applicable period (such as the Royalty Term) may be partial years as the case may be.
- "Change of Control" means, with respect to a Party: (a) that any Third Party acquires directly or indirectly the beneficial 1.18. ownership of any voting securities of such Party, or if the percentage ownership of such person or entity in the voting securities of such Party is increased through stock redemption, cancellation or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of outstanding voting securities representing more than fifty percent (50%) of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization or reorganization of such Party is consummated, other than any such transaction in which stockholders or equity holders of such Party immediately prior to such transaction beneficially own, directly or indirectly, at least fifty percent (50%) of the voting securities of the surviving entity (or its parent entity) immediately following such transaction; (c) that the stockholders or equity holders of such Party approve a plan of complete liquidation of such Party; (d) that individuals who, as of the Effective Date, constitute the Board of Directors of such Party (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board of Directors of such Party (provided, however, that any individual becoming a director subsequent to the date hereof whose election, or nomination for election by such Party's stockholders, was recommended or approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of any person other than the Board of Directors of such Party); or (e) the sale or disposition to a Third Party of all or substantially all of such Party's assets taken as a whole.
- 1.19. "Clinical Trial" means any Phase I Clinical Trial, Phase II Clinical Trial, Phase II/III Clinical Trial or Phase III Clinical Trial.
- 1.20. "Combination Product" means: (a) any Licensed Product that contains a Licensed Compound and one or more other active pharmaceutical ingredient(s), where such Licensed Compound and other active pharmaceutical ingredient(s) are co-formulated into a single product; or (b) any combination, package or bundle of a Licensed Product with one or more other pharmaceutical products that are not Licensed Products sold together for a single invoiced price.
- 1.21. "Commercialization" means any activities directed to marketing, promoting, educating, informing, distributing, importing, offering to sell and/or selling a pharmaceutical product. When used as a verb, "Commercialize" means to engage in Commercialization activities.

- 1.22. "Commercially Reasonable Efforts" means: (a) with respect to Licensee's performance of Development activities with respect to a Program during the Development Term, the carrying out of such activities using reasonable, good faith efforts and resources (including, at a minimum, allocating time, effort, equipment and skilled personnel to perform the activities set forth in the Development Plans on a timely basis); (b) with respect to the Development, seeking and obtaining Marketing Approval, Manufacture or Commercialization of a Licensed Product in a country by or on behalf of Licensee during the License Term, those reasonable, good faith efforts normally used by biopharmaceutical companies of similar size and stage of development under similar circumstances for similar products or product candidates owned or controlled by such company, or to which such company has similar rights, which product or product candidate is of similar market potential in such country and is at a similar stage in its development or product life, taking into account (with respect to those efforts described in this clause (b) only) all Relevant Factors; or (c) with respect to the efforts to be expended by either Party with respect to any objective or activity other than those described in clause (a) or (b) of this Section 1.22, those reasonable, good faith efforts to accomplish such objective or perform such activity as such Party would normally use to accomplish a similar objective under similar circumstances.
- 1.23. "Competing Product" means (a) with respect to the AR Mutant Program, an AR Competing Product; and (b) with respect to the NIK Program, a NIK Competing Product.
- 1.24. "Confidential Information" means: (a) all non-public or proprietary information (including Know-How) that is disclosed by a Party (or any of its Affiliates) to the other Party (or any of its Affiliates) pursuant to or in connection with this Agreement; and (b) all other non-public or proprietary information (including Know-How) that is expressly deemed in this Agreement to be Confidential Information, whether or not disclosed by a Party (or any of its Affiliates) to the other Party (or any of its Affiliates), in each case ((a) or (b)), without regard as to whether any of the foregoing is marked "confidential" or "proprietary," or in oral, written, graphic or electronic form.
- 1.25. "Control" or "Controlled" means, with respect to any Know-How, Patent Right or other intellectual property right, possession by a Party (whether by ownership or license or otherwise, but without taking into account any rights granted pursuant to this Agreement), directly or through an Affiliate of such Party, of the ability to transfer, or grant a license or sublicense under, such right as provided for herein without violating the terms of any contract with any Third Party that exists on the Effective Date, or, subject to Section 2.5, any contract or other binding arrangement with any Third Party that exists after the Effective Date with regard to any Know-How, Patent Right or other intellectual property right licensed to or acquired by a Party from a Third Party after the Effective Date; provided, however, that any Know-How, Patent Right or other intellectual property right that is owned or licensed by an Acquirer of a Party or any Affiliate of such Acquirer (excluding any Affiliate that was an Affiliate of such Party prior to a Change of Control and became an Affiliate of such Acquirer as a result of such Change of Control) shall not be deemed to be Controlled by such Party for purposes of this Agreement, except to the extent, and only to the extent that, such Know-How, Patent Right or other intellectual property right is either (a) actually used by such Party, the Acquirer or any of their respective Affiliates in the performance of Development, Manufacturing or Commercialization activities with respect to any Licensed Compound or Licensed Product following the

consummation of the Change of Control of such Party, or (b) made, conceived or reduced to practice by the Acquirer or any such Affiliates through the use of any Licensed Technology, Development Program Know-How, Development Program Patents or Patent Rights set forth on Schedule AR Mutant Diagnostic Patent of the Schedule Letter following the consummation of the Change of Control of such Party.

- 1.26. "Cover", "Covering" and "Covered" means, with respect to a Patent Right and an invention, that, in the absence of ownership of or a license under such Patent Right, the practice of such invention (e.g., with respect to a Patent Right in the U.S., the manufacture, use, sale, offer for sale or importation of such invention) would infringe a Valid Claim of such Patent Right (in the case of a pending patent application, if the claims of such patent application as then existing were issued).
- 1.27. "**Data Package**" means: (a) with respect to the AR Mutant Program, an AR Mutant Data Package; and (b) with respect to the NIK Program, a NIK Data Package.
- 1.28. "**Development**" means all research and non-clinical and clinical drug development activities and processes, including toxicology, pharmacology, project management and other non-clinical efforts, formulation development, delivery system development, statistical analysis, manufacturing development, the performance of Clinical Trials (including the manufacturing of products for use in clinical trials), or other activities reasonably necessary in order to obtain and maintain, Marketing Approval of a pharmaceutical product. When used as a verb, "**Develop**" means to engage in Development activities.
- 1.29. "Development Program Know-How" means, with respect to a Program, any Know-How that is generated (or, in the case of an invention, reduced to practice) by a Party's, or its Affiliates' or Third Party Subcontractors', employees or agents in performing any Development activities with Licensed Compounds or Licensed Products with respect to such Program during the applicable Development Term, *provided* that Third Party Subcontractor Reserved Technology shall be excluded to the extent not assigned or licensed to a Party.
- 1.30. "**Development Program Invention**" means, with respect to a Program, any Development Program Know-How with respect to such Program that is an invention.
- 1.31. "**Development Term**" means: (a) with respect to the AR Mutant Program, the period beginning on the Effective Date and ending upon the expiration of the Option in accordance with Section 3.3.2, unless terminated earlier pursuant to Section 3.3.1, 11.2, 11.3 or 11.4; and (b) with respect to the NIK Program, the period beginning on the Effective Date and ending upon the expiration of the ROFN Period, unless terminated earlier pursuant to Section 3.4.1(d), 11.2, 11.3 or 11.4.
- 1.32. "**Drug Approval Application**" means: (a) a new drug application submitted to the FDA pursuant to Section 505(b) of the FFDCA, 21 U.S.C. § 355(b) (an "**NDA**"); or (b) an application for authorization to market and/or sell a drug product submitted to a Regulatory Authority in any country or jurisdiction other than the U.S., in each case ((a) and (b)), including all amendments and supplements thereto.

- 1.33. "EMA" means the European Medicines Agency or any successor agency for the EU with responsibilities comparable to those of the European Medicines Agency.
- 1.34. "**EPO**" means the European Patent Organization, or any successor entity with responsibilities comparable to those of the European Patent Organization.
- 1.35. "EU" means the countries of the European Economic Area, as it is constituted on the Effective Date and as it may be modified from time to time after the Effective Date.
- 1.36. "Executive Officers" means the Chief Executive Officer of Licensee and the Global Head, Oncology Therapeutic Area of Janssen Research & Development LLC, an Affiliate of Janssen.
- 1.37. "FDA" means the United States Food and Drug Administration or any successor agency in the United States with responsibilities comparable to those of the United States Food and Drug Administration.
- 1.38. "FFDCA" means the U.S. Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.), as amended from time to time.
- 1.39. "Field" means all uses.
- 1.40. "First Commercial Sale" means, with respect to a given Licensed Product and a given country, the first arm's-length commercial sale of such Licensed Product to a Third Party in the Field in such country after the receipt of Marketing Approval for such Licensed Product in such country. Sales for Clinical Trial purposes, early access or compassionate use programs, or similar uses, shall not constitute a First Commercial Sale. In addition, sales of a Licensed Product by and between Licensee and its Affiliates, distributors and (sub)licensees, or between the Parties (or their respective Affiliates, distributors or (sub)licensees), shall not constitute a First Commercial Sale.
- 1.41. "FTE" means the equivalent of work devoted to or in direct support of the AR Mutant Pre-Phase III Activities by qualified employees, contractors or consultants of Licensee or its Affiliates, as measured in accordance with Licensee's normal time allocation practices, *provided* that, such employees, contractors or consultants must be scientific or technical personnel with [...\*\*\*...], but shall not include personnel performing administrative and corporate functions (including human resources, finance, legal and investor relations).
- 1.42. "FTE Costs" means, with respect to any period, the FTE Rate multiplied by the FTE hours expended during such period.
- 1.43. "FTE Rate" means a rate of [...\*\*\*...] per FTE hour per Calendar Year (pro-rated for the period beginning on the Effective Date and ending on the last day of the first Calendar Year of the Term).

1.44.

\*\*\*Confidential Treatment Requested

"Governmental Authority" means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other instrumentality of (a) any

government of any country or territory, (b) any nation, state, province, county, city or other political subdivision thereof or (c) any supranational body.

- 1.45. "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.
- 1.46. "IND" means (a) an Investigational New Drug application as defined in the FFDCA and applicable regulations promulgated thereunder by the FDA; (b) a clinical trial authorization application for a product filed with a Regulatory Authority in any other regulatory jurisdiction outside the U.S., the filing of which (in the case of (a) or (b)) is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction; or (c) documentation issued by a Regulatory Authority that permits the conduct of clinical testing of a product in humans in such jurisdiction.
- 1.47. "Indication" means a discrete clinically recognized form of a disease. For purposes of this Agreement, treatment of different subpopulations within a population of patients having a disease shall not be treated as separate Indications (e.g., front-line treatment, second-line or relapsed refractory treatment and maintenance treatment of prostate cancer shall not be treated as separate Indications; provided, however, that front-line treatment, second-line or relapsed refractory treatment and maintenance treatment of prostate cancer shall be treated as separate Indications with respect to the AR Mutant Program only.
- 1.48. "Internal Research" means research that is controlled by Janssen, whether conducted internally by Janssen or any of its Affiliates or by Third Party contractors on behalf of Janssen or any of its Affiliates, where Janssen or its Affiliate owns the data or intellectual property generated in such research, including research employing standards (i) to initially identify active compounds against a target or (ii) to validate activity of test compounds in animal models. For the avoidance of doubt, and notwithstanding the foregoing, Internal Research specifically excludes any GLP-compliant or other IND-enabling preclinical study and clinical trials and any research conducted by academic collaborators.
- 1.49. "IP Disclosure Document" means (a) with respect to the AR Mutant Program, a document in the form attached to the AR Mutant License Agreement describing the Licensee Program Know-How, Licensee Program Patents, Licensee-Owned Development Program Know-How, Licensee-Owned Development Program Patents and Joint Development Program Patents applicable to the AR Mutant Program as of such date; and (b) with respect to the NIK Program, a document substantially similar to the document described in clause (a) describing the Licensee Program Know-How, Licensee Program Patents, Licensee-Owned Development Program Know-How, Licensee-Owned Development Program Patents and Joint Development Program Patents applicable to the NIK Program as of such date.
- 1.50. "Janssen AR Mutant Activities" means the activities with respect to the AR Mutant Program described on Schedule Janssen AR Mutant Activities of the Schedule Letter.
- 1.51. "Janssen License Agreements" means the agreements set forth on <u>Schedule Janssen License Agreements</u> of the Schedule Letter.

- 1.52. "**Janssen Program Know-How**" means: (a) with respect to the AR Mutant Program, the AR Mutant Program Know-How; and (b) with respect to the NIK Program, the NIK Program Know-How.
- 1.53. "Janssen Program Patents" means: (a) with respect to the AR Mutant Program, the AR Mutant Program Patents; and (b) with respect to the NIK Program, the NIK Program Patents.
- 1.54. "Know-How" means any non-public or proprietary information, inventions, discoveries, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, trade secrets, technology, techniques, designs, drawings, correspondence, computer programs, documents, apparatus, results, strategies, Regulatory Documentation, information and submissions pertaining to, or made in association with, filings with any Regulatory Authority or patent office, data (including pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions), devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable.
- 1.55. "Licensed Compound" means any AR Mutant Compound or NIK Compound.
- 1.56. "Licensed Product" means any AR Mutant Product or NIK Product.
- 1.57. "Licensed Technology" means, with respect to a Program: (a) the Janssen Program Know-How; (b) the Janssen-Owned Development Program Know-How; (c) the Janssen Program Patents; (d) the Janssen-Owned Development Program Patents; and (e) Janssen's interest in the Joint Development Program Patents, in each case ((a) through (e)), with respect to such Program.
- 1.58. "Licensee NIK Program Technology" means: (a) the Licensee Program Know-How; provided, however, that with regard to Know-How regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Know-How that is applied to or used to make any AR Mutant Product as such AR Mutant Product exists as of the effective date of the Janssen NIK License Agreement is included, and any other formulation or Manufacturing method Know-How is excluded; (b) the Licensee-Owned Development Program Know-How; (c) the Licensee Program Patents; provided, however, that with regard to Patent Rights regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Patent Rights that are applied to such Licensed Product as such Licensed Product exists as of the effective date of the Janssen NIK License Agreement are included, and any other formulation or Manufacturing method Patent Rights are excluded; (d) the Licensee-Owned Development Program Patents; and (e) Licensee's interest in the Joint Development Program Patents, in each case ((a) through (e)), only with respect to the NIK Program.
- 1.59. "Licensee Program Know-How" means, with respect to a Program, any Know-How Controlled by Licensee or any of its Affiliates on the Effective Date or during the Term (other than Licensee-Owned Development Program Know-How) that is necessary to make, have made, use, have used, import, have imported, sell, have sold, offer for sale or have offered for sale

Licensed Compounds and Licensed Products only with respect to such Program. For clarification, Licensee Program Know-How does not include any Know-How with respect to any active ingredient(s) in any Combination Product other than a Licensed Compound.

- 1.60. "Licensee Program Patents" means, with respect to a Program, any Patent Rights Controlled by Licensee or any of its Affiliates on the Effective Date or during the Term (other than Development Program Patents) that Cover a Licensed Compound or Licensed Product with respect to such Program. For clarification, Licensee Program Patents does not include any Patent Rights with respect to any active ingredient(s) in any Combination Product other than a Licensed Compound.
- 1.61. "Major European Countries" means France, Germany, Italy, Spain and the United Kingdom.
- 1.62. "Manufacturing" means any activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a pharmaceutical product. When used as a verb, "Manufacture" means to engage in Manufacturing activities.
- 1.63. "Marketing Approval" means the approval of the applicable Regulatory Authority necessary for the marketing and sale of a pharmaceutical product for an Indication in the Field in a country, including any and all approvals that may be required in such country for pricing and reimbursement. For clarity, as of the Effective Date, no pricing and reimbursement approvals are required to market or sell a pharmaceutical product in the United States.
- 1.64. "Net Sales" means the gross amounts invoiced on sales of a Licensed Product by Licensee, or any of its Affiliates or sublicensees, to a Third Party purchaser in an arm's-length transaction, less the following customary and commercially reasonable deductions, determined in accordance with US generally accepted accounting principles and internal policies and actually taken, paid, accrued, allocated, or allowed based on good faith estimates:
  - (a) trade, cash and/or quantity discounts, allowances, deductions, fees and credits, excluding commissions for commercialization:
  - (b) excise taxes, use taxes, tariffs, sales taxes and customs duties and/or other government charges or fees imposed on the sale of Licensed Product (including VAT, but only to the extent that such VAT taxes are not reimbursable or refundable), specifically excluding, for clarity, any income taxes assessed against the income arising from such sale;
  - (c) compulsory or negotiated payments and cash rebates or other expenditures to governmental authorities (or designated beneficiaries thereof) in the context of any national or local health insurance programs or similar programs, including pay-for-performance agreements, risk sharing agreements and government-levied fees as a result of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148;
  - (d) rebates, chargebacks, administrative fees and discounts (or equivalent thereof) to managed health care organizations, group purchasing organizations, insurers, pharmacy

benefit managers (or equivalent thereof), specialty pharmacy providers, governmental authorities, or their agencies or purchasers, reimbursers, or trade customers, as well as amounts owed to patients through co-pay assistance cards or similar forms of rebate to the extent the latter are directly related to the prescribing of Licensed Product;

- (e) outbound freight, shipment, insurance and other distribution costs to the extent included in the invoiced price and separately itemized on the invoice;
- (f) retroactive price reductions, credits or allowances actually granted upon claims, rejections or returns of Licensed Product, including for recalls or damaged or expired goods, billing errors and reserves for returns; and
- (g) any invoiced amounts that are not collected by the selling party or its Affiliates, including bad debts.

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

For clarity, (x) sales of a Licensed Product by and between Licensee and any of its Affiliates or (sub)licensees shall not be considered sales to unaffiliated Third Parties and shall be excluded from Net Sales calculations for all purposes as long as such Licensed Product is subsequently resold to an unaffiliated Third Party and (y) only a single sales transaction with respect to a particular unit of Licensed Product, made at the time Licensee or any of its Affiliates or (sub)licensees sells such unit of Licensed Product to an unaffiliated Third Party purchaser in arms-length transaction, will qualify as the basis for determining the Net Sales amount for such unit of Licensed Product.

Notwithstanding the foregoing, the following sales of a Licensed Product shall be excluded from Net Sales calculations for all purposes: (i) transfer or dispositions of reasonable quantities of samples of such Licensed Product at no cost for promotional or educational purposes; (ii) transfers or dispositions of reasonable and customary quantities of such Licensed Product as free samples or donations, or for patient assistance, testing marketing programs or other similar programs at no cost; and (iii) use or sale of such Licensed Product for clinical study or other scientific testing purposes, early access programs (such as to provide patients with such Licensed Product prior to Regulatory Approval pursuant to treatment INDs or protocols, named patient programs or compassionate use programs) or any similar use.

In the event a Licensed Product is sold as part of a Combination Product in a country, the Net Sales with respect to the Combination Product in such country shall be determined by multiplying the Net Sales amount for the Combination Product during the applicable reporting period, calculated as set forth above, by the fraction A/(A+B), where A is the weighted average sale price (by sales volume) of the Licensed Product when sold separately, and B is the weighted

average sales price of the other active ingredient(s) or product(s) in the Combination Product when sold separately, in each case in the same dosage and dosage form and in the same country as the Combination Product during the applicable reporting period. If the other active ingredient(s) or product(s) in the Combination Product is not sold separately during the applicable reporting period in a country, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product by a fraction A/C where A is the weighted average sale price (by sales volume) of the Licensed Product in such country when sold separately, and C is the weighted average sale price (by Sales volume) of the Combination Product in such country. If neither sales of the Licensed Product sold separately nor sales of the other active ingredient(s) or product(s) sold separately occurred during the applicable reporting period, then the respective average sales prices during the most recent reporting period in which sales of both occurred in the same country as the Combination Product. In the event that the weighted average sale price (by sales volume) of the Licensed Product is not available in a given country for any reporting period, then the average sales prices (weighted by sales volume) of the respective products described above (in the same dosage and dosage form as the Combination Product) in a proxy country to be agreed upon by both Parties will be used (such agreement not be unreasonably withheld, delayed or conditioned), and if the Parties cannot agree upon such proxy country, or no such comparable sales figures are available in an appropriate proxy country, Net Sales for the applicable Combination Product shall be allocated based on the relative value contributed by each component (such relative value to be agreed upon by the Parties or, if the Parties cannot agree, to be determined by the dispute resolution procedures set forth in Article 12).

- 1.65. "NIK Competing Product" means a therapeutic product, an active pharmaceutical ingredient of which [...\*\*\*...].
- 1.66. "NIK Compound" means any compound (a) (i) described as a composition-of-matter as of the Effective Date in a claim of a Patent Right in the United States or the EPO or treaty country thereof (including such a claim of a Patent Cooperation Treaty application designating the United States or EPO) set forth on Schedule NIK Program Patents of the Schedule Letter, or (ii) described after the Effective Date in a claim of such a Patent Right filed within [...\*\*\*...], or (b) described in a claim of a Patent Right in the United States or the EPO or treaty country thereof (including such a claim of a Patent Cooperation Treaty application designating the United States or EPO) Controlled by a Party which also describes as a composition-of-matter a compound described in (a) above as of the [...\*\*\*...].
- 1.67. "NIK Data Package" means: (a) the NIK POC Trial Data; (b) the full tables, figures and listings from any other Clinical Trial of any NIK Product conducted by or on behalf of Licensee; (c) the data and results of all other Development activities conducted by or on behalf of Licensee with respect to any NIK Compound or NIK Product; and (d) an IP Disclosure Document for the NIK Program.
- 1.68. "NIK POC Trial" means the first Clinical Trial of a NIK Product that has [...\*\*\*...].

1.69.

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"NIK POC Trial Data" means the full tables, figures and listings from the NIK POC Trial.

- 1.70. "NIK Product" means any pharmaceutical product in any dosage form containing a NIK Compound.
- 1.71. "**NIK Program**" means the conduct of Development, Manufacturing and Commercialization activities with respect to NIK Compounds and NIK Products.
- 1.72. "NIK Program Know-How" means the Know-How Controlled by Janssen or any of its Affiliates on the Effective Date or during the Term (other than Janssen-Owned Development Program Know-How) that is necessary to make, have made, use, have used, import, have imported, sell, have sold, offer for sale or have offered for sale any NIK Compound or NIK Product, including the Know-How contained in or embodied by the items described on Schedule NIK Program Know-How of the Schedule Letter; provided, however, that with regard to Know-How regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Know-How that is applied to or used to make any NIK Product as such NIK Product exists as of the Effective Date is included, and any other formulation or Manufacturing method Know-How is excluded. For clarification, NIK Program Know-How does not include any Know-How with respect to any active ingredient(s) in any Combination Product other than a NIK Compound.
- 1.73. "NIK Program Patents" means any Patent Rights Controlled by Janssen or any of its Affiliates on the Effective Date or during the Term (other than Development Program Patents) that Cover any NIK Compound or NIK Product, including the Patent Rights set forth on Schedule NIK Program Patents of the Schedule Letter and all Patent Rights arising therefrom; provided, however, that with regard to Patent Rights regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Patent Rights that are applied to or used to make any NIK Product as such NIK Product exists as of the Effective Date is included, and any other formulation or Manufacturing method Patent Rights are excluded. For clarification, NIK Program Patents does not include any Patent Rights with respect to any active ingredient(s) in any Combination Product other than a NIK Compound.
- 1.74. "Nondisclosure Agreement" means the Confidential Disclosure Agreement between the Parties dated January 25, 2016.
- 1.75. "Patent Costs" means any out-of-pocket costs and expenses incurred by a Party or its Affiliates in prosecuting any Patent Rights.
- 1.76. "Patent Rights" means any and all (a) patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, (e) any other form of government-issued right substantially similar to any of the foregoing, and (f) all United States and foreign counterparts of any of the foregoing.
- 1.77. "**Person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.

- 1.78. "Phase I Clinical Trial" means, in reference to a clinical trial of a Licensed Product, that such trial would satisfy the requirements for a Phase I study as defined in 21 CFR § 312.21(a) or a Phase I study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).
- 1.79. "Phase II Clinical Trial" means, in reference to a clinical trial of a Licensed Product, that such trial would satisfy the requirements for a Phase 2 study as defined in 21 C.F.R. § 312.21(b) or a Phase II study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).
- 1.80. "Phase II/III Clinical Trial" means a Phase II Clinical Trial involving a sufficient number of subjects that, prior to commencement of the trial or at any other defined point in the trial, satisfies both of the following ((a) and (b)):
  - (a) such trial is designed to (i) establish that the applicable Licensed Product is safe and efficacious for its intended use, and (ii) define and determine warnings, precautions, and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed, which trial is intended to support Marketing Approval of such Product or a similar clinical study prescribed by the FDA; and
  - (b) such trial is or becomes a registration trial sufficient for filing an application for a Marketing Approval for such Licensed Product in the U.S., as evidenced by (i) an agreement with or statement from the FDA on a Special Protocol Assessment or equivalent, or (ii) other guidance or minutes issued by the FDA, for such registration trial.
- 1.81. "Phase III Clinical Trial" means, in reference to a clinical trial of a Licensed Product, that such trial is would satisfy the requirements for a Phase 3 study as defined in 21 C.F.R. § 312.21(c) or a Phase III study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).
- 1.82. "POC Trial" means (a) with respect to the AR Mutant Program, the AR Mutant POC Trial and (b) with respect to the NIK Program, the NIK POC Trial.
- 1.83. "POC Trial Notice" means, with respect to a Program, a notice from Licensee to Janssen providing the Data Package with respect to such Program.
- 1.84. "**Program**" means either of the AR Mutant Program or NIK Program.
- 1.85. "Program-Related Information" means, with respect to a Program: (a) the Development Plan for such Program; (b) the Program Records generated during the course of conducting such Program; (c) the Development reports delivered by Licensee to Janssen with respect to such Program pursuant to Section 2.2.5; (d) the Data Package(s), interim data packages and additional information delivered by Licensee to Janssen with respect to such Program pursuant to Section 3.2; and (e) non-public Development Program Know-How and Development Program Patents with respect to such Program, including non-public Licensee-Owned Development Program Know-How disclosed by Licensee to Janssen during meetings

between the Parties pursuant to Section 2.2.5 and non-public Janssen-Owned Development Program Know-How disclosed by Janssen to Licensee during meetings between the Parties pursuant to Section 2.2.5.

- 1.86. "**Regulatory Authority**" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the marketing and sale of a pharmaceutical product in a country, such as the FDA in the United States or EMA in the EU.
- 1.87. "Regulatory Approval" means any and all approvals (including Marketing Approvals), licenses (including import licenses), registrations or authorizations of any national, regional, state or local Regulatory Authority, department, bureau, commission, council or other governmental entity, that are necessary or useful to Development, Manufacture or Commercialize a pharmaceutical product in any country or jurisdiction in the Territory for one or more uses.
- 1.88. "Regulatory Documentation" means, with respect to a Program: (a) all applications for Regulatory Approval of any Licensed Compound or Licensed Product with respect to such Program; (b) all Regulatory Approvals for any Licensed Compound or Licensed Product with respect to such Program, including INDs, Drug Approval Applications and Marketing Approvals; (c) all supporting documents created for, referenced in, submitted to or received from an applicable Regulatory Authority relating to any of the applications or Regulatory Approvals described in clauses (a) or (b), including drug master files (or any equivalent thereof outside the U.S.), annual reports, regulatory drug lists, advertising and promotion documents shared with Regulatory Authorities, adverse event files, complaint files and Manufacturing records; and (d) all correspondence made to, made with or received from any Regulatory Authority (including written and electronic mail correspondence and minutes from meetings, discussions or conferences (whether in person or by audio conference or videoconference)).
- 1.89. "Regulatory Exclusivity Period" means, with respect to a given Licensed Product and given country, a period of exclusivity (other than patent exclusivity), granted or afforded by Applicable Laws or by a Regulatory Authority in such country, that confers exclusive marketing rights with respect to such Licensed Product in such country and prevents the initial market entry of a generic product with respect to such Licensed Product. In the event that such exclusivity is not available with respect to a Licensed Product in a country, the Regulatory Exclusivity Period for such Licensed Product in such country shall be deemed to expire upon the First Commercial Sale of such Licensed Product in such country
- 1.90. "Relevant Factors" means all relevant scientific, technical, operational, commercial, economic and other factors that may affect the development, Marketing Approval, manufacture or commercialization of a product, including (as applicable): actual and potential issues of safety, efficacy and/or stability; expected and actual product profile (including product modality, category and mechanism of action); stage of development or life cycle status; actual and projected development, Marketing Approval, manufacturing, and commercialization costs, timelines and budgets; any issues regarding the ability to manufacture or have manufactured the Licensed Product; the likelihood of obtaining Marketing Approvals (including satisfactory reimbursement or pricing approvals); the timing of such approvals; labeling or anticipated labeling; the then-current competitive environment and the likely competitive environment at the

time of projected entry into the market, including the expected and actual competitiveness of alternative products sold by Third Parties in the market; past performance of the product or similar products; present and future market potential; existing or projected pricing, sales, reimbursement and profitability; and expected and actual proprietary position, strength and duration of patent protection and anticipated regulatory or other exclusivity.

- 1.91. "**ROFN Exercise Deadline**" means the date that is [...\*\*\*...] after the POC Trial Notice Date with respect to the NIK Program (which shall terminate early upon termination of this Agreement in its entirety pursuant to Section 11.2, 11.3 or 11.4 or termination of this Agreement with respect to the NIK Program pursuant to Section 11.2, 11.3 or 11.4); *provided*, *however*, [...\*\*\*...].
- 1.92. "ROFN Period" means the period commencing on the Effective Date and ending on the ROFN Exercise Deadline or, if Janssen exercises the Right of First Negotiation pursuant to Section 3.4.1 on or before the ROFN Exercise Deadline, the expiration of the Negotiation Period.
- 1.93. "Royalty Term" means, with respect to a given Licensed Product and a given country, the period beginning on the date of First Commercial Sale of such Licensed Product in such country and ending on the later of: (a) ten (10) years after the date of First Commercial Sale of such Licensed Product in such country; (b) the expiration of the last to expire Valid Claim of any Janssen Program Patent, Licensee Program Patent or Development Program Patent that Covers such Licensed Product in such country; or (c) the Regulatory Exclusivity Period with respect to such Licensed Product in such country.
- 1.94. "Schedule Letter" means the letter dated as of the Effective Date between Janssen and Licensee delivering copies of certain schedules.
- 1.95. "Tax" or "Taxes" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon).
- 1.96. "**Territory**" means worldwide.
- 1.97. "**Third Party**" means any Person other than a Party or any of its Affiliates.
- 1.98. "Third Party NIK Program Agreement" means a Third Party Program Agreement with respect to the NIK Program.
- 1.99. "Third Party Program Agreement" means, with respect to a Program, an agreement (other than a Permitted Subcontract) between Licensee or any of its Affiliates, on the one hand, and a Third Party, on the other hand, to collaborate with, grant a license or sublicense to or otherwise authorize such Third Party, or grant such Third Party any rights, to Develop, Manufacture or Commercialize any Licensed Compound or Licensed Product with respect to such Program.

1.100.

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"Third Party Subcontractor Reserved Technology" means results of the activities undertaken and other intellectual property made, invented or generated by a Third Party Subcontractor's employees or agents with respect to a Program pursuant to a Permitted Subcontract solely to the extent that they are either improvements to such Third Party

Subcontractor's intellectual property or generally applicable Development or Manufacturing technology, and in either case not specific to any Licensed Compound or Licensed Product.

- 1.101. "**Trademark**" means any word, name, symbol, color, designation, or device or any combination thereof, whether registered or unregistered, including any trademark, trade dress, service mark, service name, brand mark, trade name, brand name, logo or business symbol.
- 1.102. "Valid Claim" means: (a) a claim of any issued and unexpired patent that (i) has not been dedicated to the public, disclaimed, revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or a decision of a court or governmental agency of competent jurisdiction that can be appealed, but with respect to which an appeal has not taken within the time allowed for appeal, and (ii) has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (b) a claim of any pending patent application that (i) has not been cancelled, withdrawn or abandoned, without being re-filed in another application in the applicable jurisdiction, (ii) has not been finally rejected by an administrative agency or other governmental action from which no appeal can be taken and (iii) has not been pending or filed more than [...\*\*\*...] from the earliest possible priority date for such patent application.

1.103.

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Additional Definitions. Each of the following definitions are found in the body of this Agreement as indicated:

<b>Defined Term</b>	<b>Section</b>
Acquired Compound	2.3.2(b)
Acquired Product	2.3.2(b)
Action	7.4.2
Additional NIK Program Information	3.4.1(c)
Agreement	Preamble
Anti-Corruption Laws	9.5.4
AR Mutant Development Plan	2.2.2(a)
AR Mutant Schedule Information	3.2.1
Audited Site	9.5.5
Bankruptcy Code	11.4.2
Breaching Party	11.3.1
CAPA	9.5.5
CPR Mediation Procedure	12.2.1
CPR Rules	12.3.1
CREATE Act	7.3.5
Cure Period	11.3.1
Development Program Patent	7.2.1
Development Plan	2.2.2(b)
Development Term Acquirer Activities	2.3.3
Disclosing Party	8.1.1
Dispute	12.1
Effective Date	Preamble

Existing Janssen Program Know-How	9.2.49.2.1
Existing Janssen Program Patents	13.9
Force Majeure Event	10.5
GCP	9.5.5
GLP	9.5.5
GMP	9.5.5
Indemnified Party	10.2
Indemnifying Party	10.2
Insolvency Event	11.4.1
IRB	9.5.5
Janssen	Preamble
Janssen Indemnified Party	10.1.1
Janssen NIK License Agreement	3.4.1(b)
Janssen-Owned Development Program Know-How	7.2.1
Janssen-Owned Development Program Patent	7.2.1
Janssen Personnel	
***************************************	9.2 7.2.1
Joint Development Program Patent	
Knowledge License Term	9.2 4.1
	4.1 Preamble
Licensee	
Licensee Indemnified Party	10.1.2
Licensee Party	11.4.2
Licensee-Owned Development Program Know-How	7.2.1
Licensee-Owned Development Program Patent	7.2.1
Licensor Party	11.4.2
Losses	10.1.1
Milestone Event	6.1.2
Milestone Payment	6.1.2
Missing Information Notice	3.2.2
NDA	1.32
Negotiation Period	3.4.1(b)
NIK Development Plan	2.2.2(b)
Option	3.1
Option Exercise Effective Date	3.3.1
Option Exercise Fee	3.3.1
Option Period	3.3.1
Other Invention	7.2.2
Other Patent	7.2.2
Party/Parties	Preamble
Patent Representative	7.1
Patent Term Extension	7.6
Permitted Liens	9.2
Permitted Subcontract	2.2.3(e)
POC Trial Notice Date	3.2.2
Post-Development Term Acquirer Activities	5.5.2
Product Infringement	7.4.2

Program Records	2.2.4(a)
Protocol	12.3.6
Receiving Party	8.1.1
Restricted Contract	2.1.3
Restricted Third Party NIK Program Agreement	3.4.1(c)
Right of First Negotiation (or ROFN)	3.4.1
ROFN Exercise Notice	3.4.1(b)
Royalty Records	6.5
Subcontracting Party	2.2.3(e)
Supply Agreement	2.1.6
Tail Period	3.4.1(c)
Term	11.1
Terminated Program	11.6.1
Terminating Party	11.3.1
Third Party Claim	10.1.1
Third Party Consent	2.1.3
Third Party Offer Notice	2.4
Third Party Subcontractor	2.2.3(e)
Transferred Assets	2.1.3
Transferred Contracts	2.1.3(b)
Transferred Contract Effective Date	2.1.3(b)
Transferred Materials	2.1.3(a)
Transition Period	2.1.5(a)
Transition Plan	2.1.5(a)
	· /

# Article 2 LICENSE GRANTS AND DEVELOPMENT ACTIVITIES DURING DEVELOPMENT TERM

#### 2.1. <u>Development Term License Grants; Transfer of Programs</u>.

#### 2.1.1. License Grants to Licensee.

- (a) AR Mutant Program License. Subject to the terms and conditions of this Agreement (including Section 2.1.2), during the Development Term with respect to the AR Mutant Program, Janssen hereby grants to Licensee:
  - (1) an exclusive (subject to Section 2.1.2), non-transferable (except to the extent permitted under Section 13.6), non-sublicensable license under the Licensed Technology with respect to the AR Mutant Program to make, have made, use, have used, import and have imported the AR Mutant Compounds and AR Mutant Products in the Field in the Territory, solely for the purpose of conducting: (i) the AR Mutant POC Trial; (ii) the AR Mutant Pre-Phase III Activities; and (iii) and any other Development activities, including Manufacturing activities, with respect to the AR Mutant Compounds and AR Mutant Products that are reasonably

necessary to conduct and complete the AR Mutant POC Trial or the AR Mutant Pre-Phase III Activities or to generate and deliver to Janssen a complete AR Mutant Data Package (including the AR Mutant POC Trial Data); and

- an exclusive (subject to Section 2.1.2) non-transferable (except to the extent permitted under Section 13.6), non-sublicensable license under the Patent Rights set forth on Schedule AR Mutant Diagnostic Patent of the Schedule Letter to make, have made, use, have used, import and have imported companion diagnostic products solely for use with AR Mutant Compounds and AR Mutant Products in the Field in the Territory for the purpose of conducting: (i) the AR Mutant POC Trial; (ii) the AR Mutant Pre-Phase III Activities; and (iii) and any other Development activities, including Manufacturing activities, with respect to the companion diagnostic products that are reasonably necessary to conduct and complete the AR Mutant POC Trial or the AR Mutant Pre-Phase III Activities or to generate and deliver to Janssen a complete AR Mutant Data Package (including the AR Mutant POC Trial Data).
- (b) NIK Program License. Subject to the terms and conditions of this Agreement (including Section 2.1.2), during the Development Term with respect to the NIK Program, Janssen hereby grants to Licensee an exclusive (subject to Section 2.1.2), non-transferable (except to the extent permitted under Section 13.6), non-sublicensable license under the Licensed Technology with respect to the NIK Program to make, have made, use, have used, import and have imported the NIK Compounds and NIK Products in the Territory, solely for the purpose of conducting the NIK POC Trial and any other Development activities, including Manufacturing activities, with respect to the NIK Compounds and NIK Products that are reasonably necessary to conduct and complete the NIK POC Trial or to generate and deliver to Janssen a complete NIK Data Package (including the NIK POC Trial Data).
- (c) NIK Program Covenant. Licensee covenants and agrees not to exercise any of its rights under Section 2.1.1(b) to make, have made, use, have used, import and have imported the NIK Compounds and NIK Products for any [...\*\*\*...] Indication unless and until the License Term of the NIK Program begins.

#### 2.1.2. **Janssen Retained Rights**. Licensee acknowledges and agrees that:

(a)

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Janssen and its Affiliates (i) retain the right to use the Licensed Technology and the Patent Rights set forth on Schedule AR Mutant Diagnostic Patent of the Schedule Letter to make, have made, use, have used, import and have imported Licensed Compounds and Licensed Products solely to conduct Internal Research with Licensed Compounds or Licensed Products and (ii) shall not be obligated to remove any Licensed Compound from its compound libraries that are used for Internal Research; and

- (b) Janssen and its Affiliates may use for any purpose (other than those purposes for which Licensee is granted an exclusive license pursuant to Section 2.1.1 or 5.2) [...\*\*\*...]; provided, however, that the foregoing is not intended to grant, and shall not be deemed to grant, [...\*\*\*...].
- 2.1.3. **Assignment of Transferred Assets.** Subject to the terms and conditions of this Agreement, Janssen, on behalf of itself and its Affiliates, hereby irrevocably sells, conveys, transfers and assigns to Licensee all of Janssen's and its Affiliates' right, title and interest in, to and under the following assets (collectively, the "**Transferred Assets**"):
  - (a) the assays and materials listed on <u>Schedule Transferred Materials</u> of the Schedule Letter (the "Transferred Materials");
  - (b) the contracts, agreements and commitments that will be listed on <u>Schedule Transferred Contracts</u> of the Schedule Letter by written agreement of the Parties during the Transition Period (collectively, the "**Transferred Contracts**"); *provided* that assignment of such Transferred Contracts and any other provisions of this Agreement applicable to such Transferred Contracts shall not become effective, and the Transferred Contracts shall not be Transferred Assets, without limitation of the last paragraph of this Section 2.1.3 unless and until the date that the Parties agree in writing to the <u>Schedule Transferred Contracts</u> (the "**Transferred Contract Effective Date**"); and
  - (c) all claims, counterclaims, defenses, causes of action, rights under express or implied warranties, rights of recovery, rights of set-off, rights of subrogation and all other rights of any kind against any Third Party, solely to the extent relating to any Assumed Liabilities or Transferred Assets.

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Notwithstanding anything in this Agreement to the contrary, this Agreement shall not constitute an agreement to assign or transfer any Transferred Contract that is not assignable or transferable without the consent of any Third Party (each, a "Restricted Contract"), to the extent that such consent has not been obtained prior to the Effective Date (each, a "Third Party Consent"). Janssen shall use, during the Transition Period, Commercially Reasonable Efforts to obtain, and Licensee shall use Commercially Reasonable Efforts to assist and cooperate with Janssen to obtain, all Third Party Consents; provided, however, that none of Janssen, Licensee or any of their respective Affiliates shall be required to pay money to any Third Party, commence any litigation or offer or grant any accommodation (financial or otherwise) to any Third Party to obtain any Third Party Consent. During the period beginning on the Effective Date and ending on the earlier of (a) the date on which [...\*\*\*...] and (b) the [...\*\*\*...], Janssen shall (i) use Commercially Reasonable Efforts to provide Licensee with the benefits of such Restricted Contract (or benefits substantially comparable to the benefits of such Restricted Contract), provided that Licensee performs the obligations of Janssen under such Restricted Contract, and (ii) upon the request of, for the benefit of and at the expense of Licensee, enforce any rights of Janssen arising under such Restricted Contract against any Person, including the right to seek any available remedies or to terminate

such Restricted Contract. Janssen provides no assurances to Licensee that any Third Party Consent will be granted. Subject to Janssen's compliance with this Section 2.1.3, the Parties acknowledge and agree that (x) neither Janssen nor any of its Affiliates shall be obligated to obtain any Third Party Consent and (y) neither Janssen's failure to obtain any Third Party Consent, nor any default, termination, lawsuit, action, claim, proceeding or investigation commenced or threatened by or on behalf of any Person arising from Janssen's failure to obtain any Third Party Consent, shall be deemed to be a breach of any representation, warranty or covenant of Janssen contained in this Agreement.

- 2.1.4. **Assumption of Assumed Liabilities.** Subject to the terms and conditions of this Agreement, Janssen hereby conveys, assigns and transfers to Licensee and its successors and assignees, forever, and Licensee hereby assumes, and agrees to satisfy, perform and otherwise discharge when due, all liabilities arising from or relating to the Transferred Contracts arising on or after the Transferred Contract Effective Date, but excluding all liabilities resulting from any breach of or non-compliance with any Transferred Contract by Janssen or any of its Affiliates prior to the Transferred Contract Effective Date (the "**Assumed Liabilities**"). All risk of loss with respect to the Transferred Assets (whether or not covered by insurance) shall pass to Licensee on the Effective Date or, if later with respect to any Transferred Asset, the date that such Transferred Asset is actually transferred to Licensee pursuant to the Transition Plan. Licensee does not assume any liabilities with respect to the Transferred Assets other than the Assumed Liabilities.
- 2.1.5. **Transition.** In order to effect a prompt and orderly transition of each Program from Janssen to Licensee, and to facilitate the transfer of the Janssen Program Know-How and Transferred Assets from Janssen to Licensee:
  - (a) the Parties shall comply with the provisions of the transition plan for each Program attached as <u>Schedule Transition Plan</u> of the Schedule Letter (the "**Transition Plan**") during the period beginning on the Effective Date and ending [...\*\*\*...] thereafter (the "**Transition Period**");
  - (b) Janssen shall use Commercially Reasonable Efforts to (i) deliver physical embodiments of the Janssen Program Know-How identified on Schedule AR Mutant Program Know-How or Schedule NIK Program Know-How of the Schedule Letter and the Transferred Assets to Licensee prior to the end of the Transition Period, provided that Janssen shall determine in its discretion whether to provide originals or copies of any documentation included within the Janssen Program Know-How, and (ii) respond to Licensee's requests for additional information, documents, files or assistance with respect to the items described in clause (i) during the Transition Period;

(c)

\*\*\*Confidential Treatment Requested

each Party shall appoint one individual to have primary responsibility and oversight for, and to serve as the primary point of contact regarding, the transition and transfer activities for each Program contemplated by this Section 2.1.5 and the Transition Plan; and

(d) each Party shall bear its own costs in performing its obligations under this Section 2.1.5 and the Transition Plan.

After expiration of the Transition Period, except as required elsewhere in this Agreement, Janssen will have no further obligation to provide any additional information, documents, electronic files or support to Licensee in connection with the Programs; provided, however, that following the Transition Period, if (i) either Party identifies any assets that were not transferred prior to the end of the Transition Period but that, pursuant to the provisions of this Agreement, were Transferred Assets that were required to be transferred, Janssen and its Affiliates shall, at no additional cost to Licensee, promptly take all actions to transfer such Transferred Assets to Licensee, (ii) if Janssen discovers any Janssen Program Know-How that existed on the Effective Date but was omitted from the Schedule AR Mutant Program Know-How or Schedule NIK Program Know-How of the Schedule Letter, Janssen and its Affiliates shall, at no additional cost to Licensee, promptly take all actions to transfer a copy of such Janssen Program Know-How to Licensee and (iii) Janssen and its Affiliates shall provide reasonable support to Licensee and its Affiliates after the Transition Period to the extent reasonably necessary to allow Licensee and its Affiliates to respond to requirements or requests of any Regulatory Authority or other governmental authority with respect to Licensed Compounds or Licensed Products.

- 2.1.6. **Supply and Quality Assurance Agreements.** Beginning on the Effective Date, the Parties will work together in good faith to negotiate and enter into an agreement within [...\*\*\*...] after the Effective Date for the supply of [...\*\*\*...] for use in conducting activities under the Programs on the terms specified in the <u>Schedule Supply Terms</u> of the Schedule Letter and other terms mutually agreed by the Parties and a related quality assurance agreement on terms mutually agreed by the Parties (collectively, the "**Supply Agreement**").
- 2.2. <u>Conduct of Development Activities</u>. The following provisions of this Section 2.2 shall apply during the Development Term for each Program.
  - 2.2.1. **General.** Subject to the transfer of the Janssen Program Know-How and Transferred Assets to Licensee in accordance with Sections 2.1.3 and 2.1.5 and entry into and performance of the Supply Agreements, Licensee will conduct each Program in accordance with this Article 2; *provided*, *however*, that Janssen will conduct the Janssen AR Mutant Activities in accordance with the AR Mutant Development Plan. Each Party will carry out its responsibilities set forth in each Development Plan in accordance with the terms and conditions of this Agreement, in good scientific manner and in compliance with all applicable Laws.

#### 2.2.2. **Development Plans**.

(a)

\*\*\*Confidential Treatment Requested

Licensee shall prepare and deliver to Janssen within [...\*\*\*...] after the Effective Date a written development plan for the AR Mutant Program describing the activities to be performed to up to and including the conduct and completion of the AR Mutant PoC Trial and the AR Mutant Pre-Phase III Activities, the

deliverables for such activities, target dates and estimated timelines for completion of such activities and a budget for such activities (the "AR Mutant Development Plan"). The Development Plan for the AR Mutant Program shall at all times contain [...\*\*\*...]. Janssen shall review the initial AR Mutant Development Plan within [...\*\*\*...] following receipt thereof and may provide comments on such AR Mutant Development Plan, which Licensee shall consider in good faith. Any portion of the initial AR Mutant Development Plan describing a Janssen AR Mutant Activity that is not set forth on Schedule Janssen AR Mutant Activities, or setting forth a target date or timeline for any Janssen AR Mutant Activity, will not become effective unless and until approved in writing by Janssen.

- (b) Licensee shall prepare and deliver to Janssen within [...\*\*\*...] after the Effective Date a written development plan for the NIK Program describing the activities to be performed to up to and including the conduct and completion of the NIK POC Trial, the deliverables for such activities, target dates and estimated timelines for completion of such activities and a budget for such activities (the "NIK Development Plan" and the AR Mutant Development Plan or the NIK Development Plan, a "Development Plan"). The Development Plan for the NIK Program shall at all times contain: [...\*\*\*...]. Janssen shall review the initial NIK Development Plan within [...\*\*\*...] following receipt thereof and may provide comments on such NIK Development Plan, which Licensee shall consider in good faith.
- (c) Subject to Section 2.2.2(a) or 2.2.2(b), as applicable, and Section 2.2.2(e), each Development Plan may be amended from time to time by Licensee, *provided* that no such amendment shall take effect until (i) Licensee provides Janssen with notice of and a copy of the proposed amendment, (ii) Licensee provides Janssen with [...\*\*\*...] to review and provide comments on such amendment and (iii) Licensee considers in good faith any comments made by Janssen; and *provided further* that no such amendment relating to a Janssen AR Mutant Activity shall take effect unless and until approved in writing by Janssen. For clarity, the approval of Janssen is not required to amend any Development Plan except as described in the immediately preceding sentence.
- (d) Prior to the commencement of any of the [...\*\*\*...], Licensee shall amend the AR Mutant Development Plan to include a budget for such activities and submit such amendment to Janssen for review pursuant to Section 2.2.2(c).
- (e) The Development Plan for a Program shall not contain any Development activities relating to [...\*\*\*...], and Licensee shall not conduct any such activities during the Development Term of such Program.

#### 2.2.3. Conduct of Programs.

(a)

\*\*\*Confidential Treatment Requested

Licensee Diligence. Licensee shall conduct the activities set forth in each Development Plan (and all regulatory matters relating to such activities), other

than the Janssen AR Mutant Activities, and shall use Commercially Reasonable Efforts to conduct such activities in accordance with the timelines and budget set forth in such Development Plan. Without limiting the foregoing, Licensee shall use Commercially Reasonable Efforts to:

- (1) [...\*\*\*...];
- (2) [...\*\*\*...];
- (3) [...\*\*\*...];
- (4) [...\*\*\*...]; and
- (5) [...\*\*\*...].

It is acknowledged that there may be delays in achievement of such events based upon delays by Janssen in performing its obligations under Sections 2.1.3, 2.1.5 or 2.2.3(b) or the Supply Agreement or actions of any Regulatory Authority, and any delay in achievement of such events for such reason shall not be a breach of this Section 2.2.3(a). It is further acknowledged that, due to timing of activities with respect to a given Program, [...\*\*\*...] provided that [...\*\*\*...]. During [...\*\*\*...], Licensee shall not be obligated to conduct, nor shall Licensee conduct, any Development activities with respect to the applicable Program other than [...\*\*\*...].

- (b) Janssen Diligence. Janssen shall conduct the Janssen AR Mutant Activities, and shall use Commercially Reasonable Efforts to conduct such activities in accordance with the timelines set forth in the AR Mutant Development Plan.
- (c) Responsibilities. Licensee shall be solely responsible for all aspects of conducting the Development activities set forth in the Development Plans, including Manufacturing clinical supplies of Licensed Compounds and Licensed Products necessary to conduct the Programs, except that Janssen shall be solely responsible for all aspects of conducting the Janssen AR Mutant Activities. Janssen may provide, through its review of reports delivered by Licensee, and participation in meetings with Licensee, pursuant to Section 2.2.5, such input as it deems appropriate with respect to Licensee's conduct of the Programs, which input Licensee shall consider in good faith.
- (d) *Costs*. Licensee shall conduct each Program at its sole cost and expense, except that Janssen shall conduct the Janssen AR Mutant Activities at its sole cost and expense. In addition, Licensee shall [...\*\*\*...].
- (e) Subcontracting.

(1)

\*\*\*Confidential Treatment Requested

Each Party may subcontract the performance of any Development activities, including Manufacturing activities, conducted pursuant to the

Programs to any of its Affiliates or any Third Party, *provided* that such Party shall oversee the performance by its Affiliates and Third Party Subcontractors in a manner that would be reasonably expected to result in their timely completion and shall remain responsible for the performance of such activities in accordance with this Agreement.

- With respect to any activities to be subcontracted to a Third Party (a "Third Party Subcontractor") by Licensee, or by Janssen pursuant to a subcontracting agreement with a Third Party that is first entered into after the Effective Date: (A) each such arrangement will be set forth in a written contract with such Third Party Subcontractor; and (B) all such contracts shall be consistent with and expressly made subject to the terms and conditions of this Agreement and shall include (i) restrictions on the use and disclosure of Confidential Information of the other Party and (ii) an assignment to the applicable Party entering into such contract (the "Subcontracting Party") of all rights to any and all results of the activities undertaken and other intellectual property made, invented or generated by such Third Party Subcontractor with respect to the applicable Program, except as otherwise provided in Section 2.2.3(e)(3).
- (3) Any assignment of intellectual property rights described in clause (B)(ii) of Section 2.2.3(e) (2) may exclude any Third Party Subcontractor Reserved Technology rights that are not necessary to make, have made, use, have used, import, have imported, sell, have sold, offer for sale or have offered for sale any Licensed Compound or Licensed Product. If the Subcontracting Party expects that any Third Party Subcontractor Reserved Technology rights [...\*\*\*...], then, before entering into such subcontract, the Subcontracting Party (A) shall [...\*\*\*...], (B) shall [...\*\*\*...] and (C) shall [...\*\*\*...]. If the proposed subcontract [...\*\*\*...].
- (4) A Subcontracting Party will notify the other Party of the engagement or retention of any Third Party Subcontractor to conduct any Program activities and, upon the request of such other Party, provide such other Party with a copy of the relevant contract (which may be redacted with respect to financial terms) to ensure compliance with the provisions of this Section 2.2.3(e). A contract between a Party and a Third Party Subcontractor that satisfies the requirements set forth in this Section 2.2.3(e) is referred to in this Agreement as a "**Permitted Subcontract**."

#### 2.2.4. Records; Data Requirements.

(a)

\*\*\*Confidential Treatment Requested

Each Party shall prepare and maintain, and shall cause its Affiliates and Third Party Subcontractors to prepare and maintain, complete and accurate written records, accounts, notes, reports and data with respect to the Development activities conducted by or on behalf of such Party during the Development Term with respect to a Program, including all Development Program Know-How (the "Program Records"), in sufficient detail and in good scientific manner

appropriate for patent and regulatory purposes and in conformity with Applicable Law and such Party's standard practices, which Program Records shall reflect all work done and results achieved in connection with the Programs. Each Party shall retain, and cause its Affiliates and Third Party Subcontractors to retain, the Program Records for at least [...\*\*\*...] or such longer period as may be required by Applicable Law.

- (b) Each Party shall comply with Janssen's data policies set forth on <u>Exhibit B</u> with regarding to Program Records.
- 2.2.5. **Reports.** Licensee shall submit a reasonably detailed written summary of the status of each Program [... \*\*\*...], updating Janssen on its progress with respect to the conduct of such Program, including any regulatory filings made during such [...\*\*\*...]. Licensee shall make its employees and consultants available for an in-person or telephonic meeting with Janssen at least once every [...\*\*\*...] to discuss its progress with respect to the conduct of the Programs.
- 2.2.6. **No Branding Activities**. During the Development Term of a Program, Licensee shall not use or file for protection of any Trademarks or trade names for a Licensed Product with respect to such Program.

#### 2.3. **Development Term Exclusivity**.

- 2.3.1. **Licensee Exclusivity**. During the Development Term with respect to a Program, neither Licensee nor any of its Affiliates shall: (i) [...\*\*\*...].
- 2.3.2. [...\*\*\*...]
- 2.3.3. **Exceptions**. Notwithstanding the foregoing:
  - (a) Section 2.3.1 does not prohibit Licensee and its Affiliates that are subject to Section 2.3.1, alone or through work conducted in collaboration with an Affiliate or Third Party, from conducting research and non-clinical development (or licensing or otherwise granting rights to an Affiliate or a Third Party to conduct research and non-clinical development) of compounds (other than Licensed Compounds) that (i) [...\*\*\*...] or (ii) [...\*\*\*...].
  - (b) Section 2.3.2 does not prohibit Janssen and its Affiliates, alone or through work conducted in collaboration with an Affiliate or Third Party, from conducting research and non-clinical development (or licensing or otherwise granting rights to an Affiliate or a Third Party to conduct research and non-clinical development) of compounds (other than Licensed Compounds) that [...\*\*\*...].

(c)

\*\*\*Confidential Treatment Requested

This Section 2.3 shall not apply to the Acquirer of a Party or any Affiliate of such Acquirer (excluding any Affiliate that was an Affiliate of such Party prior to a Change of Control and became an Affiliate of such Acquirer as a result of such Change of Control), provided that, if the Acquirer or such Affiliate conducts any activities described in Section 2.3.1 or 2.3.2, as applicable, during the

Development Term (the "Development Term Acquirer Activities"), such Acquirer or Affiliate shall use reasonable good faith efforts to segregate such Development Term Acquirer Activities from activities conducted with respect to the Licensed Compounds and Licensed Products pursuant to this Agreement, including by (x) not permitting personnel who perform the Development Term Acquirer Activities to have access to Program-Related Information or other Confidential Information of the other Party (including Know-How and proprietary Development or Commercialization plans or other business information); and (y) not permitting personnel who perform activities conducted with respect to the Licensed Compounds and Licensed Products pursuant to this Agreement to perform Development Term Acquirer Activities (*provided* that the foregoing shall not apply to senior management and regulatory, chemistry-manufacturing-controls, patent, legal and other similar personnel).

- (d) Neither Party shall be limited or prohibited by Section 2.3 from negotiating and completing a Change of Control, or taking any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party relating to, or engage in discussions with any Third Party relating to, a Change of Control.
- No Third Party Program Agreements. During the Development Term with respect to a Program, neither Licensee nor any of its Affiliates shall (i) enter into a Third Party Program Agreement with respect to such Program or (ii) take any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party or engage in discussions with any Third Party relating to a Third Party Program Agreement with respect to such Program. Notwithstanding anything to the contrary herein, Licensee shall not be limited or prohibited from negotiating and completing any Change of Control, or taking any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party or engage in discussions with any Third Party relating to a Change of Control. If, during the Development Term with respect to a Program, Licensee receives any inquiry, proposal or offer by or from any Third Party relating to a potential Third Party Program Agreement, Licensee shall notify Janssen in writing (a "Third Party Offer Notice") as soon as reasonably practicable of the existence of such inquiry, proposal or offer by or from a Third Party, but shall not be required to disclose the identity of the Third Party or any terms of any Third Party inquiry, proposal or offer. For clarity, such Third Party Offer Notice shall have no effect on the Option or Right of First Negotiation with respect to the applicable Program.

2.5.

\*\*\*Confidential Treatment Requested

<u>Third Party Contracts.</u> If any Know-How, Patent Right or other intellectual property right would first become Controlled by a Party after the Effective Date through a license from a Third Party, and [...\*\*\*...], such licensee Party shall first notify the other Party of [...\*\*\*...], and such Know-How, Patent Right or other intellectual property right shall not be deemed to be Controlled by such licensee Party for purposes of this Agreement, except to the extent, and only to the extent that, [...\*\*\*...], and to acknowledge that its sublicense under such license is subject to the terms and conditions of the license agreement with the Third Party.

### Article 3 OPTION AND RIGHT OF FIRST NEGOTIATION

3.1. **Grant of Option.** Subject to the terms and conditions of this Agreement, Licensee hereby grants, on behalf of itself and its Affiliates, to Janssen an exclusive option, exercisable at Janssen's sole discretion in accordance with Section 3.3.1 at any time during the Option Period, to (i) terminate the licenses and related rights granted by Janssen to Licensee pursuant to this Agreement with respect to the AR Mutant Program, (ii) obtain an exclusive license under the Licensed Technology (as defined in the AR Mutant License Agreement) to make, have made, use, have used, import, have imported, sell, have sold, offer for sale and have offered for sale the AR Mutant Compounds and AR Mutant Products on the terms and conditions set forth in the AR Mutant License Agreement and (iii) obtain the other rights set forth in the AR Mutant License Agreement (the "**Option**").

#### 3.2. <u>Delivery of POC Trial Notice and Data Package</u>.

3.2.1. **Delivery.** [...\*\*\*...], Licensee shall deliver a POC Trial Notice and Data Package for the applicable Program to Janssen. If such POC Trial Notice and Data Package relates to the AR Mutant Program, Licensee shall concurrently deliver to Janssen the draft TRACON Schedule Letter (as defined in the AR Mutant License Agreement) to be delivered with respect to the AR Mutant License Agreement, including any anticipated exceptions to the representations and warranties of Licensee with regard to Licensed Technology (as defined in the AR Mutant License Agreement) to be made in the AR Mutant License Agreement, and copies of any contracts referenced in such schedules ("AR Mutant Schedule Information"). The Parties shall review, discuss and finalize the TRACON Schedule Letter (as defined in the AR Mutant License Agreement) to be delivered with respect to the AR Mutant License Agreement before the AR Mutant License Agreement becomes effective pursuant to Section 3.3.1 in accordance with the procedures set forth on Exhibit C.

3.2.2.

\*\*\*Confidential Treatment Requested

Missing Information. Janssen shall have [...\*\*\*...] following receipt of a Data Package to notify Licensee in writing if Janssen in good faith believes that any information that is required by the definition of AR Mutant Data Package or NIK Data Package, as applicable, is missing from the Data Package (a "Missing Information Notice"), which Missing Information Notice shall identify with reasonable detail such information that Janssen believes is missing. If Janssen delivers a Missing Information Notice to Licensee, Licensee shall deliver the missing information identified in such Missing Information Notice as soon as practicable and the Data Package will be deemed complete on the date on which all such missing information has been received by Janssen. If Janssen does not deliver a Missing Information Notice to Licensee, the initial Data Package will be deemed complete on the date it was received by Janssen. For purposes of this Agreement, "POC Trial Notice Date" means the date upon which Janssen has received a POC Trial Notice and complete Data Package with respect to a Program in accordance with this Section 3.2.2. For the avoidance of doubt, this Section 3.2.2 does not require Licensee to generate new information or to perform any additional activity not contemplated by the applicable Development Plan, except to the extent

necessary to generate the information that is required to be included in the applicable Data Package.

- 3.2.3. **Updates and Additional Information**. During the [...\*\*\*...] period following the POC Trial Notice Date, Licensee shall: (a) promptly update such Data Package if any new data or information becomes available with respect to the applicable Program; (b) upon Janssen's reasonable request, provide (i) any available patent, regulatory or CMC information in Licensee's Control regarding any Licensed Compound or Licensed Product, (ii) any [...\*\*\*...] and (iii) [...\*\*\*...], in each case ((i), (ii) and (iii)) with respect to such Program; and (c) upon Janssen's reasonable request, afford to Janssen and its representatives reasonable access during normal business hours to Licensee's personnel to discuss such Data Package. If such Data Package relates to the AR Mutant Program, during such period, Licensee shall also provide any update to the AR Mutant Schedule Information.
- 3.2.4. **Interim Data Packages**. From time to time during the Development Term but no more frequently than [... \*\*\*...], Janssen may request, and Licensee shall deliver as soon as reasonably practicable, an interim data package with respect to a Program before delivery of a Data Package with respect to such Program pursuant to Section 3.2.1. Such interim data package will include the same information as a complete Data Package for such Program, but only to the extent such information exists and is available as of the date of Janssen's request. If the requested interim data package relates to the AR Mutant Program, Licensee shall concurrently deliver to Janssen the AR Mutant Schedule Information, but only to the extent such information exists and is available as of the date of Janssen's request. For clarity, such interim data package shall not constitute a Data Package or modify the Parties' rights and obligations under this Section 3.2 or under Section 3.3 or Section 3.4 unless (a) Janssen exercises the Option pursuant to Section 3.3 at any time prior to first availability of the AR Mutant POC Trial Data, in which case the interim data package last delivered with respect to the AR Mutant Program, or (b) Janssen exercises the Right of First Negotiation pursuant to Section 3.4 at any time prior to first availability of the NIK POC Trial Data, in which case the interim Data Package last delivered with respect to the NIK Program shall constitute the Data Package with respect to the NIK Program.

#### 3.3. Exercise and Expiration of Option.

3.3.1.

\*\*\*Confidential Treatment Requested

**Option Exercise**. To exercise the Option, Janssen shall provide Licensee written notice of Janssen's exercise of the Option at any time during the period commencing on [...\*\*\*...] and ending [...\*\*\*...] after the POC Trial Notice Date with respect to the AR Mutant Program (which shall terminate early upon termination of this Agreement in its entirety pursuant to Section 11.2, 11.3 or 11.4 or termination of this Agreement with respect to the AR Mutant Program pursuant to Section 11.2, 11.3 or 11.4); provided, however, [...\*\*\*...] (the "**Option Period**"). If Janssen provides written notice of exercise of the Option on or prior to the expiration of the Option Period, the Option shall be deemed to be exercised on the date such exercise notice is deemed given in accordance with Section 13.11. Following Janssen's exercise of the Option pursuant to

this Section 3.3.1, Licensee shall invoice Janssen for, and Janssen shall pay to Licensee within [...\*\*\*...] after receipt of such invoice (a) a one-time, non-creditable, non-refundable Option exercise fee of \$45,000,000 (the "Option Exercise Fee") and (b) [... \*\*\*...]. Effective upon Licensee's receipt of the Option Exercise Fee and the amounts described in clause (b) (the "Option Exercise Effective Date"): (i) the Development Term of the AR Mutant Program shall terminate, (ii) this Agreement shall expire and be of no further force and effect with respect to the AR Mutant Program (for clarity, the AR Mutant Program shall not be a Terminated Program), and (iii) the AR Mutant License Agreement shall automatically, with no further action by either Party, go into full force and effect. Upon Janssen's request, each Party shall execute and deliver to the other Party the AR Mutant License Agreement; provided, however, that any delay or failure to execute or deliver the AR Mutant License Agreement shall not affect whether or when the AR Mutant License Agreement went into full force and effect pursuant to this Section 3.3.1. Notwithstanding the foregoing, (x) Licensee shall complete in a timely manner after the Option Exercise Effective Date any [...\*\*\*...] that were not completed before the Option Exercise Effective Date and (y) Janssen shall [...\*\*\*...] within [...\*\*\*...] after receipt of invoice from Licensee.

3.3.2. **Option Expiration**. If (i) Janssen does not exercise the Option in accordance with Section 3.3.1 on or prior to the expiration of the Option Period, then upon the day immediately after the last day of the Option Period or (ii) Janssen does not make the payments to Licensee required by Section 3.3.1 within [...\*\*\*...] after receipt of invoice from Licensee, then upon the day immediately after the last day of such [...\*\*\*...] period, in either case without any further action on the part of either Party: (a) the Option shall expire and be of no further force or effect; (b) the Development Term of the AR Mutant Program shall terminate; (c) Article 4, Article 5 (other than Sections 5.2 and 5.3) and Article 6, and Sections 7.4.2, 7.6, 7.7, 7.8, 11.5 and 11.6.4 shall become effective with respect to the AR Mutant Program; and (d) Sections 2.1.1(a), 2.1.2, 2.2, 2.3, 2.4, 3.1, 3.2, 3.3.1, 8.1.2, 9.5.1, 11.2 and 11.6.1 shall terminate and be of no further force or effect with respect to the AR Mutant Program.

#### 3.3.3. Merger Control Law Compliance.

(a) As promptly as practicable following the POC Trial Notice Date, Janssen and Licensee shall reasonably cooperate to determine whether any filing or notification is necessary or advisable under any applicable Antitrust Law (a) with respect to the AR Mutant Program, if Janssen were either to exercise or not exercise the Option and (b) with respect to the NIK Program, if the Parties were or were not to enter into a Janssen NIK License Agreement.

(b)

\*\*\*Confidential Treatment Requested

If the Parties determine that such a filing or notification under any applicable Antitrust Law is necessary or advisable, then each Party shall make or cause to be made such notifications and filings as promptly as practicable (but in any event within [...\*\*\*...]) after (i) with respect to the AR Mutant Program, Janssen exercises the Option, and (ii) with respect to the NIK Program, the Parties enter into a NIK Program License Agreement.

- (c) Each Party shall be responsible for its own costs and expenses associated with such notifications and filings. If Janssen exercises the Option or ROFN, Janssen shall pay any applicable premerger filing fee under the HSR Act with respect to the relevant Program. Each Party shall use Commercially Reasonable Efforts to obtain the expiration or termination of the applicable waiting period under the HSR Act, and to obtain the termination or expiration of any other applicable waiting periods or any necessary approvals or consents under any other applicable Antitrust Law, at the earliest possible date after the date of filing.
- (d) If Janssen exercises the Option, the Option Exercise Effective Date shall be deemed to be delayed until the date on which the last waiting period under any applicable Antitrust Law has expired or been terminated or on which the last approval or consent under such Antitrust Law is granted.
- (e) Notwithstanding anything to the contrary in this Section 3.3.3, this Section 3.3.3 does not require that either Party (i) offer, negotiate, commit to or effect, by consent decree, hold separate order, trust or otherwise, the sale, divestiture, license or other disposition of any capital stock, assets, rights, products or businesses of Janssen, Licensee or their respective Affiliates, (ii) agree to any restrictions on the activities of Janssen, Licensee or their respective Affiliates, or (iii) pay any material amount or take any other action to prevent, effect the dissolution of, vacate, or lift any decree, order, judgment, injunction, temporary restraining order, or other order in any suit or proceeding that would otherwise have the effect of preventing or delaying any of the transactions contemplated by exercise of the Option or entry into a Janssen NIK License Agreement.

## 3.4. <u>NIK Program Right of First Negotiation</u>.

- 3.4.1. **Grant of ROFN**. Subject to the terms and conditions of this Agreement, Licensee hereby grants, on behalf of itself and its Affiliates, to Janssen an exclusive right of first negotiation with respect to the NIK Program on the terms set forth in this Section 3.4.1 (the "**Right of First Negotiation**" or "**ROFN**").
  - (a) Janssen may in its sole discretion elect to exercise its Right of First Negotiation by written notice of exercise delivered to Licensee at any time on or before the ROFN Exercise Deadline.

(b)

\*\*\*Confidential Treatment Requested

To exercise the Right of First Negotiation, Janssen shall give Licensee written notice of such exercise no later than the ROFN Exercise Deadline (the "ROFN Exercise Notice"). Upon Janssen's timely exercise of the ROFN in accordance with this Section 3.4, Janssen and Licensee shall negotiate in good faith on an exclusive basis for up to [...\*\*\*...] from the date the ROFN Exercise Notice is deemed given in accordance with Section 13.11 (the "Negotiation Period") a separate written agreement pursuant to which Licensee would grant Janssen exclusive (even as to Licensee) license under the Licensee NIK Program Technology to make, have made, use, have used, import, have imported, sell, have sold, offer for sale and have offered for sale NIK Compounds and NIK

Products in the Field in the Territory on commercially reasonable terms (a "Janssen NIK License Agreement"). The Negotiation Period may be extended by mutual agreement of Janssen and Licensee, such agreement to be given, withheld or conditioned by a Party in its sole discretion.

- In the event that Janssen exercises its Right of First Negotiation but the Parties do not enter into a (c) Janssen NIK License Agreement within the Negotiation Period, Licensee may thereafter negotiate with Third Parties to enter into a Third Party NIK Program Agreement, take any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party or engage in discussions with any Third Party relating to a Third Party NIK Program Agreement, and enter into a Third Party NIK Program Agreement without further obligation to Janssen under this Section 3.4.1; provided, however, that during the [...\*\*\*...] period immediately following the last day of the Negotiation Period (the "Tail Period"), Licensee may enter into a Third Party NIK Program Agreement only if the following conditions are satisfied: (i) Licensee has not provided to the applicable Third Party any material information regarding the NIK Program other than the information provided by Licensee to Janssen pursuant to Section 3.2 before or during the Negotiation Period (the "Additional NIK Program Information"); and (ii) [...\*\*\*...]; and Licensee may not enter into any Third Party NIK Program Agreement that does not satisfy either condition set forth in clause (i) or (ii) (a "Restricted Third Party NIK **Program Agreement**"), unless Licensee complies with the remainder of this Section 3.4.1(c). Prior to entering into a Restricted Third Party NIK Program Agreement, Licensee shall provide Janssen with a written notice of Licensee's intent to enter into such agreement, which notice shall include any Additional NIK Program Information and [...\*\*\*...]. Janssen shall have [...\*\*\*...] following receipt of such notice to propose an offer of [...\*\*\*...]. If Janssen proposes such an offer within such [...\*\*\*...] period, then the Parties shall negotiate in good faith and seek to enter into a Janssen NIK License Agreement on such terms proposed by Janssen for [... \*\*\*...] after Janssen proposes such offer. If (x) Janssen does not propose such an offer within such [...\*\*\*...] period or (y) the Parties do not enter into a Janssen NIK License Agreement within [...\*\*\*...] after Janssen proposes such an offer, then Licensee shall have no further obligations to Janssen under this Section 3.4. For purposes of this Section 3.4.1(c), [...\*\*\*...].
- (d) If the Parties enter into a Janssen NIK License Agreement, immediately prior to the effective date of such Janssen NIK License Agreement: (i) the Development Term of the NIK Program shall terminate; and (ii) this Agreement shall expire and be of no further force and effect with respect to the NIK Program (for clarity, the NIK Program shall not be a Terminated Program).

3.4.2.

\*\*\*Confidential Treatment Requested

**No Effect on Other Janssen Rights or Licensee Obligations**. For clarity, the provisions of this Section 3.4 are not intended to (a) prohibit or restrict Janssen from making proposals and offers to Licensee at any time (including after the ROFN Period) relating to a potential Janssen NIK License Agreement; (b) modify any of Licensee's obligations under the other applicable provisions of this Agreement (including Sections

2.3 and 2.4); or (c) obligate either Party to enter into any Janssen NIK License Agreement.

#### 3.4.3. **ROFN Expiration**.

- (a) If Janssen does not exercise the ROFN in accordance with Section 3.4.1 on or prior to the ROFN Exercise Deadline, then upon the day immediately after the ROFN Exercise Deadline, without any further action on the part of either Party: (i) the ROFN shall expire and be of no further force or effect; (ii) the Development Term of the NIK Program shall terminate; (iii) Article 4, Article 5 (other than Sections 5.2 and 5.3) and Article 6, and Sections 7.4.2, 7.6, 7.7, 7.8, 11.5 and 11.6.4 shall become effective with respect to the NIK Program; and (iv) Sections 2.1.1(b), 2.1.2, 2.2, 2.3, 2.4, 3.1, 3.2, 3.3.1, 8.1.2, 9.5.1, 11.2 and 11.6.1 shall terminate and be of no further force or effect with respect to the NIK Program.
- (b) If Janssen exercises the ROFN in accordance with Section 3.4.1 on or prior to the ROFN Exercise Deadline, but the Parties do not execute a Janssen NIK License Agreement on or prior to the expiration of the Negotiation Period, then upon the day immediately after the last day of the Negotiation Period, without any further action on the part of either Party: (i) the ROFN shall expire and be of no further force or effect, *provided* that Section 3.4.1(c) shall survive for the time period set forth therein; (ii) the Development Term of the NIK Program shall terminate; (iii) Article 4, Article 5 (other than Sections 5.2 and 5.3) and Article 6, and Sections 7.4.2, 7.6, 7.7, 7.8, 11.5 and 11.6.4 shall become effective with respect to the NIK Program; and (iv) Sections 2.1.1(b), 2.1.2, 2.2, 2.3, 2.4, 3.1, 3.2, 3.3.1, 8.1.2, 9.5.1, 11.2 and 11.6.1 shall terminate and be of no further force or effect with respect to the NIK Program.

## Article 4 ACTIVITIES AFTER DEVELOPMENT TERM

#### 4.1. General.

- 4.1.1. With respect to the AR Mutant Program, the provisions of this Article 4 shall apply to the AR Mutant Program, and Licensed Compounds and Licensed Products with respect to the AR Mutant Program, during the License Term of the AR Mutant Program if, and only if, the Option expires in accordance with Section 3.3.2. With respect to the AR Mutant Program, the "License Term" means the period beginning immediately after the date of expiration of the Option in accordance with Section 3.3.2 and ending on the expiration of the Term with respect to the AR Mutant Program, unless terminated earlier in accordance with Article 11.
- 4.1.2. With respect to the NIK Program, the provisions of this Article 4 shall apply to the NIK Program, and Licensed Compounds and Licensed Products with respect to the NIK Program, during the License Term of the NIK Program if, and only if, the ROFN expires in accordance with Section 3.4.3. With respect to the NIK Program, the "License

**Term**" means the period beginning immediately after the last day of the ROFN Period and ending on the expiration of the Term with respect to the NIK Program, unless terminated earlier in accordance with Article 11.

## 4.2. **Development**.

- 4.2.1. **General**. Licensee shall have the sole right and responsibility, at its sole cost and expense, to Develop Licensed Compounds and Licensed Products in the Field in the Territory, and for all regulatory matters relating to such activities. Licensee will conduct such Development activities in accordance with the terms and conditions of this Agreement, in good scientific manner and in compliance with all Applicable Laws.
- 4.2.2. **Diligence.** Licensee shall use Commercially Reasonable Efforts to [...\*\*\*...].
- 4.2.3. **Records.** Licensee shall prepare and maintain, and shall cause its Affiliates, sublicensees and Third Party Subcontractors to prepare and maintain, complete and accurate Program Records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in conformity with Applicable Law and Licensee's standard practices, which Program Records shall reflect all work done and results achieved in connection with the Programs. Licensee shall retain, and cause its Affiliates, sublicensees and Third Party Subcontractors to retain, the Program Records for at least [...\*\*\*...] or such longer period as may be required by Applicable Law. In addition, Licensee shall comply with Janssen's data policies set forth on Exhibit B with respect to the Program Records.
- 4.2.4. **Reports**. Licensee shall provide Janssen with a written summary of its progress with respect to the Development of Licensed Compounds and Licensed Products in the Field in the Territory [...\*\*\*...], including the [... \*\*\*...]. Upon Janssen's reasonable request, Licensee shall be available for an in-person or telephonic meeting to discuss its progress on the Development of the Licensed Compounds and Licensed Products with Janssen.
- 4.3. **Manufacturing**. Licensee shall have the sole right and responsibility, at its sole cost and expense, to Manufacture clinical and commercial supplies of Licensed Compounds and Licensed Products. Licensee will conduct such Manufacturing activities in accordance with the terms and conditions of this Agreement and in compliance with all Applicable Laws.

#### 4.4. **Commercialization**.

4.4.1. **General**. Licensee shall have the sole right and responsibility, at its sole cost and expense, to Commercialize Licensed Compounds and Licensed Products in the Field in the Territory. Licensee will conduct such Commercialization activities in accordance with the terms and conditions of this Agreement and in compliance with all Applicable Laws.

4.4.2.

\*\*\*Confidential Treatment Requested

Diligence. Licensee shall use Commercially Reasonable Efforts to Commercialize [...\*\*\*...].

### Article 5 LICENSE GRANTS

#### 5.1. **General**.

- 5.1.1. With respect to the AR Mutant Program, the provisions of this Article 5 (other than Sections 5.2 and 5.3) shall apply to the AR Mutant Program, and Licensed Compounds and Licensed Products with respect to the AR Mutant Program, during the License Term of the AR Mutant Program if, and only if, the Option expires in accordance with Section 3.3.2. Sections 5.2 and 5.3 shall apply to the AR Mutant Program during the Term of the AR Mutant Program.
- 5.1.2. With respect to the NIK Program, the provisions of this Article 5 (other than Sections 5.2 and 5.3) shall apply to the NIK Program, and Licensed Compounds and Licensed Products with respect to the NIK Program, during the License Term of the NIK Program if, and only if, the ROFN expires in accordance with Section 3.4.3. Sections 5.2 and 5.3 shall apply to the NIK Program during the Term of the NIK Program.
- 5.2. License Grant. Subject to the terms and conditions of this Agreement (including Section 5.3), during the Term with respect to a Program, Janssen hereby grants to Licensee an exclusive (subject to Section 5.3), royalty-bearing, non-transferable (except to the extent permitted under Section 13.6), sublicensable through multiple tiers of sublicense (subject to Section 5.4) license under the Licensed Technology with respect to such Program to make, have made, use, have used, import, have imported, sell, have sold, offer for sale and have offered for sale Licensed Compounds and Licensed Products with respect to such Program in the Field in the Territory. Subject to the terms and conditions of this Agreement (including Section 5.3), during the Term with respect to the AR Mutant Program, Janssen hereby grants to Licensee an exclusive (subject to Section 5.3), royalty-free, non-transferable (except to the extent permitted under Section 13.6), sublicensable through multiple tiers of sublicense (subject to Section 5.4) license under the Patent Rights set forth on Schedule AR Mutant Diagnostic Patent of the Schedule Letter to make, have made, use, have used, import, have imported, sell, have sold, offer for sale and have offered for sale companion diagnostic products solely for use with AR Mutant Compounds and AR Mutant Products Developed or Commercialized by Licensee pursuant to this Agreement in the Field in the Territory. Licensee covenants and agrees not to exercise any of its rights under this Section 5.2 with respect to a Program unless and until the License Term of such Program begins; provided that this provision shall not limit Licensee's ability to exercise its rights under and in accordance with Article 2.

#### 5.3. **Janssen Retained Rights**. Licensee acknowledges and agrees that:

5.3.1. Janssen and its Affiliates (i) retain the right to use the Licensed Technology and the Patent Rights set forth on Schedule AR Mutant Diagnostic Patent of the Schedule Letter to make, have made, use, have used, import and have imported Licensed Compounds and Licensed Products solely to conduct Internal Research with Licensed Compounds or Licensed Products and (ii) shall not be obligated to remove any Licensed Compound from its compound libraries that are used for Internal Research; and

- 5.3.2. Janssen and its Affiliates may use for any purpose (other than those purposes for which Licensee is granted an exclusive license pursuant to Section 2.1.1 or Section 5.2) any information in non-tangible and non-recorded (whether in written, electronic, visual or other media) form which may be retained in the unaided memory of any personnel of Janssen or its Affiliates who had access to the Licensed Compounds, Licensed Products, Licensed Technology and the Patent Rights set forth on Schedule AR Mutant Diagnostic Patent of the Schedule Letter prior to the Effective Date; *provided, however*, that the foregoing is not intended to grant, and shall not be deemed to grant, any right to disclose such information to any Third Party.
- 5.4. <u>Sublicensing</u>. During the Development Term of a Program, Licensee may not sublicense to any Third Party or any of its Affiliates any of the rights granted to it by Janssen under Section 5.2 with respect to such Program. During the License Term of a Program, Licensee may sublicense to any Third Party or any of its Affiliates the rights granted to it by Janssen under Section 5.2 with respect to such Program. Any such sublicense shall (i) be in writing, and (ii) be subject to, and consistent with, the terms of this Agreement. Licensee shall provide Janssen with a true and complete copy of each such sublicense and all amendments thereto within [...\*\*\*...] after execution thereof. Licensee shall remain responsible to Janssen for the performance of the financial and other obligations of its sublicensees.

#### 5.5. License Term Exclusivity.

- 5.5.1. During the period beginning on the first day of the License Term with respect to a Program and ending [... \*\*\*...] after such day, neither Licensee nor any of its Affiliates shall: [...\*\*\*...].
- 5.5.2. Notwithstanding the foregoing:
  - (a) Section 5.5.1 does not prohibit Licensee and its Affiliates that are subject to Section 5.5.1, alone or through work conducted in collaboration with an Affiliate or Third Party, from conducting research and non-clinical development (or licensing or otherwise granting rights to an Affiliate or a Third Party to conduct research and non-clinical development) of compounds (other than Licensed Compounds) that (i) [...\*\*\*...].

(b)

\*\*\*Confidential Treatment Requested

Section 5.5.1 shall not apply to the Acquirer of a Party or any Affiliate of such Acquirer (excluding any Affiliate that was an Affiliate of such Party prior to a Change of Control and became an Affiliate of such Acquirer as a result of such Change of Control), provided that, if the Acquirer or such Affiliate conducts any activities described in Section 5.5.1 during the period described in Section 5.5.1 (the "Post-Development Term Acquirer Activities"), such Acquirer or Affiliate shall use reasonable good faith efforts to segregate such Post-Development Term Acquirer Activities from activities conducted with respect to the Licensed Compounds and Licensed Products pursuant to this Agreement, including by (x) not permitting personnel who perform the Post-Development Term Acquirer Activities to have access to Program-Related Information or other Confidential Information of the other Party (including Know-How and proprietary

Development or Commercialization plans or other business information); and (y) not permitting personnel who perform activities conducted with respect to the Licensed Compounds and Licensed Products pursuant to this Agreement to perform Post-Development Term Acquirer Activities (*provided* that the foregoing shall not apply to senior management and regulatory, chemistry-manufacturing-controls, patent, legal and other similar personnel).

(c) Licensee shall not be limited or prohibited by Section 5.5.1 from negotiating and completing a Change of Control, or taking any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party relating to, or engage in discussions with any Third Party relating to, a Change of Control.

## Article 6 FINANCIAL TERMS

#### 6.1. **General**.

- 6.1.1. With respect to the AR Mutant Program, the provisions of this Article 6 shall apply to the AR Mutant Program, and Licensed Compounds and Licensed Products with respect to the AR Mutant Program, during the License Term for such Program if, and only if, the Option expires in accordance with Section 3.3.2.
- 6.1.2. With respect to the NIK Program, the provisions of this Article 6 shall apply to the NIK Program, and Licensed Compounds and Licensed Products with respect to the NIK Program, during the License Term of the NIK Program if, and only if, the ROFN expires in accordance with Section 3.4.3.
- 6.2. <u>Milestones</u>. Licensee will notify Janssen in writing within [...\*\*\*...] after the first achievement by Licensee or any of its Affiliates or sublicensees of any of the milestone events set forth in the table below with respect to a Program (each, a "Milestone Event"). In consideration of the licenses and rights granted to Licensee under this Agreement, Licensee shall pay to Janssen the applicable milestone payment set forth in the table below (each, a "Milestone Payment") within [...\*\*\*...] after receipt of an invoice from Janssen with respect to achievement of each Milestone Event. Each Milestone Payment shall be made only once, and shall be non-refundable and non-creditable.
  - 6.2.1. With respect to the AR Mutant Program:

Milestone Event	Milestone Payment
A. [***]	\$[***]
B. [***]	\$[***]

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[...\*\*\*...]

### 6.2.2. With respect to the NIK Program:

Milestone Event	Milestone Payment
C. [***]	\$[***]
D. [***]	\$[***]
E. [***]	\$[***]

[...\*\*\*...]

## 6.3. **Royalties**.

## 6.3.1. **Royalty Rates**.

- (a) In consideration of the licenses and rights granted to Licensee under this Agreement with respect to the AR Mutant Program, Licensee shall pay to Janssen a royalty of [...\*\*\*...] on Net Sales of each AR Mutant Product in each country during the Royalty Term for such AR Mutant Product in such country.
- (b) In consideration of the licenses and rights granted to Licensee under this Agreement with respect to the NIK Program, Licensee shall pay to Janssen a royalty of [...\*\*\*...] on Net Sales of each NIK Product in each country during the Royalty Term for such NIK Product in such country.

## 6.3.2. **Royalty Reductions**.

(a) Licensee shall be responsible for the payment of any amounts that become due to any Third Party(ies) under any Janssen License Agreement as a result of Licensee's activities with respect to the Licensed Compounds or Licensed Products under this Agreement during the applicable License Term, only to the extent [...\*\*\*...]. In the event Janssen makes any such payment to a Third Party, Licensee shall reimburse Janssen for such amount.

(b)

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If Licensee or its Affiliate or sublicensee is required or reasonably deems it necessary to obtain a license from a Third Party under any intellectual property rights of such Third Party that [...\*\*\*...], Licensee shall have the right to deduct, from the royalties due to Janssen pursuant to Section 6.3.1 with respect to a Licensed Product containing such Licensed Compound during a Calendar Quarter, [...\*\*\*...] of the [...\*\*\*...] payments made by Licensee or its Affiliate or sublicensee to such Third Party(ies) in exchange for such license with respect to such Licensed Compound during such Calendar Quarter, *provided* that if any agreement with such Third Party includes rights to additional compounds or products other than such Licensed Compound, any such payment that is not triggered by sales of such Licensed Product containing such Licensed Compound

shall be equitably allocated by Licensee in good faith among all compounds and products under such agreement. Licensee shall provide documentation of such allocation to Janssen and any dispute regarding such allocation shall be subject to resolution under Article 12.

- (c) On a country-by-country and Licensed Product-by-Licensed Product basis, the royalties due to Janssen pursuant to Section 6.3.1 shall be reduced during the Royalty Term for such Licensed Product in such country to [...\*\*\*...] of the amount otherwise payable from and after the date that: (i) [...\*\*\*...].
- (d) Notwithstanding the foregoing, in no event shall the total deductions under Sections 6.3.2(b) and 6.3.2(c) reduce the royalties payable to Janssen under Section 6.3.1 with respect to a given Licensed Product in a given country in any Calendar Quarter by more than [...\*\*\*...].
- 6.3.3. **Royalty Reports and Payments.** Commencing with the First Commercial Sale of a Licensed Product by Licensee or its Affiliates or sublicensees, Licensee shall provide written reports to Janssen within [...\*\*\*...] after the end of each Calendar Quarter, stating in each such report, by Licensed Product and by country, the aggregate Net Sales in U.S. Dollars of Licensed Products sold during such Calendar Quarter by Licensee and its Affiliates and sublicensees. Such report shall also include: (a) the calculation of the royalty payments due to Janssen on such Net Sales; and (b) the exchange rates used in calculating the payments due Janssen, which exchange rates shall comply with Section 6.4.2. Simultaneously with the delivery of each such report, Licensee shall pay to Janssen the total royalties, if any, due to Janssen for the Calendar Quarter that is the subject of such report. If no royalties are due with respect to a particular Calendar Quarter, Licensee shall so report.

## 6.4. **Payment Terms**.

- 6.4.1. **Payments.** All payments due under this Agreement shall be made in U.S. Dollars by wire transfer in immediately available funds to an account designated by the receiving Party or by other mutually acceptable means.
- 6.4.2. **Currency Conversion.** The rate of exchange to be used in computing the amount of currency equivalent in U.S. Dollars of Net Sales invoiced in other currencies shall be consistent with Licensee's internal accounting practices used to prepare its audited financial statements.
- 6.4.3. **Late Payments.** If a Party does not receive payment of any amount due to it under this Agreement on or before the due date, such payment shall bear interest at a rate per annum equal to [...\*\*\*...] in excess of overnight LIBOR or a comparable reference interbank rate per currency or the maximum rate allowable by Applicable Law, whichever is lower.

6.5.

\*\*\*Confidential Treatment Requested

Records; Inspection. Licensee shall keep (and cause its Affiliates and sublicensees to keep) complete, true and accurate books of account and records for the purpose of determining the royalties payable by Licensee to Janssen under Section 6.3 (the "Royalty Records"), which

Royalty Records shall be retained for at least [...\*\*\*...] following the end of the Calendar Year to which they pertain. Licensee shall, and shall cause its Affiliates and sublicensees to, make the Royalty Records available for inspection by an independent public accounting firm of national prominence selected by Janssen, and reasonably acceptable to Licensee, during normal business hours, as may be reasonably necessary for the sole purpose of verifying the royalty reports and payments delivered by Licensee pursuant to Section 6.3 during the preceding [...\*\*\*...] full Calendar Years. The records for a given Calendar Year shall be subject to audit no more than one time. Such independent public accounting firm shall execute a reasonable confidentiality agreement with Licensee prior to commencing any such inspection. Such inspections shall be made no more than once each Calendar Year at reasonable times and on reasonable notice. Janssen shall bear the costs and expenses of any inspection conducted under this Section 6.5 unless such inspection reveals an underpayment in royalties payable pursuant to Section 6.3 of more than [...\*\*\*...] of the amount payable for the period covered by such inspection, in which case Licensee shall bear the costs and expenses of such inspection. If such inspection reveals an overpayment by Licensee pursuant to Section 6.3, then Licensee shall deduct the amount of such overpayment from any payment that subsequently becomes due and payable by Licensee under this Agreement or, if no payment is anticipated to be due and payable by Licensee in the following Calendar Quarter, Licensee shall invoice Janssen for the amount of the underpayment and Janssen shall pay such invoice within [...\*\*\*...] after receipt thereof. If such inspection reveals an underpayment by Licensee pursuant to Section 6.3, then Janssen shall invoice Licensee for the amount of the underpayment and Licensee shall pay such invoice within [...\*\*\*...] after receipt thereof.

## 6.6. Withholding Taxes.

- 6.6.1. Licensee will make all payments to Janssen under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.
- 6.6.2. Any Tax required to be withheld on amounts payable under this Agreement will be paid by Licensee on behalf of Janssen to the appropriate governmental authority, and Licensee will furnish Janssen with proof of payment of such Tax. Any such Tax required to be withheld will be an expense of and borne by Janssen.
- 6.6.3. Licensee and Janssen will cooperate with respect to all documentation required by any taxing authority or reasonably requested by Licensee to secure a reduction in the rate of applicable withholding Taxes. On the date of execution of this Agreement, Janssen will deliver to Licensee an accurate and complete Internal Revenue Service Form W-8BEN-E certifying that Janssen is entitled to the applicable benefits under the Income Tax Treaty between the Kingdom of Belgium and the United States.

# Article 7 INTELLECTUAL PROPERTY

7.1.

\*\*\*Confidential Treatment Requested

Reporting of Development Program Inventions. Each Party shall designate a patent attorney or agent as its contact to coordinate with the other Party the filing, prosecution and maintenance of Patent Rights as provided in this Article (the "Patent Representative"). Each

Party shall promptly report to the other Party's Patent Representative any material Development Program Invention.

#### 7.2. **Ownership.**

- 7.2.1. **Development Program Inventions and other Development Program Know-How.** Ownership in the Territory of Development Program Inventions and Patent Rights filed after the Effective Date claiming one or more Development Program Inventions (each, a "**Development Program Patent**") shall be allocated in accordance with inventorship as determined pursuant to principles of United States patent law as follows:
  - (a) each Development Program Invention invented solely by one or more employees or agents of Janssen (or its Affiliates or Third Party Subcontractors) and each Development Program Patent to the extent claiming one or more of such Development Program Inventions shall be owned solely by Janssen;
  - (b) each Development Program Invention invented solely by one or more employees or agents of Licensee (or its Affiliates or Third Party Subcontractors) and each Development Program Patent to the extent claiming one or more of such Development Program Inventions shall be owned solely by Licensee; and
  - (c) each Development Program Invention invented jointly by one or more employees or agents of Janssen (or its Affiliates or Third Party Subcontractors) and one or more employees or agents of Licensee (or its Affiliates or Third Party Subcontractors) and each Development Program Patent to the extent claiming one or more of such Development Program Inventions shall be owned jointly by the Parties.

For purposes of this Agreement: (w) Development Program Know-How which is the basis for a Development Program Invention upon the filing of a Development Program Patent therefor will be the Confidential Information of the owner(s) of such Development Program Patent; (x) each Development Program Patent that is owned solely by Janssen pursuant to this Section 7.2.1 shall be referred to as a "Janssen-Owned Development Program Patent;" (y) each Development Program Patent that is owned solely by Licensee pursuant to this Section 7.2.1 shall be referred to as a "Licensee-Owned Development Program Patent," and (z) each Development Program Patent that is owned jointly by the Parties pursuant to this Section 7.2.1 shall be referred to as a "Joint Development Program Patent." Any Development Program Know-How generated by Janssen's or its Affiliates' or Third Party Subcontractors' employees or agents that is not otherwise allocated pursuant to Section 7.2.1(a), (b) or (c) will be the Confidential Information of Janssen ("Janssen-Owned Development Program Know-How"). Any Development Program Know-How generated by Licensee's or its Affiliates' or Third Party Subcontractors' employees or agents that is not otherwise allocated pursuant to Section 7.2.1(a), (b) or (c) will be the Confidential Information of Licensee ("Licensee-Owned Development Program Know-How").

- 7.2.2. Other Inventions. Ownership of any invention arising from any activities with respect to Licensed Compounds and/or Licensed Products conducted by a Party's or its Affiliates' or Third Party Subcontractors' employees or agents as contemplated by this Agreement (but excluding any Third Party Subcontractor Reserved Technology to the extent not assigned or licensed to a Party as contemplated by Section 2.2.3(e)), other than a Development Program Invention (each an "Other Invention"), and Patent Rights filed after the Effective Date claiming one or more Other Inventions, other than a Development Program Patent (each, an "Other Patent") shall follow inventorship as determined pursuant to principles of United States patent law. Accordingly, (a) all Other Inventions invented solely by one or more employees or agents of a Party (or its Affiliates or Third Party Subcontractors) and Other Patents to the extent claiming such Other Inventions shall be owned solely by such Party and (b) all Other Inventions invented jointly by one or more employees or agents of one Party (or its Affiliates or Third Party Subcontractors) and by one or more employees or agents of the other Party (or its Affiliates or Third Party Subcontractors) and Other Patents to the extent claiming such Other Inventions shall be owned jointly by the Parties. For clarity, if any Development Program Patent includes any claim Covering any Other Invention, such Patent Right shall remain a Development Program Patent subject to the terms hereof. Other Inventions and Other Patents solely owned by Janssen and Janssen's interest in Other Inventions and Other Patents jointly owned by Janssen and Licensee shall be included in AR Mutant Program Know-How, AR Mutant Program Patents, NIK Program Know-How or NIK Program Patents, as applicable. Other Inventions and Other Patents solely owned by Licensee and Licensee's interest in Other Inventions and Other Patents jointly owned by Janssen and Licensee shall be included in Licensee Program Know-How or Licensee Program Patents, as applicable.
- 7.2.3. Confirmatory Assignments; Inventor Compensation. Each Party shall take all reasonable actions requested by the other Party responsible for prosecuting any Development Program Patent to perfect or separately document the other Party's ownership interest rights in such Development Program Patent as provided for in this Agreement, including by causing its and its applicable Affiliates' and Third Party Subcontractors' employees and agents to execute appropriate assignment documents, and the requesting Party shall not be required to pay any remuneration to the other Party or its Affiliates or Third Party Subcontractors, or any of their employees, or agents, for the execution of any assignments or other papers pursuant to this Section. For clarity, each Party (directly or through its applicable Affiliate or Third Party Subcontractors) shall be solely responsible for any compensation due to its and its Affiliates' and Third Party Subcontractors' employees and agents in connection with the assignment of their respective rights to any Development Program Inventions and associated Development Program Patents pursuant to this Agreement or the exploitation of any Party or its Affiliates or Third Party sublicensees hereunder of any such Development Program Inventions or associated Development Program Patents with respect to Licensed Compounds or Licensed Products, including any required by operation of Applicable Law on account of any Commercialization of any such Development Program Inventions with respect to Licensed Compounds or Licensed Products hereunder.

7.2.4. **Right to Practice Jointly Owned Technology**. Except to the extent either Party is restricted by the express terms of this Agreement, with respect to any Development Program Inventions, Development Program Patents, Other Inventions and Other Patents that are owned jointly by the Parties pursuant to Section 7.2.1 or 7.2.2, each Party shall have the right to practice and exploit such Development Program Inventions, Development Program Patents, Other Inventions and Other Patents, with full rights to sublicense in the Territory, and without the duty of accounting to or any duty to seek consent from the other Party, and upon the reasonable request of either Party, the other Party shall execute documents that evidence or confirm the requesting Party's right to engage in such activities.

#### 7.3. **Prosecution of Patent Rights.**

- 7.3.1. **Communications.** Each Party shall use reasonable efforts to handle all communications between the Parties under this Section 7.3 through their Patent Representatives and keep such communications in strict confidence to protect their attorney-client privileged status.
- 7.3.2. **Reporting of Filings.** A Party planning on filing any priority-establishing or original (in each case, with respect to any claims or new matter described in the patent specification) patent application within the Development Program Patents hereunder shall use reasonable efforts to provide to the other Party with reasonable advance time prior to proposed prosecution filing in a patent office (such as a draft application or response to an official action), provide the other Party an opportunity to comment thereon through its Patent Representative, and give good faith consideration to the other Party's comments. Each Party shall provide to the other, promptly after filing, a copy of each priority-establishing or original (whether provisional or non-provisional) patent application within the Development Program Patents as filed in the patent office and each other substantive prosecution filing (including any other patent application filed within the Development Program Patents).

#### 7.3.3. Prosecution Responsibility and Coordination.

- (a) Janssen Program Patents and Janssen-Owned Development Program Patents During the Development Term. With respect to the Janssen Program Patents and Janssen-Owned Development Program Patents, during the Development Term for a Program:
  - (1) Janssen shall be primarily responsible, through outside patent counsel mutually acceptable to the Parties and engaged by both Parties, to prosecute AR Mutant Program Patents and Janssen-Owned Development Program Patents with respect to the AR Program, *provided* that Janssen shall: (i) consider the reasonable suggestions of Licensee's Patent Representative as to selection of country patent offices in the Territory for filing or validating applications to form a family of related such Patent Rights and as to the abandonment of any such Patent Rights; and (ii) consider in good faith any reasonable comments of Licensee as

provided by its designated Patent Representative in prosecuting any such Patent Rights, including with respect to the filing of any continuation, divisional or other continuing applications.

- Licensee shall be primarily responsible, through outside patent counsel mutually acceptable to the Parties and engaged by both Parties, to prosecute NIK Program Patents and Janssen-Owned Development Program Patents with respect to the NIK Program, *provided* that Licensee shall: (i) consider the reasonable suggestions of Janssen's Patent Representative as to selection of country patent offices in the Territory for filing or validating applications to form a family of related such Patent Rights and as to the abandonment of any such Patent Rights; and (ii) consider in good faith any reasonable comments of Janssen as provided by its designated Patent Representative in prosecuting any such Patent Rights, including with respect to the filing of any continuation, divisional or other continuing applications.
- (b) Janssen Program Patents and Janssen-Owned Development Program Patents During the License Term. With respect to the Janssen Program Patents and Janssen-Owned Development Program Patents, during the License Term for a Program, Licensee shall be primarily responsible, through outside patent counsel mutually acceptable to the Parties and engaged by both Parties, to prosecute such Patent Rights with respect to a Program, provided that Licensee shall: (i) consider the reasonable suggestions of Janssen's Patent Representative as to selection of country patent offices in the Territory for filing or validating applications to form a family of related such Patent Rights and as to the abandonment of any such Patent Rights; and (ii) consider in good faith any reasonable comments of Janssen as provided by its designated Patent Representative in prosecuting any such Patent Rights, including with respect to the filing of any continuation, divisional or other continuing applications.
- (c) Duties Imposed by Law. Sections (a) and (b) of this Section 7.3.3 notwithstanding, it will not be a breach of this Agreement that a Party, in good faith, does not execute a document or withholds or revokes consent to an action in the course of filing, prosecuting or maintaining a Patent Right hereunder that such Party reasonably believes to violate a duty imposed by law on such Party as the owner of such a Patent Right.
- (d) Prosecution Costs for Janssen Program Patents and Janssen-Owned Development Program Patents. Subject to Section 7.3.3(h), Janssen shall be solely responsible for (i) all Patent Costs incurred in prosecuting any Janssen Program Patents on or before the Effective Date and (ii) all Patent Costs incurred by or on behalf of Janssen in prosecuting any Janssen Program Patents or Janssen-Owned Development Program Patents with respect to the AR Mutant Program during the Development Term with respect to the AR Mutant Program. Subject to Section 7.3.3(h), Licensee shall be solely responsible for all Patent Costs incurred in prosecuting (x) any Janssen Program Patents or Janssen-Owned Development

Program Patents with respect to the NIK Program during the Development Term with respect to the NIK Program and (y) any Janssen Program Patents or Janssen-Owned Development Program Patents with respect to a Program during the License Term with respect to such Program.

- (e) Janssen Covenant. Janssen and its Affiliates will not [...\*\*\*...],
- Licensee Program Patents, Licensee-Owned Development Program Patents, Joint Development Program Patents and Jointly Owned Other Patents. Licensee shall be primarily responsible, through outside patent counsel mutually selected and engaged by the Parties, for prosecuting any Licensee Program Patents, Licensee-Owned Development Program Patents, Joint Development Program Patents and jointly owned Other Patents during the Term with respect to the applicable Program, provided that Licensee shall: (i) consider the reasonable suggestions of Janssen's Patent Representative as to selection of country patent offices in the Territory for filing or validating applications to form a family of related such Patent Rights and as to the abandonment of any such Patent Rights; and (ii) consider in good faith any reasonable comments of Janssen in prosecuting any such Patent Rights, including with respect to the filing of any continuation, divisional, or other continuing applications. After the Term with respect to the applicable Program, responsibility for prosecuting any Joint Development Program Patents and jointly owned Other Patents and the Patent Costs incurred in such prosecution shall be subject to mutual written agreement of the Parties.
- (g) Prosecution Costs for Licensee Program Patents, Licensee-Owned Development Program Patents, Joint Development Program Patents and Jointly Owned Other Patents. Subject to Section 7.3.3(h), Licensee shall be responsible for all Patent Costs incurred by or on behalf of Licensee in prosecuting any Licensee Program Patents, Licensee-Owned Development Program Patents, Joint Development Program Patents or jointly owned Other Patents during the Term with respect to the applicable Program.

(h)

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Step-In Rights. If the applicable Party prosecuting a Patent Right hereunder intends in its discretion to abandon or not maintain (so as to permit to lapse) any Janssen Program Patent, Licensee Program Patent, Development Program Patent or jointly owned Other Patent in any jurisdiction in the Territory, then the prosecuting Party shall provide the other Party with written notice of such intent within a period of time reasonably necessary to allow the other Party to determine its interest in such Patent Right (which notice from the prosecuting Party shall be given no later than [...\*\*\*...] prior to any final deadline for any pending action or response that may be due with respect to such Patent Right with the applicable patent office). If the other Party provides written notice to the prosecuting Party expressing its interest in preserving such Patent Right, the prosecuting Party shall cooperate with the other Party in providing the other Party the right to prosecute such Patent Right in such jurisdiction. The Party assuming the right to prosecute a Patent Right under this Section shall be responsible for all Patent Costs incurred by such Party in prosecuting such Patent Right.

Notwithstanding the foregoing, if Licensee determines that it does not want to prosecute any Janssen Program Patent or Janssen-Owned Development Program Patent for which it is responsible pursuant to this Section 7.3.3, Licensee shall so notify Janssen and, following the date that such notice is given, the applicable Patent Right shall no longer be a Janssen Program Patent or Janssen-Owned Development Program Patent, as applicable, for purposes of this Agreement (and, if such Patent Right was set forth on <u>Schedule NIK Program Patents</u>).

- 7.3.4. **Prosecution Cooperation.** Each Party shall, at its own expense, provide all reasonable assistance requested by the other Party for prosecuting any Janssen Program Patents, Licensee Program Patents, Development Program Patents or jointly owned Other Patents consistent with the terms hereof, including with respect to the timely completion of filings of prosecution papers, compliance with Applicable Laws and recording of assignments to reflect ownership consistent with the terms hereof. A Party prosecuting any Janssen Program Patents, Licensee Program Patents or Development Program Patents hereunder shall use reasonable efforts to provide the other Party with copies of all material prosecution papers as filed in or received from any patent offices. The Party prosecuting any Janssen Program Patents, Licensee Program Patents, Development Program Patents or jointly owned Other Patents hereunder shall, on an annual basis during the Term, provide the other Party with a report identifying the status of any such Patent Rights; *provided*, *however*, that for Joint Development Program Patents or jointly owned Other Patents, the Parties shall cooperate to jointly prepare such status report.
- 7.3.5. **CREATE Act.** The Parties acknowledge that, during the course of the Development Term with respect to a Program, Development Program Patents with respect to such Program may be generated with different assigning entities which, during the course of U.S. patent prosecution, may benefit from use of the CREATE Act of 2004 (70 Fed. Reg. 177(54259-54267) as amended by the Leahy-Smith America Invents Act of 2011 (35 U.S.C. §§102(b)(2)(c) and 102(c)) (the "**CREATE Act**"). For the purposes of the benefit of the CREATE Act, the Parties deem this Agreement and/or the written memorialization of transactions contemplated hereunder, such as pertaining to the Development pursuant to a Program, to constitute a qualifying written Joint Research Agreement and agree that, if deemed necessary to effectuate the use of the CREATE Act, appropriate patent applications may be amended to include the names of the Parties. The Parties also acknowledge that a terminal disclaimer submitted during patent prosecution under the CREATE Act, if likewise deemed necessary, may include a provision pursuant to Applicable Law that the assigning entity of a second-filed patent application in prosecution waives the right to separately enforce a first-filed patent application made in the course of the Development pursuant to a Program, and a patent issuing on the second-filed application will not be enforceable if separately litigated. For clarity, a Party submitting a terminal disclaimer under the CREATE Act shall provide a copy of such terminal disclaimer to the other Party's Patent Representative.

## 7.4. **Patent Enforcement.**

#### 7.4.1. **Notice.**

- (a) Each Party shall notify the other promptly of any apparent, threatened, or actual infringement by a Third Party of any Janssen Program Patent, Licensee Program Patent Development Program Patent or jointly owned Other Patent, or misappropriation of any Janssen Program Know-How, Licensee Program Know-How, Development Program Know-How or jointly owned Other Patent, of which the Party becomes aware. The notifying Party shall promptly furnish the other with all known details or evidence of such infringement or misappropriation.
- (b) Each Party shall promptly notify the other of any Third Party communications pertaining to any Janssen Program Patent, Licensee Program Patent, Development Program Patent or jointly owned Other Patent that the Party receives pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 or similar such notice, including notices pursuant to §§ 101 and 103 of such act from Persons who have filed an abbreviated NDA (ANDA) or a paper NDA.
- 7.4.2. Enforcement Actions. During the License Term with respect to a Program, Licensee shall have the initial right, at its expense and in its own name (or in the name of Janssen as may be required under Applicable Law), for bringing any infringement suit or other enforcement action (an "Action") on account of any Third Party infringement of any Janssen Program Patent, Licensee Program Patent, Development Program Patent or any jointly owned Other Patent with respect to such Program based on any alleged making, using, selling, offering for sale, importing or other exploitation of any product that is competitive with a Licensed Product with respect to such Program in the infringement of any such Patent Rights, or based on misappropriation of any Janssen Program Know-How, Licensee Program Know-How or Development Program Know-How with respect to such Program providing any Regulatory Exclusivity for any such Licensed Product (each a "Product Infringement"), by counsel of its own choice, and Janssen will cooperate with Licensee as Licensee may reasonably request in connection with any such Action, including by becoming a party to such Action at Licensee's cost, provided that Licensee shall reimburse Janssen for its out-of-pocket costs reasonably incurred in connection with rendering such assistance. If Licensee declines to initiate such an Action against any unabated Product Infringement, it shall so notify Janssen, who shall thereafter have the right (but not the obligation), at Janssen's expense and in its own name, to initiate such Action on account of any Third Party infringement of any Janssen Program Patent, Janssen-Owned Development Program Patent or Joint Development Program Patent by counsel of its choice, and Licensee shall cooperate with Janssen as Janssen may reasonably request, including by becoming a party to such action at Janssen's cost, and Janssen shall reimburse Licensee for its out-of-pocket costs reasonably incurred in connection with rendering such assistance. A settlement or consent judgment or other voluntary final disposition of an Action brought by a Party under this Section may be entered into without the consent of the other Party, provided that such settlement, consent judgment, or other disposition does not admit the invalidity

or unenforceability of any Patent Rights Controlled by the other Party and, provided further that any rights granted to a Third Party to continue any activity upon which such Action was based in such settlement, consent judgment, or other disposition shall be limited to the Third Party's product or activity that was the subject of the Action. Damages recovered and any other amounts awarded in any Actions for Product Infringement under this Section shall be allocated to the Party who brought the Action, after reimbursement of each Party's actual expenses incurred in such Actions as provided hereunder, provided that Licensee shall pay to Janssen: (a) as to damage amounts recovered by Licensee due to a Product Infringement in the form of lost profits or reasonable royalties assessed on account of the Third Party's sales of infringing product, an amount equal to the royalty that would be payable pursuant to this Agreement on the imputed amount of Net Sales of the relevant Licensed Product(s) in the country(ies) where such Product Infringement occurred; and (b) as to damage amounts recovered by Licensee due to a Product Infringement other than in the form of lost profits or reasonable royalties assessed on account of the Third Party's sales of infringing product, an amount equal to the royalty that would be payable pursuant to this Agreement on such damage amounts treated as Net Sales of the relevant Licensed Product(s) in the country(ies) where such Product Infringement occurred.

- 7.4.3. Other Enforcement Actions. Janssen acknowledges that the outcome of any Action on account of any Third Party infringement, other than a Product Infringement, of any Janssen Program Patent or Development Program Patent licensed to Licensee under this Agreement may detrimentally impact the scope, validity, or enforceability of such Patent Right with respect to potential Product Infringements. Accordingly, during the License Term with respect to a Program, the Parties shall reasonably cooperate with each other with respect to any Action on account of any Third Party infringement of any Janssen Program Patent or Development Program Patent licensed to Licensee under this Agreement, other than Product Infringements. For clarity, Janssen will not be required to enforce any Janssen Program Patent against any Third Party infringement.
- 7.5. Third Party Patent Rights. Each Party shall promptly inform the other Party, orally through the Patent Representatives, in the event such Party becomes aware of any Third Party's Patent Rights that may pertain to any Development, Manufacturing or Commercialization activities of Licensee related to a Licensed Compound or Licensed Product.
- 7.6. Patent Term Extensions. During the License Term with respect to a Program, upon Licensee's written request (which shall be by a written notice identifying the date of the applicable Marketing Approval of a Licensed Product with respect to such Program and the deadline for filing a patent term extension, supplemental protection certificate or their equivalent (each a "Patent Term Extension")), the Party prosecuting a relevant Patent Right shall use reasonable efforts, in each country or jurisdiction where Marketing Approval for any such Licensed Product has been obtained, and if the Applicable Law of such country or jurisdiction permits application for a Patent Term Extension, to apply, at the reasonable direction of Licensee's Patent Representative, for a Patent Term Extension for a patent within the Janssen Program Patents or Janssen-Owned Development Program Patents including a Valid Claim Covering such Licensed Product, which patent (if any) shall be selected at Licensee's reasonable judgment after considering the opinion of Licensee's patent counsel regarding its eligibility for a

Patent Term Extension. Licensee shall have the right to: (a) identify in any list of patents in a Drug Approval Application for a Licensed Product with respect to such Program the applicable Janssen Program Patent(s), Licensee Program Patent(s) and Development Program Patent(s), as Licensee reasonably believes is appropriate; (b) for clarity, commence an Action for any Product Infringement of any such Janssen Program Patent(s) or Janssen-Owned Development Program Patent(s) under Applicable Law as permitted under Section 7.4.2; and (c) subject to specific limitations of this Agreement, exercise any rights that may be exercisable by a patent owner, including applying for a Patent Term Extension, of any Janssen Program Patent(s) or Janssen-Owned Development Program Patent(s) pertaining to an approved Licensed Product with respect to such Program licensed to Licensee and Commercialized by Licensee during the License Term with respect to such Program. Janssen agrees to cooperate with Licensee and its Affiliate and Third Party sublicensees of Licensed Products, as applicable, upon Licensee's reasonable request in the exercise of the authorizations under this Section, and Janssen shall execute such documents and take such additional action as Licensee may reasonably request in connection therewith, *provided* that Licensee shall reimburse Janssen all reasonable out-of-pocket costs incurred by Janssen in taking such action.

- 7.7. **Product Trademarks.** During the License Term with respect to a Program, Licensee shall have (directly and through its Affiliates and Third Party sublicensees Commercializing Licensed Products with respect to such Program) the right to brand, at its discretion, Licensed Products with respect to such Program using Trademarks and trade names selected at its discretion and to file for, obtain, and maintain at its discretion and cost Trademarks for such Licensed Products in its own name.
- 7.8. Correction of Licensed Patents without Patent Challenge. During the License Term with respect to a Program, if a Party becomes aware of any good-faith error in any Janssen Program Patent or Development Program Patent that would render the only issued claim(s) therein Covering any marketed Licensed Product with respect to such Program invalid, such Party shall inform the other Party (orally through the Parties' Patent Representatives) and the applicable Party prosecuting such Patent Right shall, subject to this Article 7, use Commercially Reasonable Efforts to correct such error by reissue or reexamination (if such error is so correctable under Applicable Law).

## Article 8 CONFIDENTIALITY; PUBLICITY

## 8.1. **Nondisclosure**.

8.1.1. Each Party agrees that, during the Term and for a period of five (5) years thereafter, the Party (the "Receiving Party") receiving Confidential Information of the other Party (the "Disclosing Party") shall: (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own confidential or proprietary information of similar kind and value (but no less than reasonable efforts); (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted in Sections 8.3 and 8.4; and (c) not use such Confidential Information for any purpose except those permitted by this Agreement (it being

understood that this Article 8 shall not create or imply any rights or licenses not expressly granted under this Agreement).

- Notwithstanding the foregoing, during the Development Term with respect to a Program, all Program-Related 8.1.2. Information relating to such Program shall be deemed to be Confidential Information of each Party and each Party shall: (a) maintain in confidence all Program-Related Information relating to such Program using not less than the efforts such Party uses to maintain in confidence its own confidential or proprietary information of similar kind and value (but no less than reasonable efforts); (b) not disclose any Program-Related Information relating to such Program to any Third Party without the prior written consent of the other Party, except for disclosures expressly permitted in Sections 8.3 and 8.4; and (c) not use any Program-Related Information relating to such Program for any purpose except those permitted by this Agreement (it being understood that this Article 8 shall not create or imply any rights or licenses not expressly granted under this Agreement), in each case ((a), (b) and (c)), regardless of which Party is the Disclosing Party and which Party is the Receiving Party with respect to such Program-Related Information. In addition, during the Development Term with respect to a Program, neither Party shall grant any right to any Third Party with respect to any Development Program Know-How relating to such Program, other than to the extent permitted under Section 2.2.3(e). During the License Term with respect to a Program, any information embodied or contained in the Transferred Assets and Program-Related Information relating to such Program (which, for clarity, does not include any Janssen Program Know-How), other than Janssen-Owned Development Program Know-How, shall be deemed to be Confidential Information of Licensee for the purposes of this Article 8 and Licensee shall be deemed the Disclosing Party and Janssen shall be deemed the Receiving Party with respect to such information.
- 8.2. **Exceptions.** The obligations in Section 8.1 shall not apply to the extent of any portion of the Confidential Information that the Receiving Party can show by competent evidence:
  - (a) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party under this Agreement;
  - (b) is known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, in each case, to the Disclosing Party, prior to disclosure to the Receiving Party or any of its Affiliates by the Disclosing Party (*provided* that this exception shall not apply to any Program-Related Information during the Development Term);
  - (c) is subsequently disclosed to the Receiving Party or any of its Affiliates on a non-confidential basis by a Third Party that, to the Receiving Party's knowledge, is not bound by a similar duty of confidentiality or restriction on its use, in each case, to the Disclosing Party;
  - (d) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party or any of its Affiliates in violation of this Agreement,

generally known or available, either before or after it is disclosed to the Receiving Party by the Disclosing Party; or

- (e) is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates without the use of or reference to the Confidential Information of the Disclosing Party.
- 8.3. <u>Authorized Disclosure</u>. The Receiving Party may disclose Confidential Information of the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances, or to the extent permissible under the other applicable provisions of this Agreement:
  - (a) filing, prosecuting, maintaining, enforcing or defending Patent Rights as permitted by this Agreement;
  - (b) as reasonably required in generating Regulatory Documentation and obtaining Regulatory Approvals as permitted by this Agreement;
  - (c) prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation;
  - (d) subject to Section 8.4, complying with Applicable Law or court or administrative orders;
  - (e) complying with any obligation under this Agreement;
  - (f) in communications with existing investors or bona fide prospective investors, consultants and advisors of the Receiving Party in connection with equity financing transactions or bona fide prospective equity financing transactions with the foregoing, in each case on a "need-to-know" basis and under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement; *provided*, *however*, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Third Party who receives Confidential Information pursuant to this Section 8.3(f); *provided further*, *however*, that, [...\*\*\*...];

(g)

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to its Affiliates, (sub)licensees or prospective (sub)licensees, subcontractors or prospective subcontractors, consultants, agents and advisors on a "need-to-know" basis in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement; *provided, however*, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Person who receives Confidential Information pursuant to this Section 8.3(g); and *provided, further, however* that, during the Development Term of a Program, this Section 8.3(g) does not apply to the disclosure by Licensee of any Confidential Information with respect to such Program to any prospective (sub) licensee; or

(h) by either Party to one or more Third Parties regarding an actual or potential Change of Control of such Party, each of whom prior to disclosure must be bound under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement; *provided*, *however*, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Person who receives Confidential Information pursuant to this Section 8.3(h); and *provided*, *further*, *however* that, [...\*\*\*...].

If and whenever any Confidential Information is disclosed in accordance with this Section 8.3, such disclosure shall not cause any such information to cease to be Confidential Information for purposes of this Agreement, except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing: (x) in the event a Party intends to make a disclosure of the other Party's Confidential Information pursuant to Section 8.3(c) or Section 8.3(d), it will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure and use not less than the same efforts to secure confidential treatment of such information as it would to protect its own confidential information from disclosure; and (y) in the event Licensee intends to make a disclosure of Janssen's Confidential Information relating to a Program during the Development Term of such Program pursuant to Section 8.3(f), 8.3(g) or 8.3(h), it will give reasonable advance notice of such disclosure to Janssen (which shall not include the name of the party accessing Janssen Confidential Information or the nature of the transaction being contemplated).

- 8.4. Terms of this Agreement. The Parties acknowledge and agree that this Agreement and all of the respective terms of this Agreement shall be treated as Confidential Information of each Party. In addition to the disclosures permitted under Section 8.3, either Party may disclose the terms of this Agreement and other information relating to this Agreement or the transactions contemplated by this Agreement to the extent required, in the reasonable opinion of such Party's counsel, to comply with the rules and regulations promulgated by the United States Securities and Exchange Commission or the Nasdaq Stock Market or similar security regulatory authorities or stock market in other countries. If a Party intends to disclose this Agreement or any of its terms or other such information in accordance with this Section 8.4, such Party will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure and seek confidential treatment of portions of this Agreement or such terms or information, as may be reasonably requested by the other Party.
- 8.5. **Public Announcements.** Except as required to comply with Applicable Law or as permitted by Section 8.3 or 8.4, each Party agrees not to issue any press release or other public statement disclosing the execution of this Agreement or any other information relating to this Agreement or the transactions contemplated by this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. In the event that a Party intends to issue such a press release or other public statement as required to comply with Applicable Law, such Party will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure.

8.6.

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<u>Prior Non-Disclosure Agreement.</u> As of the Effective Date, the terms of this Article 8 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the

Parties (or their Affiliates) dealing with the subject of this Agreement, including the Nondisclosure Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

- 8.7. **Equitable Relief.** Given the nature of the Confidential Information and the competitive damage that may result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 8. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 8.
- 8.8. Scientific Publications. Licensee may make oral or written publications (such as any abstracts, manuscripts, posters, slide presentations or other materials) of any activities or results relating to a Program, provided that (a) during the Development Term, Janssen shall first have the right to review and comment on a draft of any such material proposed for publication by Licensee, including for purposes of ensuring that none of its Confidential Information is disclosed without its permission and (b) Licensee may not include any Confidential Information of Janssen in such publication without Janssen's prior written consent. Licensee shall deliver a complete draft to Janssen at least [...\*\*\*...] ([...\*\*\*...] days in the case of abstracts) prior to submitting the material to a publisher or initiating any other release. Janssen shall review any such material and give its comments to Licensee within [...\*\*\*...] ([...\*\*\*...] in the case of abstracts) after the delivery of such draft to Janssen. Licensee shall comply with Janssen's request to: delete from any such proposed publication material prior to its submission or release any references to Janssen or any of its Confidential Information; or delay any submission or release for a period of up to an additional [...\*\*\*...] days to permit Licensee to prepare and file, or have prepared and filed, any patent applications for any Development Program Inventions as contemplated hereunder. For the avoidance of doubt, this Section 8.8 shall not apply to public disclosures required by Applicable Laws or the rules of the United States Securities and Exchange Commission or the Nasdaq Stock Market or similar security regulatory authorities or stock market in other countries, as applicable, which are governed by Sections 8.4 and 8.5.

# Article 9 REPRESENTATIONS AND WARRANTIES

- 9.1. <u>Mutual Representations and Warranties</u>. Each Party represents, warrants and covenants to the other Party that, as of the Effective Date:
  - 9.1.1. it is duly organized and validly existing under the laws of its state or country of incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions of this Agreement;
  - 9.1.2. this Agreement has been duly executed by it and constitutes a legal, valid and binding obligation of it, enforceable in accordance with its terms;

9.1.3.

\*\*\*Confidential Treatment Requested

the execution, delivery and performance of this Agreement by it does not conflict with any material agreement, instrument or understanding, oral or written, to which it is a

party or by which it is bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and

- 9.1.4. it has not granted, and shall not grant during the Term, any right to any Third Party that would conflict with the rights granted to the other Party under this Agreement (including by granting a license after the Effective Date to a Third Party under any intellectual property that is Controlled by the granting Party on the Effective Date that would conflict with the rights to such intellectual property granted to the other Party under this Agreement).
- 9.2. <u>Additional Representations and Warranties of Janssen</u>. Janssen represents and warrants to Licensee that, as of the Effective Date (or with respect to Transferred Contracts, as of the Transferred Contract Effective Date):
  - 9.2.1. <u>Schedule AR Mutant Program Patents</u>, <u>Schedule AR Mutant Diagnostic Patent</u> and <u>Schedule NIK Program Patents</u> list all Patent Rights existing as of the Effective Date that are owned or licensed by Janssen or any of its Affiliates and include any claim Covering any AR Mutant Compound or AR Mutant Product (as it exists on the Effective Date) or any NIK Compound or NIK Product (as it exists on the Effective Date), as applicable, or its formulation, Manufacture or use (the "**Existing Janssen Program Patents**");
  - 9.2.2. <u>Schedule AR Mutant Program Patents</u> and <u>Schedule NIK Program Patents</u> identify any Janssen License Agreement pursuant to which any Existing Janssen Program Patents are licensed to Janssen or any of its Affiliates;
  - 9.2.3. Janssen or its Affiliate are the sole and exclusive owners or exclusive licensees of the Existing Janssen Program Patents (as specified in Schedule AR Mutant Program Patents, Schedule AR Mutant Diagnostic Patent and Schedule NIK Program Patents) and is listed (or is in the process of becoming listed) in the records of the appropriate governmental authorities as the sole and exclusive owner of record, if applicable, for each registration, grant and application included in such Patent Rights, except as otherwise noted therein; and Janssen is entitled to grant the licenses under such Patent Rights specified herein;
  - 9.2.4. to the Knowledge of Janssen, Janssen has the right to use and disclose and to enable Licensee to use and disclose (in each case under appropriate conditions of confidentiality) the Janssen Program Know-How set forth on Schedule AR Mutant Program Know-How and Schedule NIK Program Know-How (the "Existing Janssen Program Know-How") to the extent that Licensee is granted the right to use and disclose such Existing Janssen Program Know-How pursuant to this Agreement;
  - 9.2.5. to the Knowledge of Janssen, neither Janssen nor any of its Affiliates owns or licenses, with the right to sublicense, any Know-How or Patent Rights used by Janssen and its Affiliates in the conduct of the Programs within the thirty-six (36) months prior to the Effective Date, other than the Existing Janssen Program Know-How and Existing Janssen Program Patents;

- 9.2.6. neither Janssen nor any of its Affiliates is subject to any royalty or other payment obligation to any Third Party with respect to the practice, or the grant of rights to Licensee to practice, any of the Existing Janssen Program Know-How and Existing Janssen Program Patents with respect to the Licensed Compounds or Licensed Products under this Agreement, other than those set forth in the Janssen License Agreements as specifically described on <u>Schedule Janssen License Agreements</u>;
- 9.2.7. neither Janssen nor any of its Affiliates has received written notice of any claim or threatened claim by any Third Party, and to the Knowledge of Janssen, Janssen is not otherwise aware, that (i) any Third Party has any rights to any of the Existing Janssen Program Know-How or Existing Janssen Program Patents, (ii) any of the Existing Janssen Program Patents (to the extent representing issued Patent Rights) are invalid or unenforceable, or (iii) any research, Development or Manufacture of any Licensed Compound or Licensed Product by or on behalf of Janssen or its Affiliate prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party;
- 9.2.8. there are no pending actions, claims, investigations, suits or proceedings against Janssen or any of its Affiliates, at law or in equity, or before or by any Regulatory Authority, and neither Janssen nor any of its Affiliates has received any written notice regarding any pending or threatened actions, claims, investigations, suits or proceedings against Janssen or any of its Affiliates, at law or in equity, or before or by any Regulatory Authority, in either case with respect to the Existing Janssen Program Know-How or Existing Janssen Program Patents, and no Existing Janssen Program Patent is the subject of any interference, opposition, cancellation or other protest proceeding;
- 9.2.9. to the Knowledge of Janssen, there is no actual infringement of any Existing Janssen Program Patents by any Third Party;
- 9.2.10. neither Janssen nor any of its Affiliates, nor its or their employees, officers, directors, or agents, has been debarred by the FDA, is the subject of a conviction described in 21 U.S.C. 335a, or is subject to any similar sanction;
- 9.2.11. Janssen and its Affiliates have conducted Development activities with respect to each Program in material compliance with Applicable Law and regulatory standards, including as applicable those relating to GLP, GCP, pharmacovigilance and safety reporting, and requirements for the protection of human subjects;
- 9.2.12. Janssen owns good and valid title to and has the right to transfer (or cause to be transferred), the Transferred Assets as provided for herein, free and clear of all liens and other encumbrances, except for Permitted Liens;
- 9.2.13. Janssen has made available to Licensee true and complete copies of each Transferred Contract;
- 9.2.14. each Transferred Contract is in effect and is valid and binding on Janssen or its Affiliate, enforceable in accordance with its terms, and neither Janssen nor any of its Affiliates, nor to the Knowledge of Janssen any other party thereto, is in material breach

of, or material default under, any Transferred Contract, and no event has occurred that, with the giving of notice or lapse of time or both, would constitute a material breach or material default by Janssen or any of its Affiliates thereunder or result in the payment of any damages or penalties or result in the creation of any lien or encumbrance with respect thereto; and

9.2.15. neither Janssen nor any of its Affiliates has received any written notice from a Third Party at any time during the past three (3) years regarding any actual, alleged or potential material breach or default under any of the Transferred Contracts or stating that such Third Party intends to terminate, cancel or make any material change to any Transferred Contract.

As used in this Section 9.2: (a) "Knowledge" means the actual knowledge of the Janssen Personnel after reasonable inquiry of individuals responsible for operational activities with respect to the applicable Program; (b) "Janssen Personnel" means the individuals whose names are set forth on <u>Schedule Janssen Personnel</u>; and (c) "Permitted Liens" means (i) liens for taxes not yet due, payable, delinquent or subject to penalties for nonpayment, or which are being contested in good faith in the ordinary course of business by appropriate proceedings or (ii) mechanics', materialmens', carriers', workmens', warehousemens', repairmens', landlords' or other like liens and security obligations that are incurred in the ordinary course of business and are not delinquent.

9.3. Additional Representations and Warranties of Licensee. Licensee represents and warrants to Janssen that, as of the Effective Date, neither Licensee nor any of its Affiliates, nor its or their employees, officers, directors, or agents, has been debarred by the FDA, is the subject of a conviction described in 21 U.S.C. 335a, or is subject to any similar sanction.

#### 9.4. **Disclaimer of Warranties; Limitations.**

- 9.4.1. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY NOR ANY OF ITS AFFILIATES MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE PROGRAMS, LICENSED COMPOUNDS, LICENSED PRODUCTS, TRANSFERRED ASSETS, LICENSED TECHNOLOGY OR OTHER PATENT RIGHTS THAT ARE LICENSED OR TRANSFERRED TO THE OTHER PARTY OR SUBJECT TO ANY OPTION OR RIGHT TO LICENSE UNDER THIS AGREEMENT, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT ANY OF THE DEVELOPMENT, MANUFACTURING OR COMMERCIALIZATION EFFORTS WITH REGARD TO ANY LICENSED COMPOUND OR LICENSED PRODUCT WILL BE SUCCESSFUL.
- 9.4.2. Subject to Sections 2.3, 2.4, 5.5 and 11.6.1(h), each Party acknowledges that (a) the other Party and its Affiliates may have present or future initiatives or opportunities, including initiatives or opportunities with Third Parties, involving similar

products, programs, technologies or processes that may compete with products, programs, technologies or processes covered by this Agreement; (b) nothing in this Agreement will be construed as a representation, warranty, covenant or inference that the other Party or its Affiliates will not itself develop, manufacture or market or enter into business relationships with one or more Third Parties to develop, manufacture or market products, programs, technologies or processes that are similar to or that may compete with any product, program, technology or process covered by this Agreement (including those in the Field); and (c) the other Party or any of its Affiliates may, in their sole discretion, decide to acquire, research, develop and/or market devices, drugs or other products which may compete with any Licensed Product or continue such activity in which they currently are engaged; *provided* that, in each case of clauses (a), (b) and (c), in no event shall a Party or its Affiliates use Confidential Information of the other Party in breach of this Agreement, and in no event may Janssen or its Affiliates practice or use, or grant any Third Party the right to practice or use, any Licensed Technology in conflict with the licenses granted hereunder.

## 9.5. Additional Representations, Warranties and Covenants.

9.5.1. **Assignments**. Each Party shall ensure that each individual employee or agent performing activities under a Program on behalf of such Party or its Affiliate during the Development Term of such Program shall have entered into an agreement with such Party or its Affiliate prior to the performance of any work thereunder by such employee or agent providing for the assignment to such Party or its Affiliate of all inventions and discoveries, whether or not patentable, made or arising in the course of the performance of such activities.

## 9.5.2. **Healthcare Compliance**.

- (a) Anti-Kickback and Stark Compliance. Each Party represents and warrants to the other Party as of the Effective Date, and covenants to such other Party, that the Party making such representation and warranty and its Affiliates that are or have been involved in a Program is in compliance and will continue to comply with all applicable state and federal laws, rules and regulations, including the federal anti-kickback statute (42 U.S.C. § 1320a-7b), the related safe harbor regulations, and the Limitation on Certain Physician Referrals, also referred to as the "Stark Law" (42 U.S.C. § 1395nn) in connection with its activities under this Agreement and, in the case of Janssen, has complied with the foregoing in connection with its activities with respect to a Program prior to the Effective Date. No part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services; nor are the payments intended to induce illegal referrals of business.
- (b) **Exclusion from Federal Health Care Programs**. Each Party shall conduct activities pursuant to this Agreement, and Janssen and its Affiliates have conducted activities with respect to a Program prior to the Effective Date, in accordance with applicable state and federal laws and any applicable regulations regarding Medicare, Medicaid, and other third party-payer programs, if any. Each

Party represents and warrants to the other Party, as of the Effective Date, that (1) it is not excluded from, and has not been convicted of any crime or engaged in any conduct that could result in exclusion from, participation in any state or federal healthcare program, as defined in 42 U.S.C. §1320a-7b(f), for the provision of items or services for which payment may be made by a federal healthcare program; (2) it has not contracted with any employee, contractor, agent, or vendor to perform work under this Agreement who is excluded from participation in any state or federal healthcare program, and in the case of Janssen, did not contract with any employee, contractor, agent, or vendor to perform work under a Program prior to the Effective Date who was excluded from participation in any state or federal healthcare program; and (3) it is not subject to a final adverse action, as defined in 42 U.S.C.§ 1320a-7a(e) and 42 U.S.C. § 1320a-7a(g), and has no adverse action pending or threatened against it. Each Party shall notify the other Party of any final adverse action, discovery of contract with an excluded entity or individual, or exclusion within thirty (30) days of such action.

- 9.5.3. **No Debarred Individuals.** Each Party agrees that it shall not engage, in any capacity in connection with this Agreement, any person who has been debarred by FDA, is the subject of a conviction described in 21 U.S.C. 335a, or is subject to any similar sanction, and in the case of Janssen, Janssen represents and warrants to Licensee that neither Janssen nor any of its Affiliates engaged any such person in connection with a Program prior to the Effective Date. Each Party shall promptly inform the other Party in writing if such Party or any person performing activities under this Agreement on such Party's behalf is debarred or is the subject of a conviction described in 21 U.S.C. 335a, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or threatened relating to the debarment of conviction of such Party or any such person performing activities in connection with this Agreement on such Party's behalf. Upon written request from the other Party, a Party shall, within ten (10) days, provide written confirmation that it has complied with the foregoing obligation.
- 9.5.4. **Anti-Corruption Laws**. Neither a Party nor any of its Affiliates shall perform any actions in connection with this Agreement that are prohibited by local and other anti-corruption laws (collectively "**Anti-Corruption Laws**") that may be applicable to such Party, and in the case of Janssen, Janssen represents and warrants to Licensee that neither Janssen nor any of its Affiliates has performed any actions in connection with a Program prior to the Effective Date that are prohibited by Anti-Corruption Laws that were applicable to Janssen or its Affiliates. Without limiting the foregoing, neither Party nor any of its Affiliates shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political party official or candidate for political office or to any other Third Party related to the transactions contemplated by this Agreement in a manner that would violate Anti-Corruption Laws.
- 9.5.5. **Development Compliance Matters**. With respect to each Program, the provisions of this Section 9.5.5 shall apply during the Development Term and License Term of such Program.

- (a) **Responsibility for Development**. Licensee shall be solely responsible for the activities of clinical development related to Licensed Products in the Territory under the terms of this Agreement (other than the Janssen AR Mutant Activities), including any post-marketing surveillance studies or Clinical Trials eventually required by Regulatory Authorities or any studies voluntarily undertaken by Licensee.
- (b) **IRB**. Licensee shall be responsible for obtaining any necessary approvals from institutional review boards (each, an "**IRB**") including, where applicable, obtaining approval of all Clinical Trial protocols, informed consents, investigator brochures, subject recruitment materials or plans, authorization of disclosure of confidential subject information, and any alterations to or waivers of the same, prior to commencement of any study. Licensee shall not modify the protocol or the informed consent without the prior written agreement of the IRB.
- (c) **Informed Consent and Patient Authorization**. Licensee shall be responsible for obtaining (i) an informed consent document, which shall have been approved by the IRB, signed by or on behalf of each human study subject prior to the subject's participation in the Clinical Trial; and (ii) a HIPAA patient authorization signed by or on behalf of each human study subject, as described in 45 C.F.R. Part 164.
- (d) **INDs**. Licensee shall be responsible for obtaining and maintaining any IND or comparable regulatory filing in other jurisdictions required for the Clinical Trial.
- (e) **Study Conduct**. Licensee shall conduct Clinical Trials in compliance with Applicable Law and regulatory standards, including, as applicable, those relating to Good Laboratory Practices ("GLP"), Good Clinical Practices ("GCP"), pharmacovigilance and safety reporting, and requirements for the protection of human subjects.
- (f) Clinical Study Registration and Results Reporting. Licensee shall be responsible for registering Clinical Trials in the appropriate clinical study registry and reporting Clinical Trial results as required under Applicable Law.
- (g) **Subcontracting**. To the extent that Licensee enters into arrangements with any Third Party involved in conducting or supporting a Clinical Trial, including clinical investigators, study sites, or a contract research organization, any such arrangements shall be made in writing and consistent with this Agreement.
- (h) **Audits**. With respect to any facility or site at which Licensee conducts Clinical Trials or other Development activities or Manufacturing activities pursuant to this Agreement, and subject to the terms of any agreement between Licensee and any applicable Third Party Subcontractor with respect to any facility or site of such Third Party Subcontractor, Janssen shall have the right, at its own

expense, upon reasonable written notice to Licensee, and during normal business hours, to inspect such site and facility of Licensee or to accompany Licensee to inspect any Third Party Subcontractor site and any records relating thereto once per year and also for cause, to verify Licensee's compliance with Applicable Law in carrying out its obligations under this Agreement, including those relating to GLP, GCP, Good Manufacturing Practices ("GMP"), pharmacovigilance and safety reporting, and requirements for the protection of human subjects. In the event that any such facility or site is found to be non-compliant with GLP, GCP, GMP, pharmacovigilance and safety reporting, or requirements for the protection of human subjects during such an audit, and such non-compliance relates to or impacts any Licensed Product, Licensee shall submit to Janssen proposed Corrective and Preventative Actions ("CAPA") within thirty (30) days after Janssen provides notice of such non-compliance. Janssen shall have the right during the License Term, to review and comment on such CAPA, which comments Licensee shall consider in good faith. Licensee shall use Commercially Reasonable Efforts to implement such CAPA promptly after review and comment by Janssen.

- Authority inspections of any site or facility where Clinical Trials or other Development activities or Manufacturing activities are conducted pursuant to this Agreement by Licensee or on its behalf, whether such site or facility is Licensee's, an Affiliate's, or a subcontractor's (each, an "Audited Site"). Licensee shall inform Janssen as promptly as practicable and in any event within forty-eight (48) hours of receiving notice of such a Regulatory Authority audit and shall provide daily updates regarding the audit status. In the event that any Audited Site is found to be non-compliant with one or more of GLP, GCP, GMP, current standards for pharmacovigilance and safety reporting, or requirements related to the protection of human subjects, and such non-compliance relates to or impacts any Licensed Product, Licensee shall submit to Janssen proposed CAPA within thirty (30) days after Licensee, its Affiliate, or its subcontractor receives notification of such non-compliance from the relevant Regulatory Authority. Janssen shall have the right during the Licensee Term, to review and comment on such CAPA, which comments Licensee shall consider in good faith. Licensee shall use Commercially Reasonable Efforts to implement such CAPA promptly after review and comment by Janssen.
- 9.5.6. **Amendment to Janssen License Agreements**. Janssen may not amend any Janssen License Agreement in any manner that would adversely affect any rights granted to Licensee hereunder, including to increase any amount payable by Janssen for which Licensee would be responsible pursuant to Section 6.3.2(a), except with Licensee's prior written consent.

## Article 10 INDEMNIFICATION AND INSURANCE

#### 10.1. **Indemnification.**

- 10.1.1. **Indemnification by Licensee.** Subject to Section 10.2, Licensee shall defend, indemnify and hold harmless Janssen and any of its Affiliates, and each of its and their directors, officers, employees and agents (each, a "**Janssen Indemnified Party**") from and against any and all damages, losses, liabilities, judgments, fines, amounts paid in settlement, costs and expenses (including the reasonable costs and expenses of attorneys and other professionals) (collectively, "**Losses**") incurred by any Janssen Indemnified Party resulting from any claim, action or proceeding brought or initiated by a Third Party ("**Third Party Claim**") against a Janssen Indemnified Party, to the extent that such Losses arise out of or relate to, directly or indirectly:
  - (a) the Assumed Liabilities;
  - (b) the breach by Licensee of any of its representations, warranties or covenants set forth herein;
  - (c) the negligence, recklessness or wrongful intentional acts or omissions of any Licensee Indemnified Party; or
  - (d) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Licensee or any of its Affiliates on or after the Effective Date and during the Term (or any post-termination or post-expiration period pursuant to Section 11.6) with respect to the applicable Program;

except, in each case ((a) through (d)), to the extent such Losses arise directly or indirectly from (i) the breach by Janssen of any of its representations, warranties, or covenants set forth herein, (ii) the negligence, recklessness or wrongful intentional acts or omissions of any Janssen Indemnified Party, (iii) the Janssen AR Mutant Activities, or (iv) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Janssen or any of its Affiliates prior to the Effective Date or during any post-termination or post-expiration period pursuant to Section 11.6 with respect to the applicable Program.

- 10.1.2. **Indemnification by Janssen.** Subject to Section 10.2, Janssen shall defend, indemnify and hold harmless Licensee and any of their Affiliates, and each of its and their directors, officers, employees and agents (each, a "**Licensee Indemnified Party**"), from and against any and all Losses incurred by any Licensee Indemnified Party resulting from any Third Party Claim against a Janssen Indemnified Party, to the extent that such Losses arise out of or relate to, directly or indirectly:
  - (a) all liabilities arising from or relating to the Transferred Assets arising prior to the Effective Date, or after the Effective Date to the extent of any breach of or

non-compliance with any Transferred Contract by Janssen or any of its Affiliates prior to the Effective Date;

- (b) the breach by Janssen of any of its representations, warranties or covenants set forth herein; and
- (c) the negligence, recklessness or wrongful intentional acts or omissions of any Janssen Indemnified Party;
- (d) the Janssen AR Mutant Activities; or
- (e) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Janssen or any of its Affiliates prior to the Effective Date or during any post-termination or post-expiration period pursuant to Section 11.6 with respect to the applicable Program;

except, in each case ((a) through (d)), to the extent such Losses arise directly or indirectly from (i) the breach by Licensee of any of its representations, warranties, or covenants set forth herein, (ii) the negligence, recklessness or wrongful intentional acts or omissions of any Licensee Indemnified Party, or (iii) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Licensee or any of its Affiliates on or after to the Effective Date and during the Term (or any post-termination or post-expiration period pursuant to Section 11.6) with respect to the applicable Program.

- Conditions to Indemnification. If either a Janssen Indemnified Party or a Licensee Indemnified Party (each, an "Indemnified Party") intends to seek indemnification under Section 10.1, the Indemnified Party must: (a) give the other Party (the "Indemnifying Party") reasonably prompt written notice of any Loss with respect to which such Indemnified Party intends to seek indemnification; (b) reasonably cooperate with the Indemnifying Party at the Indemnifying Party's request and expense, in the defense or settlement of the claim; and (c) give the Indemnifying Party the right to control the defense or settlement of the claim, provided that the Indemnifying Party will not enter into any settlement that adversely affects the Indemnified Party's rights or obligations without the Indemnified Party's prior express written consent, which will not be unreasonably withheld, conditioned or delayed. The Indemnified Party may participate in the defense or settlement of any such claim at its own expense with counsel of its choosing. Notwithstanding the foregoing, any failure of the Indemnified Party to comply with the provisions of clause (a) of this Section 10.2 will not relieve the Indemnifying Party of any defense or indemnity obligations under this Agreement except to the extent that the Indemnifying Party is prejudiced by such failure.
- 10.3. <u>Limitations of Liability.</u> EXCEPT TO THE EXTENT INCLUDED IN LOSSES RESULTING FROM A THIRD PARTY CLAIM FOR WHICH ONE PARTY IS OBLIGATED TO INDEMNIFY THE OTHER PARTY (OR AN INDEMNIFIED PARTY OF SUCH OTHER PARTY) PURSUANT TO THIS ARTICLE 10 OR ANY BREACH OF ARTICLE 8 (CONFIDENTIALITY), IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES OR SUBLICENSEES) IN

CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

10.4. <u>Insurance</u>. Licensee shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated, at all times during which any Licensed Product is being tested by or on behalf of Licensee, during the period of commercialization of any Licensed Product and for at least [...\*\*\*...] thereafter. At a minimum, Licensee shall be insured for [...\*\*\*...] to cover its obligations under this Agreement. Janssen shall be named as an additional insured under Licensee's product liability and general liability insurance policies. It is understood that such insurance shall not be construed to create a limit of Licensee's liability with respect to its indemnification obligations under this Article 10. Licensee shall provide Janssen with written evidence of such insurance upon request and shall provide Janssen with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance which materially adversely affects the rights of Janssen hereunder.

## Article 11 TERM AND TERMINATION

- 11.1. **Term.** The term of this Agreement (the "**Term**") will commence on the Effective Date and, unless this Agreement is terminated earlier in accordance with this Article 11:
  - (a) with respect to the AR Mutant Program: (i) if the Option is exercised by Janssen in accordance with Section 3.3.1, this Agreement will expire with respect to the AR Mutant Program on the Option Exercise Effective Date; and (ii) if the Option is not exercised by Janssen in accordance with Section 3.3.1, this Agreement will expire with respect to the AR Mutant Program upon expiration of all of the payment obligations under Article 6 with respect to all AR Mutant Products in all countries; *provided* that, on an AR Mutant Product-by-AR Mutant Product and country-by-country basis, upon expiration of all of the payment obligations under Article 6 with respect to a given AR Mutant Product in a given country, the licenses granted herein with respect to such AR Mutant Product in such country shall survive on a fully-paid, royalty-free, non-exclusive, irrevocable and perpetual basis; and

## \*\*\*Confidential Treatment Requested

(b) with respect to the NIK Program: (i) if Janssen and Licensee enter into a Janssen NIK License Agreement in accordance with Section 3.4 or otherwise, this Agreement will expire with respect to the NIK Program upon the effective date of such Janssen NIK License Agreement; and (ii) if the ROFN expires in accordance with Section 3.4.3 and Janssen and Licensee have not entered into a Janssen NIK License Agreement prior to such expiration, this Agreement will expire with respect to the NIK Program upon expiration of all of the payment obligations under Article 6 with respect to all NIK Products in all countries; provided that, on a NIK Product-by-NIK Product and country-

by-country basis, upon expiration of all of the payment obligations under Article 6 with respect to a given NIK Product in a given country, the licenses granted herein with respect to such NIK Product in such country shall survive on a fully-paid, royalty-free, non-exclusive, irrevocable and perpetual basis.

- 11.2. **Termination during Development Term.** The following provisions of this Section 11.2 shall apply during the Development Term with respect to each Program.
  - 11.2.1. **Termination for Safety or Technical Reasons.** If Licensee reasonably determines, based upon the results of activities conducted pursuant to the applicable Development Plan for a Program, that (a) it is not feasible for material safety reasons to continue Development with respect to a Program and desires to terminate this Agreement with respect to such Program, or (b) after [...\*\*\*...], it is not feasible for material technical reasons to continue Development with respect to the NIK Program and desires to terminate this Agreement with respect to the NIK Program, in either case of clause (a) or (b), Licensee may so notify Janssen in writing, which notice shall include a reasonably detailed explanation for Licensee's determination, and, if requested by Janssen, the Parties shall meet to discuss such determination within thirty (30) days following such notice. The Agreement shall terminate with respect to such Program on the date of such notice or upon the date of such meeting between the Parties held within thirty (30) days following such notice.
  - 11.2.2. **Termination for Licensee Material Breach**. Janssen may terminate this Agreement with respect to a Program during the Development Term of such Program if Licensee has materially breached (i) its covenant under Section 2.1.1(c), (ii) any of its obligations under Section 2.2.3(a) with respect to such Program, (iii) its covenant under Section 2.3.1 with respect to such Program, (iv) its covenant under Section 2.4 with respect to such Program or (v) its covenant under Section 5.2 during the Development Term with respect to such Program, in any case of clause (i), (ii), (iii), (iv) or (v), by providing written notice of such material breach to Licensee describing such alleged material breach in reasonable detail. Any termination of this Agreement pursuant to this Section 11.2.2 shall become effective sixty (60) days after such notice is given unless Licensee cures such breach prior to such date (or, in the case of clause (ii) only, if such breach is not reasonably able to be cured within sixty (60) days after notice of termination is given pursuant to this Section 11.2.2, such termination shall not become effective until the earlier of the date such breach is cured or one hundred twenty (120) days after notice of termination is given pursuant to this Section 11.2.2, provided that (a) Licensee notifies Janssen of its plan for curing such breach within sixty (60) days after such notice is given, (b) Licensee commences such plan during such sixty (60) day period and (c) Licensee uses diligent efforts to perform such plan and cure such breach as soon as reasonably practicable).

#### 11.3. **Termination for Breach.**

11.3.1.

\*\*\*Confidential Treatment Requested

A Party (the "Terminating Party") may terminate this Agreement (a) with respect to a Program in the event the other Party (the "Breaching Party") has materially breached this Agreement only with respect to such Program or (b) in its entirety in the

Breaching Party has materially breached this Agreement (other than a material breach only with respect to one Program, in which case clause (a) of this Section 11.3.1 shall apply), and, in either case of clause (a) or (b), such material breach has not been cured within sixty (60) days after written notice of such breach is given by the Terminating Party to the Breaching Party (the "Cure Period"). This Section 11.3.1 shall not apply to any alleged material breach of Section 2.1.1(c), 2.2.3(a), 2.3.1, 2.4 or 5.2 by Licensee during the Development Term, which is instead subject to Section 11.2.2. The written notice describing the alleged material breach shall provide sufficient detail to put the Breaching Party on notice of such material breach. Any termination of this Agreement with respect to a Program or in its entirety pursuant to this Section 11.3.1 shall become effective at the end of the Cure Period unless the Breaching Party has cured any such material breach prior to the expiration of such Cure Period (or, if such breach (other than a breach of payment obligations) is not reasonably able to be cured within the Cure Period, such termination shall not become effective until the earlier of the date such breach is cured or one hundred and twenty (120) days after notice of termination is given pursuant to this Section 11.3.1, provided that (i) the Breaching Party notifies the other Party of its plan for curing such breach during the Cure Period, (ii) the Breaching Party commences such plan during the Cure Period and (iii) the Breaching Party uses diligent efforts to perform such plan and cure such breach as soon as reasonably practicable). The right of either Party to terminate this Agreement with respect to a Program or in its entirety as provided in this Section 11.3.1 shall not be affected in any way by such Party's waiver of or failure to take action with respect to any previous breach under this Agreement.

11.3.2. If the Parties reasonably and in good faith disagree as to whether there has been a material breach or a cure thereof, the Party that disputes whether there has been a material breach or a cure may contest the allegation in accordance with Article 12. Notwithstanding anything to the contrary contained in Section 11.3.1, the Cure Period for any material breach that is the subject of a Dispute will run from the date that written notice was first given to the Breaching Party by the Terminating Party through the resolution of such Dispute pursuant to Article 12 and for 10 days thereafter, and no termination pursuant to Section 11.3.1 shall become effective during such period. During the pendency of such Dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder; *provided* that the Parties' performance of their respective obligations and exercise of their respective rights hereunder that specify a date by which such obligations must be performed or such rights must be exercised shall be tolled through the resolution of such Dispute pursuant to Article 12 and for 10 days thereafter.

## 11.4. **Termination for Bankruptcy.**

11.4.1. A Party may terminate this Agreement in its entirety upon providing written notice to the other Party on or after the time that such other Party makes a general assignment for the benefit of creditors, files a voluntary petition in bankruptcy, consents to an order for relief in connection with an involuntary petition in bankruptcy filed against such Party (or an involuntary petition in bankruptcy filed against such Party remains un-dismissed or un-stayed for a period of more than sixty (60) days), petitions

for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors, or becomes a party to any proceeding or action of the type described above (each, an "Insolvency Event").

- All rights and licenses now or hereafter granted under or pursuant to any Section of this Agreement are rights to "intellectual property" (as defined in Section 101(35A) of Title 11 of the United States Code, as amended (such Title 11, the "Bankruptcy Code")). In the event this Agreement is rejected under Section 365 of the Bankruptcy Code by or on behalf of a Party (including by any receiver, trustee or similar officer appointed with respect to such Party), such Party (the "Licensor Party") hereby grants to the other Party (the "Licensee Party"), subject to the Licensee Party's obligations under Sections 365(n)(2)(A) and (B), a right of access and to obtain possession of and to benefit from embodiments of intellectual property pursuant to Section 365(n) of the Bankruptcy Code (including Program-Related Information and Know-How Controlled by the Licenser Party with respect to Licensed Compounds or Licensed Products and Regulatory Documentation with respect to Licensed Products, all of which constitute embodiments of intellectual property pursuant to Section 365(n) of the Bankruptcy Code) to the extent related to the Licensee Party's exercise of its license rights to any Licensed Compound or Licensed Product or otherwise related to any rights or licenses granted to the Licensee Party under or pursuant to any Section of this Agreement. The Licensor Party agrees not to interfere with the Licensee Party's exercise under the Bankruptcy Code of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement.
- 11.5. <u>Termination Without Cause After Development Term.</u> During the License Term with respect to a Program, Licensee shall have the right to terminate this Agreement with respect to such Program (but not the Agreement in its entirety) without cause by providing Janssen sixty (60) days' prior written notice of such termination. After the end of the Development Terms of both Programs, Licensee shall have the right to terminate this Agreement in its entirety without cause by providing Janssen sixty (60) days' prior written notice of such termination.

## 11.6. <u>Effects of Termination or Expiration</u>.

- 11.6.1. **Effects of Termination during Development Term**. If this Agreement is terminated with respect to only one Program (the "**Terminated Program**") or in its entirety pursuant to Section 11.2, then the provisions of this Section 11.6.1 shall apply with respect to the Terminated Program or, if this Agreement is terminated in its entirety, with respect to both of the Programs.
  - (a) The Development Term with respect to the Terminated Program shall end on the date of such termination.
  - (b) The licenses and other rights granted to Licensee under this Agreement with respect to the Terminated Program, other than those that expressly survive

termination of this Agreement, shall terminate on the effective date of termination.

- (c) If Licensee is conducting any Development activity with respect to the terminated Program immediately prior to the effective date of termination, then Janssen shall notify Licensee within [...\*\*\*...] after the notice of termination (i) with regard to any Clinical Trial, whether Janssen elects to have Licensee complete such activity (which may involve wind-down of such activity) or transfer such activity to Janssen and (ii) with regard to any other Development activity, whether Janssen elects to have Licensee transfer such activity to Janssen.
  - (1) With regard to any Clinical Trial, if Janssen notifies Licensee of its election to have Licensee complete such activity (or fails to provide notice within such [...\*\*\*...] period), then Licensee shall complete or wind-down such activity at its sole cost and expense.
  - (2) If Janssen notifies Licensee of its election to have Licensee transfer such activity to Janssen, then Licensee shall use Commercially Reasonable Efforts to transfer, and Janssen shall use Commercially Reasonable Efforts to assume, such activity as promptly as practicable (and, in any event, within [...\*\*\*...]) after the effective date of termination. Licensee shall bear the costs of such activity incurred by Licensee until the completion of such transfer, and Janssen shall bear the costs of such activity after the completion of such transfer.
- (d) Licensee shall, within [...\*\*\*...] after the effective date of termination and at Licensee's expense, return or destroy, at Janssen's election, all Janssen Program Know-How and other Confidential Information of Janssen that is solely related to the Terminated Program (*provided* that (i) Licensee may keep one copy of such Confidential Information subject to an ongoing obligation of confidentiality for archival purposes only, (ii) it is acknowledged that, with regard to any such Confidential Information disclosed to subcontractors, consultants, agents, advisors and other Third Parties as permitted by Section 8.3, Licensee's use of Commercially Reasonable Efforts to return or destroy such Confidential Information shall satisfy its obligation under this Section 11.6.1(d) and (iii) Licensee may retain and continue to use Janssen Program Know-How and other Confidential Information of Janssen to practice any licenses and other rights granted to Licensee under this Agreement with respect to such Program that expressly survive expiration of this Agreement as to such Program).

(e)

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Licensee shall, and hereby does, assign to Janssen, as of the effective date of termination, all of its right, title and interest in, to and under all of Licensee's ownership interest in any Development Program Know-How and Development Program Patents with respect to the Terminated Program, and Licensee shall transfer all such Development Program Know-How owned solely by Licensee to Janssen promptly after the effective date of termination (to the extent that such Know-How has not previously been transferred to Janssen).

- (f) Licensee shall, and hereby does, assign to Janssen, as of the effective date of termination, all of its right, title and interest in, to and under all of Licensee's ownership interest in any Regulatory Documentation, including any Regulatory Approvals, with respect to the Terminated Program, and Licensee shall transfer all such Regulatory Documentation to Janssen promptly after the effective date of termination.
- (g) Licensee shall, and hereby does, grant to Janssen, as of the effective date of termination, an exclusive, perpetual, royalty-free, freely sublicensable, transferable license under any Licensee Program Know-How and Licensee Program Patents to make, have made, use, have used, import, have imported, sell, have sold, offer for sale and have offered for sale Licensed Compounds and Licensed Products with respect to such Terminated Program in the Field in the Territory.
- (h) During the period beginning on the effective date of termination with respect to a Program and ending [...\*\*\*...] thereafter, neither Licensee nor any of its Affiliates shall: [...\*\*\*...]. Notwithstanding the foregoing:
  - (1) Section 11.6.1(h) does not prohibit Licensee and its Affiliates that are subject to Section 11.6.1(h), alone or through work conducted in collaboration with an Affiliate or Third Party, from conducting research and non-clinical development (or licensing or otherwise granting rights to an Affiliate or a Third Party to conduct research and non-clinical development) of compounds (other than Licensed Compounds) that (i) [...\*\*\*...].
  - (2) Section 11.6.1(h) shall not apply to the Acquirer of a Party or any Affiliate of such Acquirer (excluding any Affiliate that was an Affiliate of such Party prior to a Change of Control and became an Affiliate of such Acquirer as a result of such Change of Control).
  - (3) Licensee shall not be limited or prohibited by Section 11.6.1(h) from negotiating and completing a Change of Control, or taking any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party relating to, or engage in discussions with any Third Party relating to, a Change of Control.

(i)

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Licensee shall assign to Janssen any Third Party agreements to which Licensee or any of its Affiliates are a party (including any Transferred Contracts) that solely relate to the Terminated Program, solely to the extent that such agreements are assignable without cost to Licensee (or Janssen agrees to bear such costs) and Janssen assumes all liabilities under such agreements that arise following the effective date of such assignment (other than due to a breach or violation of such agreement by Licensee or its Affiliate that occurred prior to the effective date of such assignment).

- (j) At Janssen's request, Licensee shall assign and transfer to Janssen any inventory of Licensed Compounds or Licensed Products with respect to the Terminated Program then in Licensee's or its Affiliate's possession or control subject to Janssen's reimbursement of Licensee's reasonable costs incurred in acquiring such inventory and with respect to shipping thereof.
- (k) At Janssen's request, Licensee shall assign and transfer to Janssen any Transferred Assets (other than Transferred Contracts) then in Licensee's or its Affiliate's possession or control that solely relate to the Terminated Program at no cost to Janssen.
- (l) For clarity, Janssen shall not be obligated to pay the Option Exercise Fee or to reimburse the out-of-pocket expenses incurred by Licensee or any of its Affiliates in the performance of the [...\*\*\*...] (if applicable) with respect to the Terminated Program.
- (m) Licensee shall take such other actions, and execute any instruments, assignments and documents, as reasonably requested by Janssen as may be necessary to effect the foregoing provisions of this Section 11.6.1.
- 11.6.2. **Effects of Termination for Breach.** If this Agreement is terminated by Janssen pursuant to Section 11.3 with respect to a Terminated Program or in its entirety, then the following provisions shall apply to such Terminated Program or to both Programs, as applicable: Sections 11.6.1(a) (if any Development Term is then in effect), 11.6.1(b), 11.6.1(c), 11.6.1(d), 11.6.1(e), 11.6.1(f), 11.6.1(g), 11.6.1(h), 11.6.1(i), 11.6.1(j), 11.6.1(k), 11.6.1(l) and 11.6.1(m) shall apply. If this Agreement is terminated by Licensee pursuant to Section 11.3 with respect to a Terminated Program or in its entirety, then the following provisions shall apply to such Terminated Program or to both Programs, as applicable: Sections 11.6.1(a) (if any Development Term is then in effect), 11.6.1(b), 11.6.1(c) (but [...\*\*\*...] shall determine whether to complete or transfer such activity and [...\*\*\*...] shall bear the costs of any completion or transfer of activities), 11.6.1(d), and 11.6.1(l).
- 11.6.3. **Effects of Termination for Bankruptcy.** If this Agreement is terminated by Janssen pursuant to Section 11.4, then the provisions of Sections 11.6.1(a) (if any Development Term is then in effect), 11.6.1(b), 11.6.1(c), 11.6.1(d), 11.6.1(e), 11.6.1(f), 11.6.1(g), 11.6.1(h), 11.6.1(i), 11.6.1(j), 11.6.1(k), 11.6.1(l) and 11.6.1(m) shall apply. If this Agreement is terminated by Licensee pursuant to Section 11.4, then the provisions of Sections 11.6.1(a) (if any Development Term is then in effect), 11.6.1(b), 11.6.1(c), 11.6.1(d), and 11.6.1(l) shall apply.

11.6.4.

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Effects of Termination Without Cause. If this Agreement is terminated by Licensee pursuant to Section 11.5 with respect to a Terminated Program or in its entirety, then the following provisions shall apply to such Terminated Program or to both Programs, as applicable: Sections 11.6.1(b), 11.6.1(c), 11.6.1(d), 11.6.1(e), 11.6.1(f), 11.6.1(g), 11.6.1(h), 11.6.1(j), 11.6.1(j), 11.6.1(k), 11.6.1(l) and 11.6.1(m).

- 11.6.5. **Licensee Confidential Information.** Janssen shall, within thirty (30) days after the effective date of expiration or termination of this Agreement with respect to a Program or in its entirety, and at Janssen's expense, return or destroy, at Licensee's election, all Confidential Information of Licensee that is solely related to such Program(s) (*provided* that (i) Janssen may keep one copy of such Confidential Information subject to an ongoing obligation of confidentiality for archival purposes only, (ii) it is acknowledged that, with regard to any such Confidential Information disclosed to subcontractors, consultants, agents, advisors and other Third Parties as permitted by Section 8.3, Janssen's use of Commercially Reasonable Efforts to return or destroy such Confidential Information shall satisfy its obligation under this Section 11.6.5 and (iii) Janssen may retain and continue to use Confidential Information of Licensee to practice any licenses and other rights granted to Licensee under this Agreement with respect to such Program that expressly survive expiration of this Agreement as to such Program).
- 11.6.6. **Effects of Expiration.** If the Term expires with respect to a Program or with respect to this Agreement in its entirety pursuant to Section 11.1, then the provisions of Sections 11.6.1(b), 11.6.1(c), and 11.6.1(d) shall apply with respect to the Program with respect to which the Term has expired or, if this Agreement expires in its entirety, with respect to all of the Programs; *provided* that Licensee may retain and continue to use Janssen Program Know-How and other Confidential Information of Janssen to practice any licenses and other rights granted to Licensee under this Agreement with respect to such Program(s) that expressly survive expiration of this Agreement as to such Program(s).
- Additional Effects of Expiration or Termination for any Reason. Termination or expiration of this Agreement will not relieve the Parties of any obligations accruing prior to such expiration or termination, and any such expiration or termination will be without prejudice to the rights of either Party accruing prior to such expiration or termination. The Parties acknowledge and agree that termination of this Agreement is not the sole remedy under this Agreement and, whether or not termination is effected, all other remedies will remain available except as expressly agreed to otherwise herein. The provisions of Article 1, Article 8, Article 12 and Article 13 and Sections 2.2.4 (for the period specified therein), 6.5 (for the period specified therein), 7.2, 9.4, 10.1, 10.2, 10.3, 10.4 (for the period specified therein), 11.1 (the provisos regarding survival of licenses) and 11.6 (and the provisions referenced therein as applicable) shall survive expiration or termination of this Agreement for any reason. If this Agreement expires or is terminated only with respect to one Program, this Agreement shall continue in full force and effect with respect to the other Program and all terms and conditions other than those that apply only to the Terminated Program.

# Article 12 DISPUTE RESOLUTION

12.1. <u>Escalation; Decision-Making Authority</u>. In the case of any dispute, claim or controversy between the Parties arising from or related to this Agreement, or the interpretation, application, breach, termination or validity of this Agreement (a "**Dispute**"), the Parties will

discuss and negotiate in good faith a solution acceptable to the Parties and in the spirit of this Agreement. If, after negotiating in good faith pursuant to the foregoing sentence, the Parties fail to reach agreement within [...\*\*\*...] (or such longer period as agreed in writing by the Parties), then the Dispute may be referred to the Executive Officers for resolution at the request of either Party. If, after negotiating in good faith, the Executive Officers fail to reach agreement within [...\*\*\*...] of submission to the Executive Officers (or such longer period as agreed in writing by the Parties), then either Party may upon written notice to the other submit the Dispute to non-binding mediation pursuant to Section 12.2.

### 12.2. **Mediation.**

- 12.2.1. If the Parties fail to resolve the Dispute pursuant to Section 12.1, the Parties shall attempt in good faith to resolve any Dispute by confidential mediation in accordance with the then current *Mediation Procedure of the International Institute for Conflict Prevention and Resolution* ("CPR Mediation Procedure") (www.cpradr.org) before initiating arbitration. The CPR Mediation Procedure shall control, except where it conflicts with these provisions, in which case these provisions control. The mediator shall be chosen pursuant to CPR Mediation Procedure. The mediation shall be held in New York, New York.
- 12.2.2. Either Party may initiate mediation by written notice to the other Party of the existence of a Dispute. The Parties agree to select a mediator within [...\*\*\*...] of the notice and the mediation will begin promptly after the selection. The mediation will continue until the mediator, or either Party, declares in writing, no sooner than after the conclusion of one full day of a substantive mediation conference attended on behalf of each Party by a senior business person with authority to resolve the Dispute, that the Dispute cannot be resolved by mediation. In no event, however, shall mediation continue more than [...\*\*\*...] from the initial notice by a Party to initiate mediation unless the Parties agree in writing to extend that period.
- 12.2.3. Any period of limitations that would otherwise expire between the initiation of mediation and its conclusion shall be extended until [...\*\*\*...] after the conclusion of the mediation.

### 12.3. **Arbitration.**

12.3.1. If the Parties fail to resolve the Dispute pursuant to Section 12.1 or Section 12.2, and a Party desires to pursuar resolution of the Dispute, subject to Section 12.3.10, the Dispute shall be submitted by either Party for resolution in arbitration pursuant to the then current *CPR Non- Administered Arbitration Rules* ("**CPR Rules**") (www.cpradr.org), except where they conflict with these provisions, in which case these provisions control. The arbitration will be held in New York, New York. All aspects of the arbitration shall be treated as confidential.

12.3.2.

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The arbitrators will be chosen from the CPR Panel of Distinguished Neutrals, unless a candidate not on such panel is approved by both Parties. Each arbitrator shall be a lawyer with at least fifteen (15) years' experience with a law firm or corporate law

department of over twenty-five (25) lawyers or who was a judge of a court of general jurisdiction. To the extent that the Dispute requires special expertise, the Parties will so inform CPR prior to the beginning of the selection process.

- 12.3.3. The arbitration tribunal shall consist of three (3) arbitrators, of whom each Party shall designate one in accordance with the "screened" appointment procedure provided in CPR Rule 5.4. The chair will be chosen in accordance with CPR Rule 6.4. If, however, the aggregate award sought by the Parties is less than Five Million U.S. Dollars (\$5,000,000) and equitable relief is not sought, a single arbitrator shall be chosen in accordance with the CPR Rules. Candidates for the arbitrator position(s) may be interviewed by representatives of the Parties in advance of their selection, *provided* that all Parties are represented.
- 12.3.4. The Parties agree to select the arbitrator(s) within forty-five (45) days of initiation of the arbitration. The hearing will be concluded within nine (9) months after selection of the arbitrator(s) and the award will be rendered within sixty (60) days of the conclusion of the hearing, or of any post-hearing briefing, which briefing will be completed by both sides within forty-five (45) days after the conclusion of the hearing. In the event the Parties cannot agree upon a schedule, then the arbitrator(s) shall set the schedule following the time limits set forth above as closely as practical.
- 12.3.5. The hearing will be concluded in ten (10) hearing days or less. Multiple hearing days will be scheduled consecutively to the greatest extent possible. A transcript of the testimony adduced at the hearing shall be made and shall be made available to each Party.
- 12.3.6. The arbitrator(s) shall be guided, but not bound, by the *CPR Protocol on Disclosure of Documents and Presentation of Witnesses in Commercial Arbitration* (www.cpradr.org) ("**Protocol**"). The Parties will attempt to agree on modes of document disclosure, electronic discovery, witness presentation, etc. within the parameters of the Protocol. If the Parties cannot agree on discovery and presentation issues, the arbitrator(s) shall decide on presentation modes and provide for discovery within the Protocol, understanding that the Parties contemplate reasonable discovery.
- 12.3.7. The arbitrator(s) shall decide the merits of any Dispute in accordance with the law governing this Agreement, without application of any principle of conflict of laws that would result in reference to a different law. The arbitrator(s) may not apply principles such as "amiable compositeur" or "natural justice and equity."
- 12.3.8. The arbitrator(s) are expressly empowered to decide dispositive motions in advance of any hearing and shall endeavor to decide such motions as would a United States District Court Judge sitting in the jurisdiction whose substantive law governs.
- 12.3.9. The arbitrator(s) shall render a written opinion stating the reasons upon which the award is based. The Parties consent to the jurisdiction of the United States District Court for the district in which the arbitration is held for the enforcement of these provisions and the entry of judgment on any award rendered hereunder. Should such court for any reason lack jurisdiction, any court with jurisdiction may act in the same fashion.

12.3.10. Notwithstanding any provision to the contrary contained in this Agreement, each Party has the right to seek from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin or other equitable relief to avoid irreparable harm, maintain the status quo, preserve its status and priority as a creditor or preserve the subject matter of the Dispute. Rule 14 of the CPR Rules does not apply to this Agreement.

### Article 13 MISCELLANEOUS

- 13.1. **Performance by Affiliates.** To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations. A Party may use one or more of its Affiliates to perform its obligations and duties or exercise its rights hereunder, *provided* that such Party will remain liable hereunder for the prompt payment and performance of all of their respective obligations hereunder. Any breach by an Affiliate of a Party of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.
- 13.2. **Retained Rights**. All licenses and rights are granted only as expressly provided in this Agreement, and no license or other right is or shall be created or granted under this Agreement by implication, estoppel, or otherwise. All rights not expressly granted by a Party under this Agreement are reserved by such Party and may not be used by the other Party for any purpose.
- 13.3. Entire Agreement. This Agreement and each of the Schedules and Exhibits hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter of this Agreement and cancels and supersedes any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties (including the Nondisclosure Agreement, *provided* that all information shared by the Parties or their Affiliates pursuant to such Nondisclosure Agreement shall be deemed Confidential Information of the disclosing Party under this Agreement, and the use and disclosure thereof shall be governed by Article 8), whether oral or written, regarding such subject matter.
- 13.4. **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 13.5. **Binding Effect.** This Agreement and the rights granted herein will be binding upon, and will inure to the benefit of Janssen, Licensee and their respective lawful successors and permitted assigns.
- 13.6. **Assignment.** Neither Party may assign or transfer this Agreement in its entirety or any rights or obligations hereunder without the prior written consent of the other Party, except that:
  - (a) Janssen may assign or transfer this Agreement in its entirety or any rights or obligations hereunder to an Affiliate without Licensee's consent;

- (b) after the end of the Development Term of a Program, Licensee may assign any rights or obligations hereunder relating to such Program to an Affiliate without Janssen's consent;
- (c) after the end of the Development Terms of both Programs, Licensee may assign or transfer this Agreement in its entirety to an Affiliate without Janssen's consent;
- (d) Janssen may assign or transfer this Agreement in its entirety to a Third Party acquirer of that portion of its business relating to the subject matter of this Agreement in a sale of assets or other similar transaction without Licensee's consent;
- (e) after the end of the Development Terms of both Programs, Licensee may assign or transfer this Agreement in its entirety to a Third Party acquirer of that portion of its business relating to the subject matter of this Agreement in a sale of assets or other similar transaction without Janssen's consent (other than in a Change of Control); and
- (f) either Party may assign or transfer this Agreement in its entirety pursuant to any Change of Control of such Party.

The assigning Party shall provide the other Party with prompt written notice of any such assignment pursuant to any of Section 13.6(b) through 13.6(f). Janssen shall use diligent efforts to provide Licensee with written notice of any assignment to an Affiliate pursuant to Section 13.6(a) within a reasonable period of time after the occurrence of such assignment. Any permitted assignment shall be binding on the successors and permitted assignees of the assigning Party, and the successor (if the successor is an entity other than a Party) or assignee shall confirm the same in writing to the other Party. Any assignment, transfer or attempted assignment or transfer by either Party in violation of the terms of this Section 13.6 shall be null, void and of no legal effect.

- 13.7. <u>Use of Names.</u> Neither Party shall use the name, physical likeness, employee names or Trademarks of the other Party for any purpose without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed; *provided*, *however*, that nothing contained herein shall be construed to prevent either Party from using the name of the other Party for purposes of preparing necessary filings with the United States Securities and Exchange Commission or complying with its regulations, or other regulations applicable to the public sale of securities, including preparing proxy statements or prospectuses. Nothing contained herein shall be construed as granting either Party any rights or license to use any of the other Party's Trademarks without separate, express written permission of the owner of such Trademark.
- 13.8. <u>Amendment; No Waiver.</u> No waiver, modification or amendment of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party. The failure of either Party to assert a right hereunder or to insist upon

compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition.

- 13.9. Force Majeure Event. Except for obligations to make payments under this Agreement when due, the failure of a Party to perform any obligation under this Agreement by reason of force majeure, limited to acts of God, war, terrorism (actual or threatened), strikes, revolutions, laws or other causes of a similar magnitude beyond the reasonable control of such Party (each, a "Force Majeure Event"), will not be deemed to be a breach of this Agreement. The Party affected by any Force Majeure Event will contact the other Party for discussion of possible emergency measures.
- 13.10. <u>Independent Contractors</u>. The Parties are independent contractors and not agents or employees of the other Parties under this Agreement. Nothing contained in this Agreement is intended nor is to be construed so as to constitute Janssen and Licensee as partners or joint venturers with respect to this Agreement. No Party will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Parties or to bind the other Parties to any other contract, agreement or undertaking with any Third Party except as may be explicitly provided for herein or authorized in writing.
- 13.11. Notices and Deliveries. Any notices, request, delivery, approval or consent required or permitted to be given under this Agreement will be in writing and will be deemed to have been sufficiently given when it is received, whether delivered in person, transmitted by facsimile with contemporaneous confirmation, delivered by registered letter (or its equivalent) or delivered by certified overnight courier service, to the Party to which it is directed at its address shown below or such other address as such Party will have last given by notice to the other Party.

If to Licensee:

TRACON Pharmaceuticals, Inc. 8910 University Center Lane Suite 700 San Diego, CA 92122 USA Attention: Chief Business Officer Facsimile No.: +1 858-550-0786

with a copy to:

Cooley LLP 4401 Eastgate Mall San Diego, CA 92121 USA Attention: L. Kay Chandler Facsimile No.: +1 858-550-6420

If to Janssen:

Janssen Pharmaceutica NV Legal Affairs Department Turnhoutseweg 30 B-2340 Beerse Belgium

Facsimile: As may be provided to TRACON by Janssen

with a copy to:

Office of General Counsel Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933 Facsimile: 732-524-2788

- 13.12. <u>Headings</u>. The captions to the sections and articles in this Agreement are not a part of this Agreement, and are included merely for convenience of reference only and will not affect its meaning or interpretation.
- 13.13. <u>Severability</u>. In the event that any provision of this Agreement will, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability will not affect any other provision hereof, and this Agreement will be construed as if such invalid or unenforceable provision had not been included herein.
- 13.14. Governing Law. This Agreement will be governed by and interpreted in accordance with the laws of the State of New York without reference to its choice of laws or conflicts of laws provisions. The United Nations Conventions on Contracts for the International Sale of Goods shall not be applicable to this Agreement. Each Party (a) submits to the exclusive jurisdiction of the state and federal courts sitting in New York, New York, with respect to actions or proceedings arising out of or relating to this Agreement in which a Party brings an action in aid of arbitration, (b) agrees that all claims in respect of such action or proceeding may be heard and determined only in any such court, and (c) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court, other than an action or proceeding seeking injunctive relief or brought to enforce an arbitration ruling issued pursuant to Section 12.3. Each Party waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of the other Party with respect thereto. Each Party may make service on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for the giving of notices in Section 13.11. Nothing in this Section 13.14, however, will affect the right of any Party to serve legal process in any other manner permitted by New York law.
- 13.15. Advice of Counsel. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will exist or be implied against the Party which drafted such terms and provisions.
- 13.16. <u>Counterparts.</u> This Agreement may be executed in any number of counterparts (including by facsimile or electronic transmission), each of which need not contain the signature

of more than one Party, but all such counterparts taken together will constitute one and the same agreement. Signatures provided by facsimile transmission or in Adobe<sup>TM</sup> Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

13.17. **Construction.** Whenever this Agreement refers to a number of days without using a term otherwise defined herein, such number refers to calendar days. Except where the context otherwise requires, (a) wherever used, the singular shall include the plural, the plural shall include the singular; (b) the use of any gender shall be applicable to all genders; (c) the terms "including," "include," "include," "includes" or "for example" shall not limit the generality of any description preceding such term and, as used herein, shall have the same meaning as "including, but not limited to," and/or "including, without limitation"; (d) the words "herein", "hereof" and hereunder", and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; (d) the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (e) the word "will" means "shall"; (f) if a period of time is specified and dates from a given day or business day, or the day or business day of an act or event, it is to be calculated exclusive of that day or business day; (g) references to a particular entity include such entity's successors and assigns to the extent not prohibited by this Agreement; (h) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein shall be interpreted in a correlative manner; and (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein).

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

### JANSSEN PHARMACEUTICA N.V.

By:	/s/ Tom Heyman		
Name:	Tom Heyman		
Title:	Managing_Director		
JANSSEN PHARMACEUTICA N.V.			
By:	/s/ Hilde Claes		
Name:	Hilde Claes		
Title:	Member of the Board of Directors		
TRACON PHARMACEUTICALS, INC.			
By:	/s/ Charles P. Theuer		
Name:	Charles P. Theuer		
Title:	CEO		

# EXHIBIT A AR MUTANT PROGRAM LICENSE AGREEMENT

LICENSE AGREEMENT
BY AND BETWEEN
TRACON PHARMACEUTICALS, INC.

AND

JANSSEN PHARMACEUTICA N.V.

### LICENSE AGREEMENT

This LICENSE AGREEMENT (this "Agreement") is made and effective as of the Effective Date (as defined below) by and between TRACON Pharmaceuticals, Inc., a Delaware corporation ("TRACON") and Janssen Pharmaceutica N.V. ("Janssen"). Each of TRACON and Janssen is sometimes referred to herein individually as a "Party" and collectively as the "Parties." In the event a Party assigned the License and Option Agreement (as defined below) in its entirety prior to the Effective Date (as defined below) pursuant to Section 13.6 of the License and Option Agreement, or a lawful successor of a Party became bound by the License and Option Agreement prior to the Effective Date, the references to such Party in this Agreement shall be deemed to refer to such permitted assignee or lawful successor.

### **RECITALS**

WHEREAS, TRACON has developed certain technology and owns or has a license to certain intellectual property rights relating to the AR Mutant Program (as defined below) conducted by TRACON and its Affiliates prior to the Effective Date pursuant to the License and Option Agreement (as defined below); and

WHEREAS, Janssen exercised the exclusive option granted under the License and Option Agreement to terminate the licenses and related rights granted by Janssen to TRACON pursuant to the License and Option Agreement and obtain, and TRACON is obligated to grant to Janssen, an exclusive, worldwide license under the Licensed Technology (as defined below) to develop, manufacture and commercialize Licensed Compounds (as defined below) and Licensed Products (as defined below) on the terms and subject to the conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the various promises and covenants set forth herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

# Article 1 DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, will have the meaning set forth below or, if not listed below, the meaning designated where first used in this Agreement.

- 1.1. "Acquirer" means any Third Party that is a party to any Change of Control transaction and any of such Third Party's Affiliates.
- 1.2. "Affiliate" means, with respect to any Party, any corporation or other business entity that directly or indirectly controls, is controlled by, or is under common control with such Party at the time at which the determination of affiliation is being made. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to any Party, means the possession of at least 50% of the voting stock or other ownership interest of the other corporation or entity, or the power to

direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint at least 50% of the members of the governing body of the corporation or other entity through the ownership of the outstanding voting securities or by contract or otherwise.

- 1.3. "Applicable Law" means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any Governmental Authority, including the FFDCA, Prescription Drug Marketing Act of 1987 (21 U.S.C. §§331, 333, 353, 381), the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335(a) et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal False Claims Act (31 U.S.C. §3729 et seq.), and the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder.
- 1.4. "AR Mutant Compound" means any compound that is (a) (i) described as a composition-of-matter as of the License and Option Agreement Effective Date in a claim of a Patent Right in the United States or the EPO or treaty country thereof (including such a claim of a Patent Cooperation Treaty application designating the United States or EPO) set forth on Schedule AR Mutant Program Patents of the Schedule Letter or (ii) described after the License and Option Agreement Effective Date in a claim of such a Patent Right filed within [...\*\*\*...], or (b) described in a claim of a Patent Right in the United States or the EPO or treaty country thereof (including such a claim of a Patent Cooperation Treaty application designating the United States or EPO) Controlled by a Party which also describes as a composition-of-matter a compound described in (a) above as of the [...\*\*\*...]. AR Mutant Compound includes the compound specifically set forth on Schedule AR Mutant Compound of the Schedule Letter.
- 1.5. "AR Mutant Development Plan" shall have the meaning given to it in the License and Option Agreement.
- 1.6. "AR Mutant Product" means any pharmaceutical product in any dosage form containing an AR Mutant Compound.
- 1.7. "**AR Mutant Program**" means the conduct of Development, Manufacturing and Commercialization activities with respect to AR Mutant Compounds and AR Mutant Products.
- 1.8. "Calendar Quarter" means a financial quarter based on the Johnson & Johnson Universal Calendar; *provided*, *however*, that the first Calendar Quarter of the Term shall begin on the Effective Date and end on the last day of the then-current Calendar Quarter and the last Calendar Quarter of the Term shall begin on the first day of such Calendar Quarter and end on the effective date of termination or expiration of this Agreement.
- 1.9. "Calendar Year" means a year based on the Johnson & Johnson Universal Calendar, *provided*, *however*, that the first Calendar Year of the Term shall begin on the Effective Date and end on the last day of the then-current Calendar Year and the last Calendar Year of the Term shall begin on the first day of such Calendar Year and end on the effective date of termination or expiration of this Agreement.

1.10.

\*\*\*Confidential Treatment Requested

"Change of Control" means, with respect to a Party: (a) that any Third Party acquires directly or indirectly the beneficial ownership of any voting securities of such Party, or if the

percentage ownership of such person or entity in the voting securities of such Party is increased through stock redemption, cancellation or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of outstanding voting securities representing more than fifty percent (50%) of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization or reorganization of such Party is consummated, other than any such transaction in which stockholders or equity holders of such Party immediately prior to such transaction beneficially own, directly or indirectly, at least fifty percent (50%) of the voting securities of the surviving entity (or its parent entity) immediately following such transaction; (c) that the stockholders or equity holders of such Party approve a plan of complete liquidation of such Party; (d) that individuals who, as of the Effective Date, constitute the Board of Directors of such Party (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board of Directors of such Party (provided, however, that any individual becoming a director subsequent to the date hereof whose election, or nomination for election by such Party's stockholders, was recommended or approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of any person other than the Board of Directors of such Party); or (e) the sale or disposition to a Third Party of all or substantially all of such Party's assets taken as a whole.

- 1.11. "Clinical Trial" means any Phase I Clinical Trial, Phase II Clinical Trial, Phase II/III Clinical Trial or Phase III Clinical Trial.
- 1.12. "Combination Product" means: (a) any Licensed Product that contains a Licensed Compound and one or more other active pharmaceutical ingredient(s), where such Licensed Compound and other active pharmaceutical ingredient(s) are co-formulated into a single product; or (b) any combination, package or bundle of a Licensed Product with one or more other pharmaceutical products that are not Licensed Products sold together for a single invoiced price.
- 1.13. "Commercialization" means any activities directed to marketing, promoting, educating, informing, distributing, importing, offering to sell and/or selling a pharmaceutical product. When used as a verb, "Commercialize" means to engage in Commercialization activities.
- 1.14. "Commercially Reasonable Efforts" means: (a) with respect to the Development, seeking and obtaining Marketing Approval, Manufacture or Commercialization of a Licensed Product in a country by or on behalf of Janssen during the License Term, those reasonable, good faith efforts normally used by biopharmaceutical companies of similar size and stage of development under similar circumstances for similar products or product candidates owned or controlled by such company, or to which such company has similar rights, which product or product candidate is of similar market potential in such country and is at a similar stage in its development or product life, taking into account (with respect to those efforts described in this clause (b) only) all Relevant Factors; or (b) with respect to the efforts to be expended by either Party with respect to any objective or activity other than those described in clause (a) of this Section 1.14, those reasonable, good faith efforts to accomplish such objective or perform such

activity as such Party would normally use to accomplish a similar objective under similar circumstances.

- 1.15. "Competing Product" means a therapeutic product, an active pharmaceutical ingredient of which [...\*\*\*...].
- 1.16. "Confidential Information" means: (a) all non-public or proprietary information (including Know-How) that is disclosed by a Party (or any of its Affiliates) to the other Party (or any of its Affiliates) pursuant to or in connection with this Agreement or the License and Option Agreement; and (b) all other non-public or proprietary information (including Know-How) that is expressly deemed in this Agreement or the License and Option Agreement to be Confidential Information, whether or not disclosed by a Party (or any of its Affiliates) to the other Party (or any of its Affiliates), in each case ((a) or (b)), without regard as to whether any of the foregoing is marked "confidential" or "proprietary," or in oral, written, graphic or electronic form.
- "Control" or "Controlled" means, with respect to any Know-How, Patent Right or other intellectual property right, possession by a Party (whether by ownership or license or otherwise, but without taking into account any rights granted pursuant to this Agreement), directly or through an Affiliate of such Party, of the ability to transfer, or grant a license or sublicense under, such right as provided for herein without violating the terms of any contract with any Third Party that exists on the Effective Date or other binding arrangement with any Third Party that exists on the Effective Date, or, subject to Section 2.2, any contract with any Third Party or other binding arrangement with any Third Party that exists after the Effective Date with regard to any Know-How, Patent Right or other intellectual property right licensed to or acquired by a Party from a Third Party after the Effective Date; provided, however, that any Know-How, Patent Right or other intellectual property right that is owned or licensed by an Acquirer of a Party or any Affiliate of such Acquirer (excluding any Affiliate that was an Affiliate of such Party prior to a Change of Control and became an Affiliate of such Acquirer as a result of such Change of Control) shall not be deemed to be Controlled by such Party for purposes of this Agreement, except to the extent, and only to the extent that, such Know-How, Patent Right or other intellectual property right is either (a) actually used by such Party, the Acquirer or any of their respective Affiliates in the performance of Development, Manufacturing or Commercialization activities with respect to any Licensed Compound or Licensed Product following the consummation of the Change of Control of such Party, or (b) made, conceived or reduced to practice by the Acquirer or any such Affiliates through the use of any Licensed Technology, Development Program Know-How or Development Program Patents following the consummation of the Change of Control of such Party.
- 1.18. "Cover", "Covering" and "Covered" means, with respect to a Patent Right and an invention, that, in the absence of ownership of or a license under such Patent Right, the practice of such invention (e.g., with respect to a Patent Right in the U.S., the manufacture, use, sale, offer for sale or importation of such invention) would infringe a Valid Claim of such Patent Right (in the case of a pending patent application, if the claims of such patent application as then existing were issued).

1.19.

\*\*\*Confidential Treatment Requested

"Data Package" shall have the meaning given to it in the License and Option Agreement.

- 1.20. "Development" means all research and non-clinical and clinical drug development activities and processes, including toxicology, pharmacology, project management and other non-clinical efforts, formulation development, delivery system development, statistical analysis, manufacturing development, the performance of Clinical Trials (including the manufacturing of products for use in clinical trials), or other activities reasonably necessary in order to obtain and maintain, Marketing Approval of a pharmaceutical product. When used as a verb, "Develop" means to engage in Development activities.
- 1.21. "Development Program Invention" means any Development Program Know-How that is an invention.
- 1.22. "Development Program Know-How" means any Know-How that was generated (or in the case of an invention, reduced to practice) by a Party's or its Affiliates' or Third Party subcontractors' employees or agents in performing any Development activities with AR Mutant Compounds or AR Mutant Products during the Development Term, including all preclinical and clinical data generated in the course of performing such activities; *provided* that Third Party Subcontractor Reserved Technology (as defined in the License and Option Agreement) shall be excluded to the extent not assigned or licensed to a Party.
- 1.23. "Development Program Patent" means any Patent Right that claims one or more Development Program Inventions.
- 1.24. "**Development Term**" means the period beginning on the License and Option Agreement Effective Date and ending immediately prior to the Effective Date of this Agreement.
- 1.25. "**Drug Approval Application**" means: (a) a new drug application submitted to the FDA pursuant to Section 505(b) of the FFDCA, 21 U.S.C. § 355(b) (an "**NDA**"); or (b) an application for authorization to market and/or sell a drug product submitted to a Regulatory Authority in any country or jurisdiction other than the U.S., in each case ((a) and (b)), including all amendments and supplements thereto.
- 1.26. "Effective Date" means the Option Exercise Effective Date as defined in the License and Option Agreement.<sup>1</sup>
- 1.27. "EMA" means the European Medicines Agency or any successor agency for the EU with responsibilities comparable to those of the European Medicines Agency.
- 1.28. "**EPO**" means the European Patent Organization, or any successor entity with responsibilities comparable to those of the European Patent Organization.
- 1.29. "EU" means the countries of the European Economic Area, as it is constituted on the Effective Date and as it may be modified from time to time after the Effective Date.

<sup>1</sup> Note to Draft: Actual calendar date to be inserted by Parties after Option is exercised.

- 1.30. "Executive Officers" means the Chief Executive Officer of TRACON and the Global Head, Oncology Therapeutic Area of Janssen Research & Development LLC, an Affiliate of Janssen.
- 1.31. "FDA" means the United States Food and Drug Administration or any successor agency in the United States with responsibilities comparable to those of the United States Food and Drug Administration.
- 1.32. "FFDCA" means the U.S. Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.), as amended from time to time.
- 1.33. "Field" means all uses.
- 1.34. "First Commercial Sale" means, with respect to a given Licensed Product and a given country, the first arm's-length commercial sale of such Licensed Product to a Third Party in the Field in such country after the receipt of Marketing Approval for such Licensed Product in such country. Sales for Clinical Trial purposes, early access or compassionate use programs, or similar uses, shall not constitute a First Commercial Sale. In addition, sales of a Licensed Product by and between Janssen and its Affiliates, distributors and (sub)licensees, or between the Parties (or their respective Affiliates, distributors or (sub)licensees), shall not constitute a First Commercial Sale.
- 1.35. "Governmental Authority" means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other instrumentality of (a) any government of any country or territory, (b) any nation, state, province, county, city or other political subdivision thereof or (c) any supranational body.
- 1.36. "IND" means (a) an Investigational New Drug application as defined in the FFDCA and applicable regulations promulgated thereunder by the FDA; (b) a clinical trial authorization application for a product filed with a Regulatory Authority in any other regulatory jurisdiction outside the U.S., the filing of which (in the case of (a) or (b)) is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction; or (c) documentation issued by a Regulatory Authority that permits the conduct of clinical testing of a product in humans in such jurisdiction.
- 1.37. "Indication" means a discrete clinically recognized form of a disease. For purposes of this Agreement, treatment of different subpopulations within a population of patients having a disease shall not be treated as separate Indications (e.g., front-line treatment, second-line or relapsed refractory treatment and maintenance treatment of prostate cancer shall not be treated as separate Indications; provided, however, that front-line treatment, second-line treatment or relapsed refractory treatment and maintenance treatment of prostate cancer shall be treated as separate Indications.
- 1.38. "Janssen-Owned Development Program Know-How" means any Development Program Know-How that is owned by Janssen pursuant to Section 7.2.1 of the License and Option Agreement.

- 1.39. "Janssen-Owned Development Program Patents" means any Development Program Patent that is owned solely by Janssen pursuant to Section 7.2.1 of the License and Option Agreement and any Patent Rights that arise from the Janssen-Owned Development Program Know-How or any Development Program Know-How included in the Transferred Assets.
- 1.40. "Janssen Program Patents" means any Patent Rights Controlled by Janssen or any of its Affiliates during the Development Term, on the Effective Date or during the Term (other than Development Program Patents) that Cover any Licensed Compound or Licensed Product, including the Patent Rights set forth on Schedule AR Mutant Program Patents of the Schedule Letter and all Patent Rights arising therefrom; provided, however, that with regard to Patent Rights regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Patent Rights that are applied to or used to make any Licensed Product as such Licensed Product existed as of the License and Option Agreement Effective Date is included, and any other formulation or Manufacturing method Patent Rights are excluded. For clarification, Janssen Program Patents does not include any Patent Rights with respect to any active ingredient(s) in any Combination Product other than a Licensed Compound.
- 1.41. "Johnson & Johnson Universal Calendar" means the universal calendar system used by Johnson & Johnson, a New Jersey Corporation, and its Affiliates (including Janssen) for internal and external reporting purposes, a copy of which for each year shall be provided by Janssen to TRACON prior to the beginning of such year.
- 1.42. "**Joint Development Program Patents**" means any Development Program Patent that is owned jointly by TRACON and Janssen pursuant to Section 7.2.1 of the License and Option Agreement.
- 1.43. "Know-How" means any non-public or proprietary information, inventions, discoveries, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, trade secrets, technology, techniques, designs, drawings, correspondence, computer programs, documents, apparatus, results, strategies, Regulatory Documentation, information and submissions pertaining to, or made in association with, filings with any Regulatory Authority or patent office, data (including pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions), devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable.
- 1.44. "License and Option Agreement" means that certain License and Option Agreement by and between TRACON and Janssen, dated as of the License and Option Agreement Effective Date.
- 1.45. "License and Option Agreement Effective Date" means September 27, 2016.
- 1.46. "Licensed Compound" means any AR Mutant Compound.
- 1.47. "Licensed Product" means any AR Mutant Product.

- 1.48. "Licensed Technology" means (a) the TRACON Program Know-How, (b) the TRACON Program Patents, (c) the TRACON-Owned Development Program Patents and (d) TRACON's interest in the Joint Development Program Patents.
- 1.49. "Major European Countries" means France, Germany, Italy, Spain and the United Kingdom.
- 1.50. "Manufacturing" means any activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a pharmaceutical product. When used as a verb, "Manufacture" means to engage in Manufacturing activities.
- 1.51. "Marketing Approval" means the approval of the applicable Regulatory Authority necessary for the marketing and sale of a pharmaceutical product for an Indication in the Field in a country, including any and all approvals that may be required in such country for pricing and reimbursement. For clarity, as of the Effective Date, no pricing and reimbursement approvals are required to market or sell a pharmaceutical product in the United States.
- 1.52. "**Net Sales**" means the gross amounts invoiced on sales of a Licensed Product by Janssen, or any of its Affiliates or (sub)licensees, to a Third Party purchaser in an arm's-length transaction, less the following customary and commercially reasonable deductions, determined in accordance with US generally accepted accounting principles and internal policies and actually taken, paid, accrued, allocated, or allowed based on good faith estimates:
  - (a) trade, cash and/or quantity discounts, allowances, deductions, fees and credits, excluding commissions for commercialization;
  - (b) excise taxes, use taxes, tariffs, sales taxes and customs duties and/or other government charges or fees imposed on the sale of Licensed Product (including VAT, but only to the extent that such VAT taxes are not reimbursable or refundable), specifically excluding, for clarity, any income taxes assessed against the income arising from such sale;
  - (c) compulsory or negotiated payments and cash rebates or other expenditures to Governmental Authorities (or designated beneficiaries thereof) in the context of any national or local health insurance programs or similar programs, including pay-for-performance agreements, risk sharing agreements and government-levied fees as a result of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148;
  - (d) rebates, chargebacks, administrative fees and discounts (or equivalent thereof) to managed health care organizations, group purchasing organizations, insurers, pharmacy benefit managers (or equivalent thereof), specialty pharmacy providers, Governmental Authorities, or their agencies or purchasers, reimbursers, or trade customers, as well as amounts owed to patients through co-pay assistance cards or similar forms of rebate to the extent the latter are directly related to the prescribing of Licensed Product;
  - (e) outbound freight, shipment, insurance and other distribution costs to the extent included in the invoiced price and separately itemized on the invoice;

- (f) retroactive price reductions, credits or allowances actually granted upon claims, rejections or returns of Licensed Product, including for recalls or damaged or expired goods, billing errors and reserves for returns; and
- (g) any invoiced amounts that are not collected by the selling party or its Affiliates, including bad debts.

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

For clarity, (x) sales of a Licensed Product by and between Janssen and any of its Affiliates or (sub)licensees shall not be considered sales to unaffiliated Third Parties and shall be excluded from Net Sales calculations for all purposes as long as such Licensed Product is subsequently resold to an unaffiliated Third Party and (y) only a single sales transaction with respect to a particular unit of Licensed Product, made at the time Janssen or any of its Affiliates or (sub)licensees sells such unit of Licensed Product to an unaffiliated Third Party purchaser in arms-length transaction, will qualify as the basis for determining the Net Sales amount for such unit of Licensed Product.

Notwithstanding the foregoing, the following sales of a Licensed Product shall be excluded from Net Sales calculations for all purposes: (i) transfer or dispositions of reasonable quantities of samples of such Licensed Product at no cost for promotional or educational purposes; (ii) transfers or dispositions of reasonable and customary quantities of such Licensed Product as free samples or donations, or for patient assistance, testing marketing programs or other similar programs at no cost; and (iii) use or sale of such Licensed Product for clinical study or other scientific testing purposes, early access programs (such as to provide patients with such Licensed Product prior to Regulatory Approval pursuant to treatment INDs or protocols, named patient programs or compassionate use programs) or any similar use.

In the event a Licensed Product is sold as part of a Combination Product in a country, the Net Sales with respect to the Combination Product in such country shall be determined by multiplying the Net Sales amount for the Combination Product during the applicable reporting period, calculated as set forth above, by the fraction A/(A+B), where A is the weighted average sale price (by sales volume) of the Licensed Product when sold separately, and B is the weighted average sales price of the other active ingredient(s) or product(s) in the Combination Product when sold separately, in each case in the same dosage and dosage form and in the same country as the Combination Product during the applicable reporting period. If the other active ingredient(s) or product(s) in the Combination Product is not sold separately during the applicable reporting period in a country, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product by a fraction A/C where A is the weighted average sale price (by sales volume) of the Licensed Product in such country when sold separately, and C is the weighted average sale price (by Sales volume) of the Combination Product in such country. If

neither sales of the Licensed Product sold separately nor sales of the other active ingredient(s) or product(s) sold separately occurred during the applicable reporting period, then the respective average sales prices during the most recent reporting period in which sales of both occurred in the same country as the Combination Product. In the event that the weighted average sale price (by sales volume) of the Licensed Product is not available in a given country for any reporting period, then the average sales prices (weighted by sales volume) of the respective products described above (in the same dosage and dosage form as the Combination Product) in a proxy country to be agreed upon by both Parties will be used (such agreement not be unreasonably withheld, delayed or conditioned), and if the Parties cannot agree upon such proxy country, or no such comparable sales figures are available in an appropriate proxy country, Net Sales for the applicable Combination Product shall be allocated based on the relative value contributed by each component (such relative value to be agreed upon by the Parties or, if the Parties cannot agree, to be determined by the dispute resolution procedures set forth in Article 11).

- 1.53. "Nondisclosure Agreement" means the Confidential Disclosure Agreement between the Parties dated January 25, 2016.
- 1.54. "Patent Costs" means any out-of-pocket costs and expenses incurred by a Party or its Affiliates in prosecuting any Patent Rights.
- 1.55. "Patent Rights" means any and all (a) patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, (e) any other form of government-issued right substantially similar to any of the foregoing, and (f) all United States and foreign counterparts of any of the foregoing.
- 1.56. "**Person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.
- 1.57. "Phase I Clinical Trial" means, in reference to a clinical trial of a Licensed Product, that such trial would satisfy the requirements for a Phase I study as defined in 21 CFR § 312.21(a) or a Phase I study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).
- 1.58. "Phase II Clinical Trial" means, in reference to a clinical trial of a Licensed Product, that such trial would satisfy the requirements for a Phase 2 study as defined in 21 C.F.R. § 312.21(b) or a Phase II study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).
- 1.59. "Phase II/III Clinical Trial" means a Phase II Clinical Trial involving a sufficient number of subjects that, prior to commencement of the trial or at any other defined point in the trial, satisfies both of the following ((a) and (b)):
  - (a) such trial is designed to (i) establish that the applicable Licensed Product is safe and efficacious for its intended use, and (ii) define and determine

warnings, precautions, and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed, which trial is intended to support Marketing Approval of such Product or a similar clinical study prescribed by the FDA; and

- (b) such trial is or becomes a registration trial sufficient for filing an application for a Marketing Approval for such Licensed Product in the U.S., as evidenced by (i) an agreement with or statement from the FDA on a Special Protocol Assessment or equivalent, or (ii) other guidance or minutes issued by the FDA, for such registration trial.
- 1.60. "Phase III Clinical Trial" means, in reference to a clinical trial of a Licensed Product, that such trial is would satisfy the requirements for a Phase 3 study as defined in 21 C.F.R. § 312.21(c) or a Phase III study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).
- 1.61. **"Program Records"** shall have the meaning given to it in the License and Option Agreement.
- 1.62. "**Regulatory Authority**" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the marketing and sale of a pharmaceutical product in a country, such as the FDA in the United States or EMA in the EU.
- 1.63. "Regulatory Approval" means any and all approvals (including Marketing Approvals), licenses (including import licenses), registrations or authorizations of any national, regional, state or local Regulatory Authority, department, bureau, commission, council or other governmental entity, that are necessary or useful to Development, Manufacture or Commercialize a pharmaceutical product in any country or jurisdiction in the Territory for one or more uses.
- 1.64. "Regulatory Documentation" means: (a) all applications for Regulatory Approval of any Licensed Compound or Licensed Product; (b) all Regulatory Approvals for any Licensed Compound or Licensed Product, including INDs, Drug Approval Applications and Marketing Approvals; (c) all supporting documents created for, referenced in, submitted to or received from an applicable Regulatory Authority relating to any of the applications or Regulatory Approvals described in clauses (a) or (b), including drug master files (or any equivalent thereof outside the U.S.), annual reports, regulatory drug lists, advertising and promotion documents shared with Regulatory Authorities, adverse event files, complaint files and Manufacturing records; and (d) all correspondence made to, made with or received from any Regulatory Authority (including written and electronic mail correspondence and minutes from meetings, discussions or conferences (whether in person or by audio conference or videoconference)).
- 1.65. "Regulatory Exclusivity Period" means, with respect to a given Licensed Product and given country, a period of exclusivity (other than patent exclusivity), granted or afforded by Applicable Laws or by a Regulatory Authority in such country, that confers exclusive marketing rights with respect to such Licensed Product in such country and prevents the initial market entry of a generic product with respect to such Licensed Product. In the event that such exclusivity is

not available with respect to a Licensed Product in a country, the Regulatory Exclusivity Period for such Licensed Product in such country shall be deemed to expire upon the First Commercial Sale of such Licensed Product in such country

- 1.66. "Relevant Factors" means all relevant scientific, technical, operational, commercial, economic and other factors that may affect the development, Marketing Approval, manufacture or commercialization of a product, including (as applicable): actual and potential issues of safety, efficacy and/or stability; expected and actual product profile (including product modality, category and mechanism of action); stage of development or life cycle status; actual and projected development, Marketing Approval, manufacturing, and commercialization costs, timelines and budgets; any issues regarding the ability to manufacture or have manufactured the Licensed Product; the likelihood of obtaining Marketing Approvals (including satisfactory reimbursement or pricing approvals); the timing of such approvals; labeling or anticipated labeling; the then-current competitive environment and the likely competitive environment at the time of projected entry into the market, including the expected and actual competitiveness of alternative products sold by Third Parties in the market; past performance of the product or similar products; present and future market potential; existing or projected pricing, sales, reimbursement and profitability; and expected and actual proprietary position, strength and duration of patent protection and anticipated regulatory or other exclusivity.
- 1.67. "Royalty Term" means, with respect to a given Licensed Product and a given country, the period beginning on the date of First Commercial Sale of such Licensed Product in such country and ending on the later of: (a) ten (10) years after the date of First Commercial Sale of such Licensed Product in such country; (b) the expiration of the last to expire Valid Claim of any Janssen Program Patent, TRACON Program Patent or Development Program Patent that Covers such Licensed Product in such country; or (c) the Regulatory Exclusivity Period with respect to such Licensed Product in such country.
- 1.68. "Schedule Letter" means the letter dated as of the License and Option Agreement Effective Date between TRACON and Janssen delivering copies of certain schedules with respect to the License and Option Agreement.
- 1.69. "Tax" or "Taxes" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon).
- 1.70. "**Territory**" means worldwide.
- 1.71. "Third Party" means any Person other than a Party or any of its Affiliates.
- 1.72. "TRACON License Agreements" means the agreements set forth on <u>Schedule TRACON License Agreements</u> to the TRACON Schedule Letter.
- 1.73. "**TRACON-Owned Development Program Patents**" means any Development Program Patent that is owned solely by TRACON pursuant to Section 7.2.1 of the License and Option Agreement.
- 1.74. "TRACON Program Know-How" means any Know-How Controlled by TRACON or any of its Affiliates during the Development Term, on the Effective Date or during the Term

(other than Development Program Know-How) that is necessary to make, have made, use, have used, import, have imported, sell, have sold, offer for sale or have offered for sale Licensed Compounds and Licensed Products; provided, however, that with regard to Know-How regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Know-How that is applied to or used to make any Licensed Product as such Licensed Product exists as of the Effective Date is included, and any other formulation or Manufacturing method Know-How is excluded. For clarification, TRACON Program Know-How does not include any Know-How with respect to any active ingredient(s) in any Combination Product other than a Licensed Compound.

- 1.75. "TRACON Program Patents" means any Patent Rights Controlled by TRACON or any of its Affiliates during the Development Term, on the Effective Date or during the Term (other than Development Program Patents) that Cover any Licensed Compound or Licensed Product, including the Patent Rights set forth on Schedule TRACON Program Patents of the TRACON Schedule Letter and all Patent Rights arising therefrom; provided, however, that with regard to Patent Rights regarding formulation of a product or a method of Manufacturing a product, only such formulation or Manufacturing method Patent Rights that are applied to or used to make any AR Mutant Product as such AR Mutant Product exists as of the Effective Date is included, and any other formulation or Manufacturing method Patent Rights are excluded. For clarification, Janssen Program Patents does not include any Patent Rights with respect to any active ingredient(s) in any Combination Product other than a Licensed Compound.
- 1.76. "TRACON Schedule Letter" means the letter dated as of the Effective Date between TRACON and Janssen delivering copies of certain schedules with respect to this Agreement pursuant to Section 3.2.1 of the License and Option Agreement.
- 1.77. "**Trademark**" means any word, name, symbol, color, designation, or device or any combination thereof, whether registered or unregistered, including any trademark, trade dress, service mark, service name, brand mark, trade name, brand name, logo or business symbol.
- 1.78. "Valid Claim" means: (a) a claim of any issued and unexpired patent that (i) has not been dedicated to the public, disclaimed, revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or a decision of a court or governmental agency of competent jurisdiction that can be appealed, but with respect to which an appeal has not taken within the time allowed for appeal, and (ii) has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (b) a claim of any pending patent application that (i) has not been cancelled, withdrawn or abandoned, without being re-filed in another application in the applicable jurisdiction, (ii) has not been finally rejected by an administrative agency or other governmental action from which no appeal can be taken and (iii) has not been pending or filed more than [...\*\*\*...] from the earliest possible priority date for such patent application.

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Additional Definitions. Each of the following definitions are found in the body of this Agreement as indicated:

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### Article 2 TRANSFER OF AR MUTANT PROGRAM TO JANSSEN

- 2.1. Termination of License and Option Agreement; Transfer of AR Mutant Program to Janssen.
  - 2.1.1. **Termination of License and Option Agreement with respect to AR Mutant Program**. The License and Option Agreement, including the licenses and other rights granted to TRACON thereunder, shall terminate in its entirety with respect to the AR Mutant Program, AR Mutant Compounds and AR Mutant Products on the Effective Date; *provided*, *however*, that any payment due and owing with respect to the AR Mutant Program shall survive and Sections 7.1 and 7.2 of the License and Option Agreement (without limiting the assignment of Development Program Know-How pursuant to Section 2.1.2(c) of this Agreement) shall survive with respect to the AR Mutant Program.
  - 2.1.2. **Assignment of Transferred Assets.** Subject to the terms and conditions of this Agreement, TRACON, on behalf of itself and its Affiliates, hereby irrevocably sells, conveys, transfers and assigns to Janssen all of TRACON's and its Affiliates' right, title and interest in, to and under the following assets (collectively, the "**AR Mutant Transferred Assets**"):
    - (a) all Transferred Assets (as defined in the License and Option Agreement) to the extent such Transferred Assets relate to the AR Mutant Program;
    - (b) all Regulatory Documentation with respect to the AR Mutant Compounds and AR Mutant Products that is Controlled by TRACON on the Effective Date, including Regulatory Approvals, if any;
    - (c) the Development Program Know-How (other than (x) Development Program Inventions that are claimed in a TRACON-Owned Development Program Patent or Joint Development Program Patent and (y) Janssen-Owned Development Program Know-How) and all physical embodiments of such Development Program Know-How, including (i) the AR Mutant Development Plan provided by TRACON to Janssen pursuant to Section 2.2.2 of the License and Option Agreement, (ii) the Program Records generated by TRACON during TRACON's conduct of the AR Mutant Program pursuant to Section 2.2.4 of the License and Option Agreement, (iii) the Data Package(s), interim data packages and additional information delivered by TRACON to Janssen with respect to the AR Mutant Program pursuant to Section 3.2 of the License and Option Agreement, (iv) the reports and other information delivered by TRACON to Janssen with respect to the AR Mutant Program pursuant to Section 2.2.5 of the License and Option Agreement, and (v) the global safety database for any AR Mutant Product;
    - (d) any inventory of AR Mutant Compounds or AR Mutant Products in TRACON's possession or Control;
    - (e) the Third Party agreements relating to the AR Mutant Program listed on <u>Schedule TRACON Transferred</u> Contracts of the TRACON Schedule Letter; and

(f) all claims, counterclaims, defenses, causes of action, rights under express or implied warranties, rights of recovery, rights of set-off, rights of subrogation and all other rights of any kind against any Third Party, solely to the extent relating to any Assumed Liabilities or AR Mutant Transferred Assets identified in clauses (a) through (e).

Notwithstanding anything in this Agreement to the contrary, this Agreement shall not constitute an agreement to assign or transfer any Third Party agreement within the AR Mutant Transferred Assets ("AR Mutant Transferred Contracts") that is not assignable or transferable without the consent of any Third Party (each, a "Restricted Contract"), to the extent that such consent has not been obtained prior to the Effective Date (each, a "Third Party Consent"). TRACON shall use, during the Transition Period, Commercially Reasonable Efforts to obtain, and Janssen shall use Commercially Reasonable Efforts to assist and cooperate with TRACON to obtain, all Third Party Consents; provided, however, that none of TRACON, Janssen or any of their respective Affiliates shall be required to pay money to any Third Party, commence any litigation or offer or grant any accommodation (financial or otherwise) to any Third Party to obtain any Third Party Consent. During the period beginning on the Effective Date and ending on the earlier of (a) the date on which [...\*\*\*...] and (b) the [...\*\*\*...], TRACON shall (i) use Commercially Reasonable Efforts to provide Janssen with the benefits of such Restricted Contract (or benefits substantially comparable to the benefits of such Restricted Contract), provided that Janssen performs the obligations of TRACON under such Restricted Contract, and (ii) upon the request of, for the benefit of and at the expense of Janssen, enforce any rights of TRACON arising under such Restricted Contract against any Person, including the right to seek any available remedies or to terminate such Restricted Contract. TRACON provides no assurances to Janssen that any Third Party Consent will be granted. Subject to TRACON's compliance with this Section 2.1.2, the Parties acknowledge and agree that (x) neither TRACON nor any of its Affiliates shall be obligated to obtain any Third Party Consent and (y) neither TRACON's failure to obtain any Third Party Consent, nor any default, termination, lawsuit, action, claim, proceeding or investigation commenced or threatened by or on behalf of any Person arising from TRACON's failure to obtain any Third Party Consent, shall be deemed to be a breach of any representation, warranty or covenant of TRACON contained in this Agreement.

2.1.3.

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Assumption of Assumed Liabilities. Subject to the terms and conditions of this Agreement, TRACON hereby conveys, assigns and transfers to Janssen and its successors and assignees, forever, and Janssen hereby assumes, and agrees to satisfy, perform and otherwise discharge when due, all liabilities arising from or relating to the AR Mutant Transferred Contracts arising on or after the Effective Date, but excluding all liabilities resulting from any breach of or non-compliance with any AR Mutant Transferred Contract by TRACON or any of its Affiliates prior to the Effective Date (the "Assumed Liabilities"). All risk of loss with respect to the AR Mutant Transferred Assets (whether or not covered by insurance) shall pass to Janssen on the Effective Date or, if later with respect to any AR Mutant Transferred Asset, the date that such AR Mutant Transferred Asset is actually transferred to Janssen pursuant to the Transition

Plan. Janssen does not assume any liabilities with respect to the AR Mutant Transferred Assets other than the Assumed Liabilities.

- 2.1.4. **Transition Plan**. Within [...\*\*\*...] following the Effective Date, the Parties shall mutually agree upon a plan for the transition of the AR Mutant Program, and the transfer of the AR Mutant Transferred Assets, from TRACON to Janssen providing for the following activities ("**Transition Plan**"):
  - (a) the return of any physical embodiments of Know-How that was licensed by Janssen to TRACON pursuant to the License and Option Agreement to the extent that such Know-How relates to the AR Mutant Program;
  - (b) the delivery of the tangible AR Mutant Transferred Assets and physical embodiments of the intangible AR Mutant Transferred Assets to Janssen;
  - (c) the transfer of ownership of any intangible AR Mutant Transferred Assets, including the transfer of ownership of any Regulatory Approvals within the AR Mutant Transferred Assets;
  - (d) the delivery of physical embodiments of the TRACON Program Know-How to Janssen;
  - (e) the completion or transfer of any Development activities with respect to the AR Mutant Compounds or AR Mutant Products that are ongoing as of the Effective Date;
  - (f) a technology transfer with respect to TRACON's Manufacturing processes for the AR Mutant Compounds and AR Mutant Products; and
  - (g) the provision of additional assistance reasonably requested by Janssen (including access to personnel who worked on the AR Mutant Program during the Development Term).

Each Party shall appoint one individual to have primary responsibility and oversight for, and to serve as the primary point of contact regarding, the transition and transfer activities for the AR Mutant Program contemplated by this Section 2.1.4 and the Transition Plan. Each Party shall bear its own costs in performing its obligations under this Section 2.1.4 and the Transition Plan.

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Unless the Parties agree otherwise, the Parties shall use Commercially Reasonable Efforts to complete the activities set forth in the Transition Plan within [...\*\*\*...] after the Effective Date (the "Transition Period"). After expiration of the Transition Period, TRACON will have no further obligation to provide any additional information, documents, electronic files or support to Janssen in connection with the AR Mutant Program or AR Mutant Transferred Assets; provided, however, that following the Transition Period, if (i) either Party identifies any assets that were not transferred prior to the end of the Transition Period but that, pursuant to the provisions of this Agreement, were AR Mutant Transferred Assets that were required to be transferred, TRACON and

its Affiliates shall, at no additional cost to Janssen, promptly take all actions to transfer such AR Mutant Transferred Assets to Janssen, and (ii) TRACON and its Affiliates shall provide reasonable support to Janssen and its Affiliates after the Transition Period to the extent reasonably necessary to allow TRACON and its Affiliates to respond to requirements or requests of any Regulatory Authority or other Governmental Authority with respect to Licensed Compounds or Licensed Products.

2.2. **Third Party Contracts**. If any Know-How, Patent Right or other intellectual property right would first become Controlled by a Party after the Effective Date through a license from a Third Party, and [...\*\*\*...], such licensee Party shall first notify the other Party of [...\*\*\*...], and such Know-How, Patent Right or other intellectual property right shall not be deemed to be Controlled by such licensee Party for purposes of this Agreement, except to the extent, and only to the extent that, [...\*\*\*...], and to acknowledge that its sublicense under such license is subject to the terms and conditions of the license agreement with the Third Party.

# Article 3 DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION

### 3.1. **Development**.

- 3.1.1. **General.** Janssen shall have the sole right and responsibility, at its sole cost and expense, to Develop Licensed Compounds and Licensed Products in the Field in the Territory, and for all regulatory matters relating to such activities. Janssen will conduct such Development activities in accordance with the terms and conditions of this Agreement, in good scientific manner and in compliance with all Applicable Laws.
- 3.1.2. **Diligence**. Janssen shall use Commercially Reasonable Efforts to [...\*\*\*...].
- 3.1.3. **Records**. Janssen shall prepare and maintain, and shall cause its Affiliates, (sub)licensees and Third Party Subcontractors to prepare and maintain, complete and accurate Program Records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in conformity with Applicable Law and Janssen's standard practices, which Program Records shall reflect all work done and results achieved in connection with the Programs. Janssen shall retain, and cause its Affiliates, (sub)licensees and Third Party Subcontractors to retain, the Program Records for at least [...\*\*\*...] or such longer period as may be required by Applicable Law.
- 3.1.4. **Reports.** Janssen shall provide TRACON with a written summary of its progress with respect to the Development of Licensed Compounds and Licensed Products in the Field in the Territory [...\*\*\*...], including the [... \*\*\*...]. Upon TRACON's reasonable request, Janssen shall be available for an in-person or telephonic meeting to discuss its progress on the Development of the Licensed Compounds and Licensed Products with TRACON.

3.2.

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Manufacturing. Janssen shall have the sole right and responsibility, at its sole cost and expense, to Manufacture clinical and commercial supplies of Licensed Compounds and Licensed

Products. Janssen will conduct such Manufacturing activities in accordance with the terms and conditions of this Agreement and in compliance with all Applicable Laws.

### 3.3. **Commercialization**.

- 3.3.1. **General.** Janssen shall have the sole right and responsibility, at its sole cost and expense, to Commercialize Licensed Compounds and Licensed Products in the Field in the Territory. Janssen will conduct such Commercialization activities in accordance with the terms and conditions of this Agreement and in compliance with all Applicable Laws.
- 3.3.2. **Diligence**. Janssen shall use Commercially Reasonable Efforts to Commercialize [...\*\*\*...].

# Article 4 LICENSE GRANT

- 4.1. <u>License Grant</u>. Subject to the terms and conditions of this Agreement, during the Term, TRACON grants to Janssen an exclusive (subject to Section 4.2), royalty-bearing, non-transferable (except to the extent permitted under Section 12.6), sublicensable (subject to Section 4.3) license under the Licensed Technology to make, have made, use, have used, import, have imported, sell, have sold, offer for sale and have offered for sale Licensed Compounds and Licensed Products in the Field in the Territory.
- 4.2. TRACON Retained Rights. Janssen acknowledges and agrees that TRACON and its Affiliates may use for any purpose (other than those purposes for which Janssen is granted an exclusive license pursuant to Section 4.1) [...\*\*\*...]; provided, however, that the foregoing is not intended to grant, [...\*\*\*...].
- 4.3. <u>Sublicensing</u>. Janssen may sublicense the rights granted to it by TRACON under Section 4.1 to any Third Party or any of its Affiliates. Any such sublicense shall (i) be in writing and (ii) be subject to, and consistent with, the terms of this Agreement. Janssen shall remain responsible to TRACON for the performance of the financial and other obligations of its sublicensees.

### 4.4. **Exclusivity**.

- 4.4.1. During the period beginning on the Effective Date and ending on the [...\*\*\*...] anniversary of the Effective Date, neither TRACON nor any of its Affiliates shall: [...\*\*\*...].
- 4.4.2. Notwithstanding the foregoing:

(a)

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Section 4.4.1 does not prohibit TRACON and its Affiliates that are subject to Section 4.4.1, alone or through work conducted in collaboration with an Affiliate or Third Party, from conducting research and non-clinical development (or licensing or otherwise granting rights to an Affiliate or a Third Party to conduct research and non-clinical development) of compounds (other than Licensed Compounds) that [...\*\*\*...].

- (b) Section 4.4.1 shall not apply to the Acquirer of TRACON or any Affiliate of such Acquirer (excluding any Affiliate that was an Affiliate of TRACON prior to a Change of Control and became an Affiliate of such Acquirer as a result of such Change of Control), *provided* that, if the Acquirer or such Affiliate conducts any activities described in Section 4.4.1 during the period described in Section 4.4.1 (the "Post-Development Term Acquirer Activities"), such Acquirer or Affiliate shall use reasonable good faith efforts to segregate such Post-Development Term Acquirer Activities from activities conducted with respect to the Licensed Compounds and Licensed Products pursuant to this Agreement.
- (c) TRACON shall not be limited or prohibited by Section 4.4.1 from negotiating and completing a Change of Control, or taking any action to solicit, initiate, encourage or assist the submission of any proposal, negotiation or offer from any Third Party relating to, or engage in discussions with any Third Party relating to, a Change of Control.

# Article 5 FINANCIAL TERMS

5.1. <u>Regulatory Milestones</u>. Janssen will notify TRACON in writing within [...\*\*\*...] after the first achievement by Janssen or any of its Affiliates, licensees or sublicensees of any of the milestone events set forth in the table below (each, a "Regulatory Milestone Event"). In consideration of the licenses and rights granted to Janssen under this Agreement, Janssen shall pay to TRACON the applicable milestone payment set forth in the table below (each, a "Regulatory Milestone Payment") within [... \*\*\*...] after receipt of an invoice from TRACON with respect to achievement of each Regulatory Milestone Event. Each Regulatory Milestone Payment shall be made only once, and shall be non-refundable and non-creditable.

Regulatory Milestone Event	Milestone Payment
A. [***]	\$[***]
B. [***]	\$[***]
C. [***]	\$[***]

[...\*\*\*...].

5.2.

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Sales Milestones. Solely upon the first occurrence (if any) of aggregate worldwide Net Sales of a given Licensed Product during a Calendar Year attaining the sales threshold as specified in the table below (each, a "Sales Milestone Event"), Janssen shall notify TRACON in writing that such Sales Milestone Event has occurred within [...\*\*\*...] following the end of the Calendar Quarter during which such Sales Milestone Event occurred. Following receipt of such notice, TRACON shall invoice Janssen for, and Janssen shall pay to TRACON with [...\*\*\*...] after receipt of such invoice, the corresponding Milestone Payment. [...\*\*\*...].

Sales Milestone Event	Milestone Payment
A. [***]	\$[***]
B. [***]	\$[***]
C. [***]	\$[***]

### 5.3. Royalties.

5.3.1. **Royalty Rate**. In consideration of the licenses and rights granted to Janssen under this Agreement, Janssen shall pay to TRACON a royalty of [...\*\*\*...] on Net Sales of each Licensed Product in each country during the Royalty Term for such Licensed Product in such country.

### 5.3.2. Royalty Reductions.

- (a) Janssen shall be responsible for the payment of any amounts that become due to any Third Party(ies) under any TRACON License Agreement as a result of Janssen's activities with respect to the Licensed Compounds or Licensed Products under this Agreement during the Term, only to the extent [...\*\*\*...]. In the event TRACON makes any such payment to a Third Party, Janssen shall reimburse TRACON for such amount.
- (b) If Janssen or its Affiliate or (sub)licensee is required or reasonably deems it necessary to obtain a license from a Third Party under any intellectual property rights of such Third Party that [...\*\*\*...], Janssen shall have the right to deduct, from the royalties due to TRACON pursuant to Section 5.3.1 with respect to a Licensed Product containing such Licensed Compound during a Calendar Quarter, [...\*\*\*...] of the [...\*\*\*...] payments made by Janssen or its Affiliate or (sub)licensee to such Third Party(ies) in exchange for such license with respect to such Licensed Compound during such Calendar Quarter, provided that if any agreement with such Third Party includes rights to additional compounds or products other than such Licensed Compound, any such payment that is not triggered by sales of such Licensed Product containing such Licensed Compound shall be equitably allocated by Janssen in good faith among all compounds and products under such agreement. Janssen shall provide documentation of such allocation to TRACON and any dispute regarding such allocation shall be subject to resolution under Article 11.
- (c) On a country-by-country and Licensed Product-by-Licensed Product basis, the royalties due to TRACON pursuant to Section 5.3.1 shall be reduced during the Royalty Term for such Licensed Product in such country to [...\*\*\*...] of the amount otherwise payable from and after the date that: (i) [...\*\*\*...].

(d)

Notwithstanding the foregoing, in no event shall the total deductions under Sections 5.3.2(b) and 5.3.2(c) reduce the royalties payable to TRACON under

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Section 5.3.1 with respect to a given Licensed Product in a given country in any Calendar Quarter by more than [...\*\*\*...].

5.3.3. **Royalty Reports and Payments.** Commencing with the First Commercial Sale of a Licensed Product by Janssen or its Affiliates or (sub)licensees, Janssen shall provide written reports to TRACON within [...\*\*\*...] after the end of each Calendar Quarter, stating in each such report, by Licensed Product and by country, the aggregate Net Sales in U.S. Dollars of Licensed Products sold during such Calendar Quarter by Janssen and its Affiliates and (sub)licensees. Such report shall also include: (a) the calculation of the royalty payments due to TRACON on such Net Sales; and (b) the exchange rates used in calculating the payments due TRACON, which exchange rates shall comply with Section 5.4.2. Simultaneously with the delivery of each such report, Janssen shall pay to TRACON the total royalties, if any, due to TRACON for the Calendar Quarter that is the subject of such report. If no royalties are due with respect to a particular Calendar Quarter, Janssen shall so report.

### 5.4. **Payment Terms**.

5.4.1. **Payments**. All payments due under this Agreement shall be made in U.S. Dollars by wire transfer in immediately available funds to an account designated by the receiving Party or by other mutually acceptable means.

### 5.4.2. Currency Conversion.

- (a) All payments under this Agreement will be made in U.S. Dollars.
- (b) For purposes of computing royalty payments for Net Sales made in currencies other than U.S. Dollars, such Net Sales shall be converted into U.S. Dollars using the Currency Hedge Rate(s). For purposes of this Section 5.4.2, the "Currency Hedge Rate(s)" shall be calculated as a weighted average hedge rate of the outstanding external foreign currency forward hedge contract(s) of Johnson & Johnson's global treasury services center ("GTSC") and its Affiliates with Third Party banks, which hedge contract(s) is entered into to protect the transactional foreign exchange risk exposures of Janssen by reducing the impact of foreign currency volatility through a systematic build-up of a yearly currency hedge rate(s).
- (c) For the upcoming Calendar Year, Janssen shall provide in writing to TRACON not later than ten (10) business days after the Currency Hedge Rate(s) are available from the GTSC (which is customarily at the end of October): (i) a Currency Hedge Rate(s) to be used for the local currency of each country of the Territory; and (ii) the details of such Currency Hedge Rate(s).

(d)

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The Currency Hedge Rate(s) will remain constant throughout the upcoming Calendar Year, and Janssen shall use the Currency Hedge Rate(s) to convert Net Sales to U.S. Dollars for the purpose of calculating royalties.

- 5.4.3. **Late Payments.** If a Party does not receive payment of any amount due to it under this Agreement on or before the due date, such payment shall bear interest at a rate per annum equal to [...\*\*\*...] in excess of overnight LIBOR or a comparable reference interbank rate per currency or the maximum rate allowable by Applicable Law, whichever is lower.
- 5.5. Records; Inspection. Janssen shall keep (and cause its Affiliates and (sub)licensees to keep) complete, true and accurate books of account and records for the purpose of determining the royalties payable by Janssen to TRACON under Section 5.3 (the "Royalty Records"), which Royalty Records shall be retained for at least [...\*\*\*...] following the end of the Calendar Year to which they pertain. Janssen shall, and shall cause its Affiliates and (sub)licensees to, make the Royalty Records available for inspection by an independent public accounting firm of national prominence selected by TRACON, and reasonably acceptable to Janssen, during normal business hours, as may be reasonably necessary for the sole purpose of verifying the royalty reports and payments delivered by Janssen pursuant to Section 5.3 during the preceding [...\*\*\*...] full Calendar Years. The records for a given Calendar Year shall be subject to audit no more than one time. Such independent public accounting firm shall execute a reasonable confidentiality agreement with Janssen prior to commencing any such inspection. Such inspections shall be made no more than once each Calendar Year at reasonable times and on reasonable notice. TRACON shall bear the costs and expenses of any inspection conducted under this Section 5.5 unless such inspection reveals an underpayment in royalties payable pursuant to Section 5.3 of more than [...\*\*\*...] of the amount payable for the period covered by such inspection, in which case Janssen shall bear the costs and expenses of such inspection. If such inspection reveals an overpayment by Janssen pursuant to Section 5.3, then Janssen shall deduct the amount of such overpayment from any payment that subsequently becomes due and payable by Janssen under this Agreement or, if no payment is anticipated to be due and payable by Janssen in the following Calendar Quarter, Janssen shall invoice TRACON for the amount of the underpayment and TRACON shall pay such invoice within [...\*\*\*...] after receipt thereof. If such inspection reveals an underpayment by Janssen pursuant to Section 5.3, then TRACON shall invoice Janssen for the amount of the underpayment and Janssen shall pay such invoice within [...\*\*\*...] after receipt thereof.

### 5.6. Withholding Taxes.

- 5.6.1. Janssen will make all payments to TRACON under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.
- 5.6.2. Any Tax required to be withheld on amounts payable under this Agreement will be paid by Janssen on behalf of TRACON to the appropriate Governmental Authority, and Janssen will furnish TRACON with proof of payment of such Tax. Any such Tax required to be withheld will be an expense of and borne by TRACON.

5.6.3.

\*\*\*Confidential Treatment Requested

Janssen and TRACON will cooperate with respect to all documentation required by any taxing authority or reasonably requested by Janssen to secure a reduction in the rate of applicable withholding Taxes.

## Article 6 INTELLECTUAL PROPERTY

#### 6.1. **Prosecution of Patent Rights.**

- 6.1.1. **Communications.** Each Party shall designate a patent attorney or agent as its contact to coordinate with the other Party the filing, prosecution and maintenance of Patent Rights as provided in this Article (the "Patent Representative"). Each Party shall use reasonable efforts to handle all communications between the Parties under this Section 6.1 through their Patent Representatives and keep such communications in strict confidence to protect their attorney-client privileged status.
- 6.1.2. **Reporting of Filings.** A Party planning on filing any priority-establishing or original (in each case, with respect to any claims or new matter described in the patent specification) patent application within the Development Program Patents hereunder shall use reasonable efforts to provide to the other Party with reasonable advance time prior to proposed prosecution filing in a patent office (such as a draft application or response to an official action), provide the other Party an opportunity to comment thereon through its Patent Representative, and give good faith consideration to the other Party's comments. Each Party shall provide to the other, promptly after filing, a copy of each priority-establishing or original (whether provisional or non-provisional) patent application within the Development Program Patents as filed in the patent office and each other substantive prosecution filing (including any other patent application filed within the Development Program Patents).

#### 6.1.3. Prosecution Responsibility and Coordination.

- (a) Janssen Program Patents and Janssen-Owned Development Program Patents. With respect to the Janssen Program Patents and Janssen-Owned Development Program Patents, after the Effective Date, Janssen shall be solely responsible, through patent counsel selected by Janssen, to prosecute such Patent Rights. Janssen shall be solely responsible for all Patent Costs incurred in prosecuting any Janssen Program Patents or Janssen-Owned Development Program Patents.
- (b) TRACON Program Patents, TRACON-Owned Development Program Patents and Joint Development Program Patents. Janssen shall be primarily responsible, through outside patent counsel mutually selected and engaged by the Parties, for prosecuting any TRACON Program Patents, TRACON-Owned Development Program Patents and Joint Development Program Patents, provided that Janssen shall: (i) consider the reasonable suggestions of TRACON's Patent Representative as to selection of country patent offices in the Territory for filing or validating applications to form a family of related such Patent Rights and as to the abandonment of any such Patent Rights; and (ii) consider in good faith any reasonable comments of TRACON as provided by its designated Patent Representative in prosecuting any such Patent Rights, including with respect to the filing of any continuation, divisional, or other continuing applications.

Subject to Section 6.1.3(d), Janssen shall be solely responsible for all Patent Costs incurred by or on behalf of Janssen in prosecuting any TRACON Program Patents, TRACON-Owned Development Program Patents and Joint Development Program Patents.

- (c) Duties Imposed by Law. Section 6.1.3(b) notwithstanding, it will not be a breach of this Agreement that a Party, in good faith, does not execute a document or withholds or revokes consent to an action in the course of filing, prosecuting or maintaining a Patent Right hereunder that such Party reasonably believes to violate a duty imposed by law on such Party as the owner of such a Patent Right.
- (d) Step-In Rights. If Janssen intends in its discretion to abandon or not maintain (so as to permit to lapse) any TRACON Program Patent, TRACON-Owned Development Program Patent or Joint Development Program Patent in any jurisdiction in the Territory, then Janssen shall provide TRACON with written notice of such intent within a period of time reasonably necessary to allow TRACON to determine its interest in such Patent Right (which notice from Janssen shall be given no later than [...\*\*\*...] prior to any final deadline for any pending action or response that may be due with respect to such Patent Right with the applicable patent office). If TRACON provides written notice to Janssen expressing its interest in preserving such Patent Right, Janssen shall cooperate with TRACON in providing TRACON the right to prosecute such Patent Right in such jurisdiction. If TRACON assumes the right to prosecute a Patent Right under this Section, TRACON shall be responsible for all Patent Costs incurred by TRACON in prosecuting such Patent Right and such Patent Right shall no longer be a TRACON Program Patent, TRACON-Owned Development Program Patent or Joint Development Program Patent, as applicable, for purposes of this Agreement.
- 6.1.4. **Prosecution Cooperation.** Each Party shall, at its own expense, provide all reasonable assistance requested by the other Party for prosecuting any TRACON Program Patents, Janssen Program Patents or Development Program Patents consistent with the terms hereof, including with respect to the timely completion of filings of prosecution papers, compliance with Applicable Laws and recording of assignments to reflect ownership consistent with the terms hereof. A Party prosecuting any TRACON Program Patents, Janssen Program Patents or Development Program Patents hereunder shall use reasonable efforts to provide the other Party with copies of all material prosecution papers as filed in or received from any patent offices. The Party prosecuting any TRACON Program Patents, Janssen Program Patents or Development Program Patents hereunder shall, on an annual basis during the Term, provide the other Party with a report identifying the status of any such Patent Rights; *provided*, *however*, that for Joint Development Program Patents, the Parties shall cooperate to jointly prepare such status report.

#### 6.2. **Patent Enforcement.**

6.2.1.

\*\*\*Confidential Treatment Requested

Notice.

- (a) Each Party shall notify the other promptly of any apparent, threatened, or actual infringement by a Third Party of any Janssen Program Patent, TRACON Program Patent or Development Program Patent, or misappropriation of any Janssen Program Know-How, TRACON Program Know-How or Development Program Know-How, of which the Party becomes aware. The notifying Party shall promptly furnish the other with all known details or evidence of such infringement or misappropriation.
- (b) Each Party shall promptly notify the other of any Third Party communications pertaining to any Janssen Program Patent, TRACON Program Patent or Development Program Patent that the Party receives pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 or similar such notice, including notices pursuant to §§ 101 and 103 of such act from Persons who have filed an abbreviated NDA (ANDA) or a paper NDA.
- 6.2.2. Enforcement Actions. During the Term, Janssen shall have the initial right, at its expense and in its own name (or in the name of TRACON as may be required under Applicable Law), for bringing any infringement suit or other enforcement action (an "Action") on account of any Third Party infringement of any Janssen Program Patent, TRACON Program Patent or Development Program Patent based on any alleged making, using, selling, offering for sale, importing or other exploitation of any product that is competitive with a Licensed Product in the infringement of any such Patent Rights, or based on misappropriation of any Janssen Program Know-How, TRACON Program Know-How or Development Program Know-How providing any Regulatory Exclusivity for any such Licensed Product (each a "Product Infringement"), by counsel of its own choice, and TRACON will cooperate with Janssen as Janssen may reasonably request in connection with any such Action, including by becoming a party to such Action at Janssen's cost, provided that Janssen shall reimburse TRACON for its out-of-pocket costs reasonably incurred in connection with rendering such assistance. If Janssen declines to initiate such an Action against any unabated Product Infringement, it shall so notify TRACON, who shall thereafter have the right (but not the obligation), at TRACON's expense and in its own name, to initiate such Action on account of any Third Party infringement of any TRACON Program Patent, TRACON-Owned Development Program Patent or Joint Development Program Patent by counsel of its choice, and Janssen shall cooperate with TRACON as TRACON may reasonably request, including by becoming a party to such action at TRACON's cost, and TRACON shall reimburse Janssen for its out-of-pocket costs reasonably incurred in connection with rendering such assistance. A settlement or consent judgment or other voluntary final disposition of an Action brought by a Party under this Section may be entered into without the consent of the other Party, provided that such settlement, consent judgment, or other disposition does not admit the invalidity or unenforceability of any Patent Rights Controlled by the other Party and, provided further that any rights granted to a Third Party to continue any activity upon which such Action was based in such settlement, consent judgment, or other disposition shall be limited to the Third Party's product or activity that was the subject of the Action. Damages recovered and any other amounts awarded in any Actions for Product Infringement under this Section shall be allocated to the Party who brought the Action, after reimbursement of each Party's actual expenses incurred in such

Actions as provided hereunder, *provided* that Janssen shall pay to TRACON: (a) as to damage amounts recovered by Janssen due to a Product Infringement in the form of lost profits or reasonable royalties assessed on account of the Third Party's sales of infringing product, an amount equal to the royalty that would be payable pursuant to this Agreement on the imputed amount of Net Sales of the relevant Licensed Product(s) in the country(ies) where such Product Infringement occurred; and (b) as to damage amounts recovered by Janssen due to a Product Infringement other than in the form of lost profits or reasonable royalties assessed on account of the Third Party's sales of infringing product, an amount equal to the royalty that would be payable pursuant to this Agreement on such damage amounts treated as Net Sales of the relevant Licensed Product(s) in the country(ies) where such Product Infringement occurred.

- 6.2.3. Other Enforcement Actions. TRACON acknowledges that the outcome of any Action on account of any Third Party infringement, other than a Product Infringement, of any TRACON Program Patent or Development Program Patent licensed to Janssen under this Agreement may detrimentally impact the scope, validity, or enforceability of such Patent Right with respect to potential Product Infringements. Accordingly, the Parties shall reasonably cooperate with each other with respect to any Action on account of any Third Party infringement of any Janssen Program Patent, TRACON Program Patent or Development Program Patent other than Product Infringements. For clarity, TRACON will not be required to enforce any TRACON Program Patent against any Third Party infringement.
- 6.3. Third Party Patent Rights. Each Party shall promptly inform the other Party, orally through the Patent Representatives, in the event such Party becomes aware of any Third Party's Patent Rights that may pertain to any Development, Manufacturing or Commercialization activities of Janssen related to a Licensed Compound or Licensed Product.
- 6.4. Patent Term Extensions. During the Term, upon Janssen's written request (which shall be by a written notice identifying the date of the applicable Marketing Approval of a Licensed Product and the deadline for filing a patent term extension, supplemental protection certificate or their equivalent (each a "Patent Term Extension")), the Party prosecuting a relevant Patent Right shall use reasonable efforts, in each country or jurisdiction where Marketing Approval for any such Licensed Product has been obtained, and if the Applicable Law of such country or jurisdiction permits application for a Patent Term Extension, to apply, at the reasonable direction of Janssen's Patent Representative, for a Patent Term Extension for a patent within the TRACON Program Patents or TRACON-Owned Development Program Patents including a Valid Claim Covering such Licensed Product, which patent (if any) shall be selected at Janssen's reasonable judgment after considering the opinion of Janssen's patent counsel regarding its eligibility for a Patent Term Extension. Janssen shall have the right to: (a) identify in any list of patents in a Drug Approval Application for a Licensed Product with respect to such Program the applicable Janssen Program Patent(s), TRACON Program Patent(s) and Development Program Patent(s), as Janssen reasonably believes is appropriate; (b) for clarity, commence an Action for any Product Infringement of any such TRACON Program Patent(s) or TRACON-Owned Development Program Patent(s) under Applicable Law as permitted under Section 6.2.2; and (c) subject to specific limitations of this Agreement, exercise any rights that may be exercisable by a patent owner, including applying for a Patent Term Extension, of any TRACON Program

Patent(s) or TRACON-Owned Development Program Patent(s) pertaining to an approved Licensed Product licensed to Janssen and Commercialized by Janssen during the Term. TRACON agrees to cooperate with Janssen and its Affiliate and Third Party (sub)licensees of Licensed Products, as applicable, upon Janssen's reasonable request in the exercise of the authorizations under this Section, and TRACON shall execute such documents and take such additional action as Janssen may reasonably request in connection therewith, *provided* that Janssen shall reimburse TRACON all reasonable out-of-pocket costs incurred by TRACON in taking such action.

- 6.5. **Product Trademarks.** During the Term, Janssen shall have (directly and through its Affiliates and Third Party (sub)licensees Commercializing Licensed Products with respect to such Program) the right to brand, at its discretion, Licensed Products using Trademarks and trade names selected at its discretion and to file for, obtain, and maintain at its discretion and cost Trademarks for Licensed Products in its own name.
- 6.6. Correction of Licensed Patents without Patent Challenge. During the Term, if a Party becomes aware of any good-faith error in any TRACON Program Patent or Development Program Patent that would render the only issued claim(s) therein Covering any marketed Licensed Product invalid, such Party shall inform the other Party (orally through the Parties' Patent Representatives) and the applicable Party prosecuting such Patent Right shall, subject to this Article 6, use Commercially Reasonable Efforts to correct such error by reissue or reexamination (if such error is so correctable under Applicable Law).

# Article 7 CONFIDENTIALITY; PUBLICITY

#### 7.1. **Nondisclosure**.

- 7.1.1. Each Party agrees that, during the Term and for a period of five (5) years thereafter, the Party (the "Receiving Party") receiving Confidential Information of the other Party (the "Disclosing Party") shall: (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own confidential or proprietary information of similar kind and value (but no less than reasonable efforts); (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted in Sections 7.3 and 7.4; and (c) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this Article 7 shall not create or imply any rights or licenses not expressly granted under this Agreement).
- 7.1.2. Notwithstanding anything to the contrary in this Agreement, any information embodied or contained in the AR Mutant Transferred Assets shall be deemed to be Confidential Information of Janssen for purposes of this Article 7, regardless of which Party is the Receiving Party and which Party is the Disclosing Party.
- 7.2. **Exceptions.** The obligations in Section 7.1 shall not apply to the extent of any portion of the Confidential Information that the Receiving Party can show by competent evidence:

- (a) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party under this Agreement;
- (b) is known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, in each case, to the Disclosing Party, prior to disclosure to the Receiving Party or any of its Affiliates by the Disclosing Party;
- (c) is subsequently disclosed to the Receiving Party or any of its Affiliates on a non-confidential basis by a Third Party that, to the Receiving Party's knowledge, is not bound by a similar duty of confidentiality or restriction on its use, in each case, to the Disclosing Party;
- (d) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party or any of its Affiliates in violation of this Agreement, generally known or available, either before or after it is disclosed to the Receiving Party by the Disclosing Party; or
- (e) is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates without the use of or reference to the Confidential Information of the Disclosing Party.
- 7.3. **Authorized Disclosure.** The Receiving Party may disclose Confidential Information of the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances, or to the extent permissible under the other applicable provisions of this Agreement:
  - (a) filing, prosecuting, maintaining, enforcing or defending Patent Rights as permitted by this Agreement;
  - (b) as reasonably required in generating Regulatory Documentation and obtaining Regulatory Approvals as permitted by this Agreement;
  - (c) prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation;
  - (d) subject to Section 7.4, complying with Applicable Law or court or administrative orders;
  - (e) complying with any obligation under this Agreement;
  - (f) in communications with existing investors or bona fide prospective investors, consultants and advisors of the Receiving Party in connection with equity financing transactions or bona fide prospective equity financing transactions with the foregoing, in each case on a "need-to-know" basis and under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement; *provided*, *however*, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by

any Third Party who receives Confidential Information pursuant to this Section 7.3(f);

- (g) to its Affiliates, (sub)licensees or prospective (sub)licensees, subcontractors or prospective subcontractors, consultants, agents and advisors on a "need-to-know" basis in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement; *provided*, *however*, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Person who receives Confidential Information pursuant to this Section 7.3(g); or
- (h) by either Party to one or more Third Parties regarding an actual or potential Change of Control of such Party, each of whom prior to disclosure must be bound under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement; *provided*, *however*, that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Person who receives Confidential Information pursuant to this Section 7.3(h).

If and whenever any Confidential Information is disclosed in accordance with this Section 7.3, such disclosure shall not cause any such information to cease to be Confidential Information for purposes of this Agreement, except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing: (x) in the event a Party intends to make a disclosure of the other Party's Confidential Information pursuant to Section 7.3(c) or Section 7.3(d), it will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure and use not less than the same efforts to secure confidential treatment of such information as it would to protect its own confidential information from disclosure.

- 7.4. Terms of this Agreement. The Parties acknowledge and agree that this Agreement and all of the respective terms of this Agreement shall be treated as Confidential Information of each Party. In addition to the disclosures permitted under Section 7.3, either Party may disclose the terms of this Agreement and other information relating to this Agreement or the transactions contemplated by this Agreement to the extent required, in the reasonable opinion of such Party's counsel, to comply with the rules and regulations promulgated by the United States Securities and Exchange Commission or the Nasdaq Stock Market or similar security regulatory authorities or stock market in other countries. If a Party intends to disclose this Agreement or any of its terms or other such information in accordance with this Section 7.4, such Party will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure and seek confidential treatment of portions of this Agreement or such terms or information, as may be reasonably requested by the other Party.
- 7.5. <u>Public Announcements</u>. Except as required to comply with Applicable Law, TRACON agrees not to issue any press release or other public statement disclosing the execution of this Agreement or any other information relating to this Agreement or the transactions contemplated

by this Agreement without the prior written consent of Janssen, such consent not to be unreasonably withheld, conditioned or delayed. In the event that TRACON intends to issue such a press release or other public statement as required to comply with Applicable Law, TRACON will, except where impracticable or not legally permitted, give reasonable advance notice to Janssen of such disclosure.

- 7.6. **Prior Non-Disclosure Agreement.** As of the Effective Date, the terms of this Article 7 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement, including the Nondisclosure Agreement and, to the extent of the AR Mutant Program only, Article 7 of the License and Option Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.
- 7.7. **Equitable Relief.** Given the nature of the Confidential Information and the competitive damage that may result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 8. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 8.

## Article 8 REPRESENTATIONS AND WARRANTIES

- 8.1. <u>Mutual Representations and Warranties</u>. Each Party represents, warrants and covenants to the other Party that, as of the Effective Date:
  - 8.1.1. it is duly organized and validly existing under the laws of its state or country of incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions of this Agreement;
  - 8.1.2. this Agreement has been duly executed by it and constitutes a legal, valid and binding obligation of it, enforceable in accordance with its terms;
  - 8.1.3. the execution, delivery and performance of this Agreement by it does not conflict with any material agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and
  - 8.1.4. it has not granted, and shall not grant during the Term, any right to any Third Party that would conflict with the rights granted to the other Party under this Agreement (including by granting a license after the Effective Date to a Third Party under any intellectual property that is Controlled by the granting Party on the Effective Date that would conflict with the rights to such intellectual property granted to the other Party under this Agreement).
- 8.2. <u>Additional Representations and Warranties of TRACON</u>. TRACON represents and warrants to Janssen that, as of the Effective Date:

- 8.2.1. <u>Schedule Existing Licensed Patents</u> of the TRACON Schedule Letter lists all Patent Rights existing as of the Effective Date that are owned or licensed by TRACON or any of its Affiliates (excluding any owned or licensed by an Affiliate that would be excluded by the definition of Control and excluding any Joint Development Program Patents) and include any claim Covering any AR Mutant Compound or AR Mutant Product, or its formulation, Manufacture or use (the "Existing Licensed Patents");
- 8.2.2. <u>Schedule Existing Licensed Patents</u> of the TRACON Schedule Letter identifies any TRACON License Agreement pursuant to which any Existing Licensed Patents are licensed to TRACON or any of its Affiliates;
- 8.2.3. TRACON or its Affiliate is the sole and exclusive owner or exclusive licensee of the Existing Licensed Patents (as specified in <u>Schedule Existing Licensed Patents</u> of the TRACON Schedule Letter) and is listed (or is in the process of becoming listed) in the records of the appropriate Governmental Authorities as the sole and exclusive owner of record, if applicable, for each registration, grant and application included in such Patent Rights, except as otherwise noted therein; and TRACON is entitled to grant the licenses under such Patent Rights specified herein;
- 8.2.4. to the Knowledge of TRACON, TRACON has the right to use and disclose and to enable Janssen to use and disclose (in each case under appropriate conditions of confidentiality) the TRACON Program Know-How existing on the Effective Date (the "Existing TRACON Know-How") to the extent that Janssen is granted the right to use and disclose such Existing TRACON Know-How pursuant to this Agreement;
- 8.2.5. to the Knowledge of TRACON, neither TRACON nor any of its Affiliates owns or licenses, with the right to sublicense, any Know-How or Patent Rights used by TRACON and its Affiliates in the conduct of the AR Mutant Program during the Development Term, other than the Existing TRACON Know-How, Existing Licensed Patents and Joint Development Program Patents;
- 8.2.6. neither TRACON nor any of its Affiliates is subject to any royalty or other payment obligation to any Third Party with respect to the practice, or the grant of rights to Janssen to practice, any of the Existing TRACON Know-How and Existing Licensed Patents with respect to the Licensed Compounds or Licensed Products under this Agreement, other than those set forth in the TRACON License Agreements as specifically described on <u>Schedule TRACON License Agreements</u> of the TRACON Schedule Letter;
- 8.2.7. neither TRACON nor any of its Affiliates has received written notice of any claim or threatened claim by any Third Party, and to the Knowledge of TRACON, TRACON is not otherwise aware, that (i) any Third Party has any rights to any of the Existing TRACON Know-How or Existing Licensed Patents, (ii) any of the Existing Licensed Patents (to the extent representing issued Patent Rights) are invalid or unenforceable, or (iii) any research, Development or Manufacture of any AR Mutant Compound or AR Mutant Product by or on behalf of TRACON or its Affiliate during the Development Term infringed or misappropriated the intellectual property rights of such Third Party;

- 8.2.8. there are no pending actions, claims, investigations, suits or proceedings against TRACON or any of its Affiliates, at law or in equity, or before or by any Regulatory Authority, and neither TRACON nor any of its Affiliates has received any written notice regarding any pending or threatened actions, claims, investigations, suits or proceedings against TRACON or any of its Affiliates, at law or in equity, or before or by any Regulatory Authority, in either case with respect to the Existing TRACON Know-How or Existing Licensed Patents, and no Existing Licensed Patent is the subject of any interference, opposition, cancellation or other protest proceeding;
- 8.2.9. to the Knowledge of TRACON, there is no actual infringement of any Existing Licensed Patents by any Third Party;
- 8.2.10. neither TRACON nor any of its Affiliates, nor its or their employees, officers, directors, or agents, has been debarred by the FDA, is the subject of a conviction described in 21 U.S.C. 335a, or is subject to any similar sanction;
- 8.2.11. TRACON and its Affiliates have conducted Development activities with respect to the AR Mutant Program in material compliance with Applicable Law and regulatory standards, including as applicable those relating to GLP, GCP, pharmacovigilance and safety reporting, and requirements for the protection of human subjects;
- 8.2.12. TRACON owns good and valid title to and has the right to transfer (or cause to be transferred), the AR Mutant Transferred Assets as provided for herein, free and clear of all liens and other encumbrances, except for Permitted Liens (except to the extent of any issues relating to title or right to transfer in connection with Janssen's assignment of Transferred Assets pursuant to the License and Option Agreement);
- 8.2.13. TRACON has made available to Janssen true and complete copies of each AR Mutant Transferred Contract;
- 8.2.14. each AR Mutant Transferred Contract is in effect and is valid and binding on TRACON or its Affiliate, enforceable in accordance with its terms, and neither TRACON nor any of its Affiliates, nor to the Knowledge of TRACON any Third Party thereto, is in material breach of, or material default under, any AR Mutant Transferred Contract, and no event has occurred that, with the giving of notice or lapse of time or both, would constitute a material breach or material default by TRACON or any of its Affiliates thereunder or result in the payment of any damages or penalties or result in the creation of any lien or encumbrance with respect thereto; and
- 8.2.15. neither TRACON nor any of its Affiliates has received any written notice from a Third Party at any time during the Development Term regarding any actual, alleged or potential material breach or default under any of the AR Mutant Transferred Contracts or stating that such Third Party intends to terminate, cancel or make any material change to any AR Mutant Transferred Contract.

As used in this Section 8.2: (a) "Knowledge" means the actual knowledge of the TRACON Personnel after reasonable inquiry of individuals responsible for operational activities with respect to the applicable Program; (b) "TRACON Personnel" means the individuals whose

names are set forth on <u>Schedule TRACON Personnel</u> of the TRACON Schedule Letter; and (c) "**Permitted Liens**" means (i) liens for taxes not yet due, payable, delinquent or subject to penalties for nonpayment, or which are being contested in good faith in the ordinary course of business by appropriate proceedings or (ii) mechanics', materialmens', carriers', workmens', warehousemens', repairmens', landlords' or other like liens and security obligations that are incurred in the ordinary course of business and are not delinquent.

#### 8.3. <u>Disclaimer of Warranties; Limitations.</u>

- 8.3.1. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY NOR ANY OF ITS AFFILIATES MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE PROGRAMS, LICENSED COMPOUNDS, LICENSED PRODUCTS, TRANSFERRED ASSETS OR LICENSED TECHNOLOGY THAT IS LICENSED OR TRANSFERRED TO THE OTHER PARTY OR SUBJECT TO ANY OPTION OR RIGHT TO LICENSE UNDER THIS AGREEMENT, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT ANY OF THE DEVELOPMENT, MANUFACTURING OR COMMERCIALIZATION EFFORTS WITH REGARD TO ANY LICENSED COMPOUND OR LICENSED PRODUCT WILL BE SUCCESSFUL.
- 8.3.2. Subject to Section 4.4, each Party acknowledges that (a) the other Party and its Affiliates may have present or future initiatives or opportunities, including initiatives or opportunities with Third Parties, involving similar products, programs, technologies or processes that may compete with products, programs, technologies or processes covered by this Agreement; (b) nothing in this Agreement will be construed as a representation, warranty, covenant or inference that the other Party or its Affiliates will not itself develop, manufacture or market or enter into business relationships with one or more Third Parties to develop, manufacture or market products, programs, technologies or processes that are similar to or that may compete with any product, program, technology or process covered by this Agreement (including those in the Field); and (c) the other Party or any of its Affiliates may, in their sole discretion, decide to acquire, research, develop and/or market devices, drugs or other products which may compete with any Licensed Product or continue such activity in which they currently are engaged; *provided* that, in each case of clauses (a), (b) and (c), in no event shall a Party or its Affiliates use Confidential Information of the other Party in breach of this Agreement, and in no event may TRACON or its Affiliates practice or use, or grant any Third Party the right to practice or use, any Licensed Technology in conflict with the licenses granted hereunder.

#### 8.4. Additional Representations, Warranties and Covenants.

#### 8.4.1. **Healthcare Compliance**.

(a) **Anti-Kickback and Stark Compliance**. Janssen represents and warrants to TRACON as of the Effective Date, and covenants to TRACON, that Janssen

and its Affiliates that are or have been involved in a Program is in compliance and will continue to comply with all applicable state and federal laws, rules and regulations, including the federal anti-kickback statute (42 U.S.C. § 1320a-7b), the related safe harbor regulations, and the Limitation on Certain Physician Referrals, also referred to as the "Stark Law" (42 U.S.C. § 1395nn) in connection with its activities under this Agreement. No part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services; nor are the payments intended to induce illegal referrals of business.

- (b) **Exclusion from Federal Health Care Programs**. Janssen shall conduct activities pursuant to this Agreement in accordance with applicable state and federal laws and any applicable regulations regarding Medicare, Medicaid, and other third party-payer programs, if any. Janssen represents and warrants to TRACON, as of the Effective Date, that (1) it is not excluded from, and has not been convicted of any crime or engaged in any conduct that could result in exclusion from, participation in any state or federal healthcare program, as defined in 42 U.S.C. §1320a-7b(f), for the provision of items or services for which payment may be made by a federal healthcare program; (2) it has not contracted with any employee, contractor, agent, or vendor to perform work under this Agreement who is excluded from participation in any state or federal healthcare program; and (3) it is not subject to a final adverse action, as defined in 42 U.S.C. § 1320a-7a(e) and 42 U.S.C. § 1320a-7a(g), and has no adverse action pending or threatened against it. Janssen shall notify TRACON of any final adverse action, discovery of contract with an excluded entity or individual, or exclusion within thirty (30) days of such action.
- 8.4.2. **No Debarred Individuals.** Janssen agrees that it shall not engage, in any capacity in connection with this Agreement, any person who has been debarred by FDA, is the subject of a conviction described in 21 U.S.C. 335a, or is subject to any similar sanction. Janssen shall promptly inform TRACON in writing if Janssen or any person performing activities under this Agreement on Janssen's behalf is debarred or is the subject of a conviction described in 21 U.S.C. 335a, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or threatened relating to the debarment of conviction of Janssen or any such person performing activities in connection with this Agreement on Janssen's behalf. Upon written request from TRACON, Janssen shall, within ten (10) days, provide written confirmation that it has complied with the foregoing obligation.
- 8.4.3. **Anti-Corruption Laws**. Neither Janssen nor any of its Affiliates shall perform any actions in connection with this Agreement that are prohibited by local and other anti-corruption laws (collectively "**Anti-Corruption Laws**") that may be applicable to Janssen. Without limiting the foregoing, Janssen nor any of its Affiliates shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political party official or candidate for political office or to any other Third Party related to the transactions contemplated by this Agreement in a manner that would violate Anti-Corruption Laws.

8.4.4. **Amendment to TRACON License Agreements**. TRACON may not amend any TRACON License Agreement in any manner that would adversely affect any rights granted to Janssen hereunder, including to increase any amount payable by TRACON for which Janssen would be responsible pursuant to Section 5.3.2(a), except with Janssen's prior written consent.

## Article 9 INDEMNIFICATION AND INSURANCE

#### 9.1. **Indemnification.**

- 9.1.1. **Indemnification by Janssen.** Subject to Section 9.2, Janssen shall defend, indemnify and hold harmless TRACON and any of its Affiliates, and each of its and their directors, officers, employees and agents (each, a "**TRACON Indemnified Party**") from and against any and all damages, losses, liabilities, judgments, fines, amounts paid in settlement, costs and expenses (including the reasonable costs and expenses of attorneys and other professionals) (collectively, "**Losses**") incurred by any TRACON Indemnified Party resulting from any claim, action or proceeding brought or initiated by a Third Party ("**Third Party Claim**") against a TRACON Indemnified Party, to the extent that such Losses arise out of or relate to, directly or indirectly:
  - (a) the Assumed Liabilities;
  - (b) the breach by Janssen of any of its representations, warranties or covenants set forth herein;
  - (c) the negligence, recklessness or wrongful intentional acts or omissions of any Janssen Indemnified Party; or
  - (d) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Janssen or any of its Affiliates on or after the Effective Date;

except, in each case ((a) through (d)), to the extent such Losses arise directly or indirectly from (i) the breach by TRACON of any of its representations, warranties, or covenants set forth herein, (ii) the negligence, recklessness or wrongful intentional acts or omissions of any TRACON Indemnified Party, or (iii) the Development or Manufacture of any AR Mutant Compound or AR Mutant Product by or on behalf of TRACON or any of its Affiliates during the Development Term and the Transition Period.

9.1.2. **Indemnification by TRACON.** Subject to Section 9.2, TRACON shall defend, indemnify and hold harmless Janssen and any of their Affiliates, and each of its and their directors, officers, employees and agents (each, a "**Janssen Indemnified Party**"), from and against any and all Losses incurred by any Janssen Indemnified Party resulting from any Third Party Claim against a TRACON Indemnified Party, to the extent that such Losses arise out of or relate to, directly or indirectly:

- (a) all liabilities arising from or relating to the AR Mutant Transferred Assets arising prior to the Effective Date, or after the Effective Date to the extent of any breach of or non-compliance with any AR Mutant Transferred Contract by TRACON or any of its Affiliates prior to the Effective Date;
- (b) the breach by TRACON of any of its representations, warranties or covenants set forth herein; and
- (c) the negligence, recklessness or wrongful intentional acts or omissions of any TRACON Indemnified Party; or
- (d) the Development or Manufacture of any AR Mutant Compound or AR Mutant Product by or on behalf of TRACON or any of its Affiliates during the Development Term and the Transition Period;

except, in each case ((a) through (d)), to the extent such Losses arise directly or indirectly from (i) the breach by Janssen of any of its representations, warranties, or covenants set forth herein, (ii) the negligence, recklessness or wrongful intentional acts or omissions of any Janssen Indemnified Party, or (iii) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Janssen or any of its Affiliates on or after the Effective Date.

- 9.2. Conditions to Indemnification. If either a TRACON Indemnified Party or a Janssen Indemnified Party (each, an "Indemnified Party") intends to seek indemnification under Section 9.1, the Indemnified Party must: (a) give the other Party (the "Indemnifying Party") reasonably prompt written notice of any Loss with respect to which such Indemnified Party intends to seek indemnification; (b) reasonably cooperate with the Indemnifying Party at the Indemnifying Party's request and expense, in the defense or settlement of the claim; and (c) give the Indemnifying Party the right to control the defense or settlement of the claim, provided that the Indemnifying Party will not enter into any settlement that adversely affects the Indemnified Party's rights or obligations without the Indemnified Party's prior express written consent, which will not be unreasonably withheld, conditioned or delayed. The Indemnified Party may participate in the defense or settlement of any such claim at its own expense with counsel of its choosing. Notwithstanding the foregoing, any failure of the Indemnified Party to comply with the provisions of clause (a) of this Section 9.2 will not relieve the Indemnifying Party of any defense or indemnity obligations under this Agreement except to the extent that the Indemnifying Party is prejudiced by such failure.
- PARTY CLAIM FOR WHICH ONE PARTY IS OBLIGATED TO INDEMNIFY THE OTHER PARTY (OR AN INDEMNIFIED PARTY OF SUCH OTHER PARTY) PURSUANT TO THIS ARTICLE 9 OR ANY BREACH OF ARTICLE 7 (CONFIDENTIALITY), IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES OR (SUB)LICENSEES) IN CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY,

INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

9.4. <u>Insurance</u>. Janssen shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated, at all times during which any Licensed Product is being tested by or on behalf of Janssen, during the period of commercialization of any Licensed Product and for at least [...\*\*\*...] thereafter. At a minimum, Janssen shall be insured for [...\*\*\*...] to cover its obligations under this Agreement. TRACON shall be named as an additional insured under Janssen's general liability insurance policy. It is understood that such insurance shall not be construed to create a limit of Janssen's liability with respect to its indemnification obligations under this Article 9. Janssen shall provide TRACON with written evidence of such insurance upon request and shall provide TRACON with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance which materially adversely affects the rights of TRACON hereunder.

# Article 10 TERM AND TERMINATION

10.1. **Term.** The term of this Agreement (the "**Term**") will commence on the Effective Date and, unless this Agreement is terminated earlier in accordance with this Article 10, this Agreement will expire upon expiration of all of the payment obligations under Article 5 with respect to all Licensed Products in all countries; *provided* that, on a Licensed Product-by-Licensed Product and country-by-country basis, upon expiration of all of the payment obligations under Article 5 with respect to a given Licensed Product in a given country, the licenses granted herein with respect to such Licensed Product in such country shall survive on a fully-paid, royalty-free, non-exclusive, irrevocable and perpetual basis.

#### 10.2. <u>Termination for Breach</u>.

10.2.1.

\*\*\*Confidential Treatment Requested

A Party (the "Terminating Party") may terminate this Agreement in its entirety in the event the other Party (the "Breaching Party") has materially breached this Agreement and such material breach has not been cured within sixty (60) days after written notice of such breach is given by the Terminating Party to the Breaching Party (the "Cure Period"). The written notice describing the alleged material breach shall provide sufficient detail to put the Breaching Party on notice of such material breach. Any termination of this Agreement in its entirety pursuant to this Section 10.2.1 shall become effective at the end of the Cure Period unless the Breaching Party has cured any such material breach prior to the expiration of such Cure Period (or, if such breach (other than a breach of payment obligations) is not reasonably able to be cured within the Cure Period, such termination shall not become effective until the earlier of the date such breach is cured or one hundred and twenty (120) days after notice of termination is given pursuant to this Section 10.2.1, provided that (i) the Breaching Party notifies the other Party of its plan for curing such breach during the Cure Period, (ii) the Breaching Party commences such plan during the Cure Period and (iii) the Breaching Party uses diligent efforts to perform such plan and cure such breach as soon as reasonably practicable). The right of either Party to terminate this Agreement in its entirety as provided in this Section

- 10.2.1 shall not be affected in any way by such Party's waiver of or failure to take action with respect to any previous breach under this Agreement.
  - 10.2.2. If the Parties reasonably and in good faith disagree as to whether there has been a material breach or a cure thereof, the Party that disputes whether there has been a material breach or a cure may contest the allegation in accordance with Article 11. Notwithstanding anything to the contrary contained in Section 10.2.1, the Cure Period for any material breach that is the subject of a Dispute will run from the date that written notice was first given to the Breaching Party by the Terminating Party through the resolution of such Dispute pursuant to Article 11 and for 10 days thereafter, and no termination pursuant to Section 10.2.1 shall become effective during such period. During the pendency of such Dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder; *provided* that the Parties' performance of their respective obligations and exercise of their respective rights hereunder that specify a date by which such obligations must be performed or such rights must be exercised shall be tolled through the resolution of such Dispute pursuant to Article 11 and for 10 days thereafter.

#### 10.3. <u>Termination for Bankruptcy</u>.

- 10.3.1. A Party may terminate this Agreement in its entirety upon providing written notice to the other Party on or after the time that such other Party makes a general assignment for the benefit of creditors, files a voluntary petition in bankruptcy, consents to an order for relief in connection with an involuntary petition in bankruptcy filed against such Party (or an involuntary petition in bankruptcy filed against such Party remains un-dismissed or un-stayed for a period of more than sixty (60) days), petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors, or becomes a party to any proceeding or action of the type described above (each, an "Insolvency Event").
- All rights and licenses now or hereafter granted under or pursuant to any Section of this Agreement are rights to "intellectual property" (as defined in Section 101(35A) of Title 11 of the United States Code, as amended (such Title 11, the "Bankruptcy Code")). In the event this Agreement is rejected under Section 365 of the Bankruptcy Code by or on behalf of a Party (including by any receiver, trustee or similar officer appointed with respect to such Party), such Party (the "Licensor Party") hereby grants to the other Party (the "Licensee Party"), subject to the Licensee Party's obligations under Sections 365(n)(2)(A) and (B), a right of access and to obtain possession of and to benefit from embodiments of intellectual property pursuant to Section 365(n) of the Bankruptcy Code (including Know-How Controlled by the Licensor Party with respect to Licensed Compounds or Licensed Products), all of which constitute embodiments of intellectual property pursuant to Section 365(n) of the Bankruptcy Code) to the extent related to the Licensee Party's exercise of its license rights to any Licensed Compound or Licensed Product or otherwise related to any rights or licenses granted to the Licensee Party under

or pursuant to any Section of this Agreement. The Licensor Party agrees not to interfere with the Licensee Party's exercise under the Bankruptcy Code of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement.

- 10.4. <u>Termination Without Cause</u>. Janssen shall have the right to terminate this Agreement in its entirety without cause at any time during the Term by providing TRACON sixty (60) days' prior written notice of such termination; *provided*, *however*, that Janssen's obligations under Article 5 shall survive with respect to [...\*\*\*...].
- 10.5. Effects of Termination or Expiration. If this Agreement is terminated or expires, all rights and obligations under this Agreement, other than those that expressly survive termination or expiration of this Agreement, shall terminate on the effective date of termination or expiration. Termination or expiration of this Agreement will not relieve the Parties of any obligations accruing prior to such termination or expiration, and any such termination or expiration will be without prejudice to the rights of either Party against the other. The Receiving Party shall, within [...\*\*\*...] after the effective date of termination or expiration of this Agreement, and at the Receiving Party's expense, return or destroy, at the Disclosing Party's election, all Confidential Information of the Disclosing Party (provided that (i) the Receiving Party may keep one copy of such Confidential Information subject to an ongoing obligation of confidentiality for archival purposes only, (ii) it is acknowledged that, with regard to any such Confidential Information disclosed to subcontractors, consultants, agents, advisors and other Third Parties as permitted by Section 7.3, the Receiving Party's use of Commercially Reasonable Efforts to return or destroy such Confidential Information shall satisfy its obligation under this Section and (iii) the Receiving Party may retain and continue to use Confidential Information of the Disclosing Party to practice any licenses and other rights granted to the Receiving Party under this Agreement that expressly survive expiration of this Agreement). The Parties acknowledge and agree that termination of this Agreement is not the sole remedy under this Agreement and, whether or not termination is effected, all other remedies will remain available except as expressly agreed to otherwise herein. The provisions of Article 1, Article 7, Article 11 and Article 12 and Sections 5.5 (for the period specified therein), 8.3, 9.1, 9.2, 9.3, 9.4 (for the period specified therein), 10.1 (the proviso regarding survival of license) and 10.5 shall survive expiration or termination of this Agreement for any reason.

## Article 11 DISPUTE RESOLUTION

11.1.

\*\*\*Confidential Treatment Requested

Escalation: Decision-Making Authority. In the case of any dispute, claim or controversy between the Parties arising from or related to this Agreement, or the interpretation, application, breach, termination or validity of this Agreement (a "**Dispute**"), the Parties will discuss and negotiate in good faith a solution acceptable to the Parties and in the spirit of this Agreement. If, after negotiating in good faith pursuant to the foregoing sentence, the Parties fail to reach agreement within [...\*\*\*...] (or such longer period as agreed in writing by the Parties), then the Dispute may be referred to the Executive Officers for resolution at the request of either Party. If, after negotiating in good faith, the Executive Officers fail to reach agreement within [...\*\*\*...] of submission to the Executive Officers (or such longer period as agreed in writing by

the Parties), then either Party may upon written notice to the other submit the Dispute to non-binding mediation pursuant to Section 11.2.

#### 11.2. **Mediation.**

- 11.2.1. If the Parties fail to resolve the Dispute pursuant to Section 11.1, the Parties shall attempt in good faith to resolve any Dispute by confidential mediation in accordance with the then current *Mediation Procedure of the International Institute for Conflict Prevention and Resolution* ("CPR Mediation Procedure") (www.cpradr.org) before initiating arbitration. The CPR Mediation Procedure shall control, except where it conflicts with these provisions, in which case these provisions control. The mediator shall be chosen pursuant to CPR Mediation Procedure. The mediation shall be held in New York, New York.
- 11.2.2. Either Party may initiate mediation by written notice to the other Party of the existence of a Dispute. The Parties agree to select a mediator within [...\*\*\*...] of the notice and the mediation will begin promptly after the selection. The mediation will continue until the mediator, or either Party, declares in writing, no sooner than after the conclusion of one full day of a substantive mediation conference attended on behalf of each Party by a senior business person with authority to resolve the Dispute, that the Dispute cannot be resolved by mediation. In no event, however, shall mediation continue more than [...\*\*\*...] from the initial notice by a Party to initiate mediation unless the Parties agree in writing to extend that period.
- 11.2.3. Any period of limitations that would otherwise expire between the initiation of mediation and its conclusion shall be extended until [...\*\*\*...] after the conclusion of the mediation.

#### 11.3. **Arbitration.**

- 11.3.1. If the Parties fail to resolve the Dispute pursuant to Section 11.1 or Section 11.2, and a Party desires to pursue resolution of the Dispute, subject to Section 11.3.10, the Dispute shall be submitted by either Party for resolution in arbitration pursuant to the then current *CPR Non- Administered Arbitration Rules* ("**CPR Rules**") (www.cpradr.org), except where they conflict with these provisions, in which case these provisions control. The arbitration will be held in New York, New York. All aspects of the arbitration shall be treated as confidential.
- 11.3.2. The arbitrators will be chosen from the CPR Panel of Distinguished Neutrals, unless a candidate not on such panel is approved by both Parties. Each arbitrator shall be a lawyer with at least fifteen (15) years' experience with a law firm or corporate law department of over twenty-five (25) lawyers or who was a judge of a court of general jurisdiction. To the extent that the Dispute requires special expertise, the Parties will so inform CPR prior to the beginning of the selection process.

11.3.3.

\*\*\*Confidential Treatment Requested

The arbitration tribunal shall consist of three (3) arbitrators, of whom each Party shall designate one in accordance with the "screened" appointment procedure provided in CPR Rule 5.4. The chair will be chosen in accordance with CPR Rule 6.4. If, however,

the aggregate award sought by the Parties is less than Five Million U.S. Dollars (\$5,000,000) and equitable relief is not sought, a single arbitrator shall be chosen in accordance with the CPR Rules. Candidates for the arbitrator position(s) may be interviewed by representatives of the Parties in advance of their selection, *provided* that all Parties are represented.

- 11.3.4. The Parties agree to select the arbitrator(s) within forty-five (45) days of initiation of the arbitration. The hearing will be concluded within nine (9) months after selection of the arbitrator(s) and the award will be rendered within sixty (60) days of the conclusion of the hearing, or of any post-hearing briefing, which briefing will be completed by both sides within forty-five (45) days after the conclusion of the hearing. In the event the Parties cannot agree upon a schedule, then the arbitrator(s) shall set the schedule following the time limits set forth above as closely as practical.
- 11.3.5. The hearing will be concluded in ten (10) hearing days or less. Multiple hearing days will be scheduled consecutively to the greatest extent possible. A transcript of the testimony adduced at the hearing shall be made and shall be made available to each Party.
- 11.3.6. The arbitrator(s) shall be guided, but not bound, by the *CPR Protocol on Disclosure of Documents and Presentation of Witnesses in Commercial Arbitration* (www.cpradr.org) ("**Protocol**"). The Parties will attempt to agree on modes of document disclosure, electronic discovery, witness presentation, etc. within the parameters of the Protocol. If the Parties cannot agree on discovery and presentation issues, the arbitrator(s) shall decide on presentation modes and provide for discovery within the Protocol, understanding that the Parties contemplate reasonable discovery.
- 11.3.7. The arbitrator(s) shall decide the merits of any Dispute in accordance with the law governing this Agreement, without application of any principle of conflict of laws that would result in reference to a different law. The arbitrator(s) may not apply principles such as "amiable compositeur" or "natural justice and equity."
- 11.3.8. The arbitrator(s) are expressly empowered to decide dispositive motions in advance of any hearing and shall endeavor to decide such motions as would a United States District Court Judge sitting in the jurisdiction whose substantive law governs.
- 11.3.9. The arbitrator(s) shall render a written opinion stating the reasons upon which the award is based. The Parties consent to the jurisdiction of the United States District Court for the district in which the arbitration is held for the enforcement of these provisions and the entry of judgment on any award rendered hereunder. Should such court for any reason lack jurisdiction, any court with jurisdiction may act in the same fashion.
- 11.3.10. Notwithstanding any provision to the contrary contained in this Agreement, each Party has the right to seek from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin or other equitable relief to avoid irreparable harm, maintain the status quo, preserve its status and priority as a creditor or preserve the subject matter of the Dispute. Rule 14 of the CPR Rules does not apply to this Agreement.

#### Article 12 MISCELLANEOUS

- 12.1. **Performance by Affiliates.** To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations. A Party may use one or more of its Affiliates to perform its obligations and duties or exercise its rights hereunder, *provided* that such Party will remain liable hereunder for the prompt payment and performance of all of their respective obligations hereunder. Any breach by an Affiliate of a Party of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.
- 12.2. **Retained Rights.** All licenses and rights are granted only as expressly provided in this Agreement, and no license or other right is or shall be created or granted under this Agreement by implication, estoppel, or otherwise. All rights not expressly granted by a Party under this Agreement are reserved by such Party and may not be used by the other Party for any purpose.
- 12.3. **Entire Agreement.** This Agreement and each of the Schedules and Exhibits hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter of this Agreement and cancels and supersedes any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter.
- 12.4. **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 12.5. **Binding Effect.** This Agreement and the rights granted herein will be binding upon, and will inure to the benefit of TRACON, Janssen and their respective lawful successors and permitted assigns.
- 12.6. **Assignment.** Neither Party may assign or transfer this Agreement in its entirety or any rights or obligations hereunder without the prior written consent of the other Party, except that:
  - (a) either Party may assign or transfer this Agreement in its entirety or any rights or obligations hereunder to an Affiliate without the other Party's consent;
  - (b) either Party may assign or transfer this Agreement in its entirety pursuant to any Change of Control of such Party without the other Party's consent, or to a Third Party acquirer of that portion of its business relating to the subject matter of this Agreement in a sale of assets or other similar transaction without the other Party's consent

The assigning Party shall provide the other Party with prompt written notice of any such assignment; provided, however, that Janssen shall be obligated only to use diligent efforts to provide TRACON with written notice of any assignment to an Affiliate pursuant to Section 12.6(a) within a reasonable period of time after the occurrence of such assignment. Any permitted assignment shall be binding on the successors and permitted assignees of the assigning Party, and

the successor (if the successor is an entity other than a Party) or assignee shall confirm the same in writing to the other Party. Any assignment, transfer or attempted assignment or transfer by either Party in violation of the terms of this Section 12.6 shall be null, void and of no legal effect.

- 12.7. **Use of Names.** Neither Party shall use the name, physical likeness, employee names or Trademarks of the other Party for any purpose without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed; *provided*, *however*, that nothing contained herein shall be construed to prevent either Party from using the name of the other Party for purposes of preparing necessary filings with the United States Securities and Exchange Commission or complying with its regulations, or other regulations applicable to the public sale of securities, including preparing proxy statements or prospectuses. Nothing contained herein shall be construed as granting either Party any rights or license to use any of the other Party's Trademarks without separate, express written permission of the owner of such Trademark.
- 12.8. Amendment; No Waiver. No waiver, modification or amendment of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition.
- 12.9. **Force Majeure Event.** Except for obligations to make payments under this Agreement when due, the failure of a Party to perform any obligation under this Agreement by reason of force majeure, limited to acts of God, war, terrorism (actual or threatened), strikes, revolutions, laws or other causes of a similar magnitude beyond the reasonable control of such Party (each, a "**Force Majeure Event**"), will not be deemed to be a breach of this Agreement. The Party affected by any Force Majeure Event will contact the other Party for discussion of possible emergency measures.
- 12.10. <u>Independent Contractors</u>. The Parties are independent contractors and not agents or employees of the other Parties under this Agreement. Nothing contained in this Agreement is intended nor is to be construed so as to constitute TRACON and Janssen as partners or joint venturers with respect to this Agreement. No Party will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Parties or to bind the other Parties to any other contract, agreement or undertaking with any Third Party except as may be explicitly provided for herein or authorized in writing.
- 12.11. Notices and Deliveries. Any notices, request, delivery, approval or consent required or permitted to be given under this Agreement will be in writing and will be deemed to have been sufficiently given when it is received, whether delivered in person, transmitted by facsimile with contemporaneous confirmation, delivered by registered letter (or its equivalent) or delivered by certified overnight courier service, to the Party to which it is directed at its address shown below or such other address as such Party will have last given by notice to the other Party.

If to TRACON:

TRACON Pharmaceuticals, Inc.

8910 University Center Lane Suite 700 San Diego, CA 92122 USA

Attention: Chief Business Officer Facsimile No.: +1 858-550-0786

with a copy to:

Cooley LLP 4401 Eastgate Mall San Diego, CA 92121 USA Attention: L. Kay Chandler Facsimile No.: +1 858-550-6420

#### If to Janssen:

Janssen Pharmaceutica NV Legal Affairs Department Turnhoutseweg 30 B-2340 Beerse Belgium

Facsimile: As may be provided to TRACON by Janssen

with a copy to:

Office of General Counsel Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933 Facsimile: 732-524-2788

- 12.12. **Headings.** The captions to the sections and articles in this Agreement are not a part of this Agreement, and are included merely for convenience of reference only and will not affect its meaning or interpretation.
- 12.13. <u>Severability</u>. In the event that any provision of this Agreement will, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability will not affect any other provision hereof, and this Agreement will be construed as if such invalid or unenforceable provision had not been included herein.
- 12.14. **Governing Law.** This Agreement will be governed by and interpreted in accordance with the laws of the State of New York without reference to its choice of laws or conflicts of laws provisions. The United Nations Conventions on Contracts for the International Sale of Goods shall not be applicable to this Agreement. Each Party (a) submits to the exclusive jurisdiction of the state and federal courts sitting in New York, New York, with respect to actions or proceedings arising out of or relating to this Agreement in which a Party brings an action in aid of arbitration, (b) agrees that all claims in respect of such action or proceeding may be heard and determined only in any such court, and (c) agrees not to bring any action or proceeding

arising out of or relating to this Agreement in any other court, other than an action or proceeding seeking injunctive relief or brought to enforce an arbitration ruling issued pursuant to Section 11.3. Each Party waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of the other Party with respect thereto. Each Party may make service on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for the giving of notices in Section 12.11. Nothing in this Section 12.14, however, will affect the right of any Party to serve legal process in any other manner permitted by New York law.

- 12.15. Advice of Counsel. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will exist or be implied against the Party which drafted such terms and provisions.
- 12.16. <u>Counterparts</u>. This Agreement may be executed in any number of counterparts (including by facsimile or electronic transmission), each of which need not contain the signature of more than one Party, but all such counterparts taken together will constitute one and the same agreement. Signatures provided by facsimile transmission or in Adobe<sup>TM</sup> Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.
- 12.17. **Construction.** Whenever this Agreement refers to a number of days without using a term otherwise defined herein, such number refers to calendar days. Except where the context otherwise requires, (a) wherever used, the singular shall include the plural, the plural shall include the singular; (b) the use of any gender shall be applicable to all genders; (c) the terms "including," "include," "include," "includes" or "for example" shall not limit the generality of any description preceding such term and, as used herein, shall have the same meaning as "including, but not limited to," and/or "including, without limitation"; (d) the words "herein", "hereof" and hereunder", and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; (d) the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (e) the word "will" means "shall"; (f) if a period of time is specified and dates from a given day or business day, or the day or business day of an act or event, it is to be calculated exclusive of that day or business day; (g) references to a particular entity include such entity's successors and assigns to the extent not prohibited by this Agreement; (h) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein shall be interpreted in a correlative manner; and (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein).

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

ANSSEN PHARMACEUTICA N.V.
Зу:
Name:
Title:
ANSSEN PHARMACEUTICA N.V.
Ву:
Name:
Title:
TRACON PHARMACEUTICALS, INC.
Ву:
Name:
Title:

### EXHIBIT B

[...\*\*\*...]

\*\*\*Confidential Treatment Requested

### EXHIBIT C

[...\*\*\*...]

\*\*\*Confidential Treatment Requested

### CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles P. Theuer, M.D., Ph.D., certify that:

- $1.\,I\,have\ reviewed\ this\ Amendment\ No.\ 1\ to\ Quarterly\ Report\ on\ Form\ 10-Q/A\ of\ TRACON\ Pharmaceuticals,\ Inc.;\ and\ Pharmaceuticals,\ Inc.;\$
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: February 15, 2017 /s/ Charles P. Theuer, M.D., Ph.D.

Charles P. Theuer, M.D., Ph.D. President and Chief Executive Officer (Principal Executive Officer)

### CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

#### I, Patricia L. Bitar, CPA, certify that:

- 1. I have reviewed this Amendment No. 1 to Quarterly Report on Form 10-Q/A of TRACON Pharmaceuticals, Inc.; and
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: February 15, 2017

/s/ Patricia L. Bitar, CPA
Patricia L. Bitar, CPA
Chief Financial Officer
(Principal Financial and Accounting Officer)