
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K/A

(Amendment No. 1)

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **May 26, 2017**

PROTAGONIST THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37852
(Commission
File Number)

98-0505495
(IRS Employer
Identification No.)

Protagonist Therapeutics, Inc.
7707 Gateway Blvd., Suite 140
Newark, California 94560-1160
(Address of principal executive offices, including zip code)

(510) 474-0170
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Explanatory Note

On May 30, 2017, Protagonist Therapeutics, Inc. (“Protagonist” or “the Company”) filed a Current Report on Form 8-K (the “Original Report”) to report, among other things, that the Company entered into an exclusive license and collaboration agreement (the “Collaboration Agreement”) with Janssen Biotech, Inc. This Current Report on Form 8-K/A amends the Original Report solely to file the Collaboration Agreement as an exhibit hereto. The other disclosures made in the Original Report remain unchanged.

Item 9.01 Financial Statement and Exhibit

(d) Exhibits

Exhibit	Description
10.1†	Exclusive License and Collaboration Agreement, by and between the Company and Janssen Biotech, Inc., dated May 26, 2017.

† Confidential portions of this exhibit have been redacted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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 hereunto duly authorized.

Protagonist Therapeutics, Inc.

Dated: July 31, 2017

By: /s/ Thomas P. O'Neil
Thomas P. O'Neil
Chief Financial Officer

INDEX TO EXHIBITS

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LICENSE AND COLLABORATION AGREEMENT

BY AND BETWEEN

JANSSEN BIOTECH, INC.

AND

PROTAGONIST THERAPEUTICS, INC.

TABLE OF CONTENTS

		<u>Page</u>
ARTICLE 1	DEFINITIONS	1
ARTICLE 2	GOVERNANCE	21
ARTICLE 3	ACTIVITIES DURING DEVELOPMENT TERM	27
ARTICLE 4	OPT-IN RIGHTS	39
ARTICLE 5	ACTIVITIES DURING LICENSE TERM	41
ARTICLE 6	LICENSE GRANTS	47
ARTICLE 7	FINANCIAL TERMS	49
ARTICLE 8	INTELLECTUAL PROPERTY	58
ARTICLE 9	CONFIDENTIALITY; PUBLICITY	71
ARTICLE 10	REPRESENTATIONS AND WARRANTIES	76
ARTICLE 11	INDEMNIFICATION AND INSURANCE	82
ARTICLE 12	TERM AND TERMINATION	84
ARTICLE 13	DISPUTE RESOLUTION	93
ARTICLE 14	MISCELLANEOUS	95

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LICENSE AND COLLABORATION AGREEMENT

This LICENSE AND COLLABORATION AGREEMENT (this “**Agreement**”) is made and effective as of May 26, 2017 (the “**Execution Date**”), by and between Janssen Biotech, Inc., a Pennsylvania corporation (“**Janssen**”) and Protagonist Therapeutics, Inc., a Delaware corporation (“**Protagonist**”). Each of Janssen and Protagonist is sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

RECITALS

WHEREAS, Protagonist has developed certain technology and owns certain intellectual property rights relating to the Licensed Compounds (as defined below) and Licensed Products (as defined below);

WHEREAS, Janssen desires to obtain, and Protagonist desires to grant to Janssen, an exclusive, worldwide license under such Protagonist technology and intellectual property rights to develop, manufacture and commercialize the Licensed Compounds and Licensed Products, on the terms and conditions set forth herein;

WHEREAS, the Parties desire to collaborate with respect to the Phase 1 Activities (as defined below), Phase 2 Activities (as defined below) and Collaboration CMC Activities (as defined below); and

WHEREAS, the right to fully exercise the license granted to Janssen by Protagonist is subject to Janssen’s obligation to make certain payments to Protagonist at the end of the Phase 2A Activities and at the end of the Phase 2B Activities, as further described herein;

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. “**Acceptance**” means, in reference to a Drug Approval Application, receipt of a written communication from the applicable Regulatory Authority acknowledging that it has received the Drug Approval Application and that the Drug Approval Application is sufficiently complete to permit a substantive review for approval purposes. For illustrative purposes, Acceptance of an NDA by the FDA may be provided in an FDA filing communication letter pursuant to 21 CFR § 314.101(a)(2). Where the NDA is submitted on a rolling basis, Acceptance will not occur until all parts or modules forming the NDA have been completed and submitted to the FDA and the FDA has acknowledged that the NDA is sufficiently complete to permit such substantive review.

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The Acceptance of a marketing approval application by the EMA may be provided in the form of written confirmation from the EMA that the marketing approval application submission is validated (with respect to eligibility for review via the centralized procedure) and considered to be sufficiently complete to permit such substantive review.

1.2. “**Acquirer**” means any Third Party that is a party to any Change of Control transaction and any of such Third Party’s Affiliates.

1.3. “**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.

1.4. “**Antitrust Laws**” means any law relating to competition that is enforced by (a) the Federal Trade Commission or the Antitrust Division of the U.S. Department of Justice or (b) any equivalent foreign authority, including the European Commission.

1.5. “**Applicable Law**” means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any Governmental Authority, including, as applicable, the FDCA, Public Health Service Act, 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.

1.6. “**Business Day**” means a day other than Saturday, Sunday or any other day on which banking institutions in New York, New York are closed for business.

1.7. “**Calendar Quarter**” means a financial quarter based on the Johnson & Johnson Universal Calendar; *provided, however*, that the first Calendar Quarter for the first Calendar Year extends from the Effective Date to the end of the then-current Calendar Quarter and the last Calendar Quarter extends from the first day of such Calendar Quarter until the effective date of the termination or expiration of this Agreement.

1.8. “**Calendar Year**” means a year based on the Johnson & Johnson Universal Calendar for that year. The last Calendar Year of the Term begins on the first day of the Johnson & Johnson Universal Calendar Year for the year during which termination or expiration of this Agreement occurs, and the last day of such Calendar Year will be the effective date of such termination or expiration.

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1.9. “**CD**” means the treatment of Crohn’s disease.

1.10. “**CD Phase 2 Clinical Trial**” means the Phase 2 Clinical Trial of the Initial Product for CD set forth in the initial Clinical Development Plan, which includes both a Phase 2A portion and Phase 2B portion or any Phase 2 Clinical Trial conducted in its stead under this Agreement.

1.11. “**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 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 Execution 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. For purposes of this definition, “beneficial ownership” shall have the meaning accorded in the U.S. Securities Exchange Act of 1934 and the rules of the U.S. SEC thereunder in effect as of the Execution Date. Notwithstanding the foregoing, a transaction solely to change the domicile of a Party shall not constitute a Change of Control.

1.12. “**Clinical Development Plan**” means the Parties’ written plan for the clinical Development of the Initial Product during the Development Term, as amended from time to time pursuant to Section 3.2.2, including the budget and timelines described in Section 3.2.1(a). The initial Clinical Development Plan is attached hereto as Exhibit A.

1.13. “**Clinical Manufacturing Cost**” means a Party’s reasonable, attributable and necessary internal costs and reasonable, documented Third Party costs incurred in clinical manufacturing or acquisition and supply of Licensed Compound or Licensed Product, determined in accordance with such Party’s accounting policies that are in accordance with U.S. generally accepted accounting principles and consistently applied across such Party’s clinical manufacturing supply network to other products that such Party or one of its Affiliates manufactures.

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1.14. “**Clinical Trial**” means any Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial or any other clinical trial of a Licensed Compound or Licensed Product.

1.15. “**CMC Development**” means Development activities related to the composition, manufacture and specification of drug substance and drug product intended to assure the proper identification, quality, purity and strength of the drug, including: test method development and stability testing, process development, drug substance development, process validation, process scale-up, formulation development, quality assurance and quality control development.

1.16. “**CMC Development Plan**” means the Parties’ written plan for CMC Development and Manufacturing of the Initial Compound and Initial Product during the Development Term, as amended from time to time pursuant to Section 3.2.2, including the budget and timelines described in Section 3.2.1(b). The initial CMC Development Plan is attached hereto as Exhibit B.

1.17. “**Collaboration Activities**” means, collectively, the Phase 1 Activities, Phase 2 Activities and Collaboration CMC Activities.

1.18. “**Collaboration CMC Activities**” means, collectively, the CMC Development and Manufacturing activities set forth in the CMC Development Plan.

1.19. “**Collaboration CMC Costs**” means (a) with respect to the Manufacturing of clinical supplies of Compound API or Drug Product for the Phase 1 Activities or Phase 2 Activities pursuant to the CMC Development Plan, the Clinical Manufacturing Costs incurred by either Party or any of its Affiliates in performing such activities and (b) with respect to all other Collaboration CMC Activities, the reasonable, attributable and required internal costs and reasonable, documented Third Party costs incurred by a Party or its Affiliates in performing such activities.

1.20. “**Collaboration Information**” means: (a) the Clinical Development Plan and CMC Development Plan; (b) the JSC minutes prepared in accordance with Section 2.1.4(b) and the Collaboration Records; (c) the reports delivered by the Parties pursuant to Section 3.6.4; (d) the Phase 1 Data Package, Phase 2A Results, Phase 2 Data Package and any final clinical study reports for the Phase 1 Clinical Trial of the Initial Product set forth in the Development Plan or CD Phase 2 Clinical Trial; and (e) non-public Collaboration Know-How and non-public Collaboration Patent Rights.

1.21. “**Collaboration Invention**” means any Collaboration Know-How that is an invention.

1.22. “**Collaboration Know-How**” means any Know-How that is generated (or, in the case of an invention, conceived of or reduced to practice) by a Party’s, or its Affiliates’ or Third Party Subcontractors’, employees or agents in Developing, Manufacturing or Commercializing the Licensed Compounds or Licensed Products pursuant to this Agreement.

1.23. “**Combination Product**” means any product containing: (a) as a single formulation, two or more active pharmaceutical ingredients as components including (i) a Licensed Compound

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and (ii) one or more other active pharmaceutical ingredients; or (b) in a single package or container and intended for coordinated use, two or more products as components including (i) a Licensed Product containing a Licensed Compound as its sole active pharmaceutical ingredient, and (ii) one or more other products for therapeutic administration or diagnostic use.

1.24. “**Commercialization**” means any activities directed to marketing, promoting, educating, informing, distributing, importing, offering to sell and/or selling a pharmaceutical or biologic product. When used as a verb, “**Commercialize**” means to engage in Commercialization activities.

1.25. “**Commercially Reasonable Efforts**” means: (a) with respect to the Development (other than the conduct of the Collaboration Activities), seeking and obtaining Marketing Approval, Manufacture or Commercialization of a Licensed Product in a country by or on behalf of Janssen, those reasonable, good faith efforts normally used by [*] under similar circumstances for similar products or product candidates owned or controlled by Janssen and its Affiliates, or to which Janssen or any of its Affiliates 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 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 1.25, those reasonable, good faith efforts to accomplish such objective or perform such activity as [*] would normally use to accomplish a similar objective under similar circumstances.

1.26. “**Compound API**” means the active pharmaceutical ingredient for a Licensed Compound.

1.27. “**Confidential Information**” means: (a) all non-public or proprietary information (including Know-How) that is disclosed by or on behalf of a Party (or any of its Affiliates) to the other Party, any of its Affiliates or any of their respective employees, agents or contractors 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 or on behalf of a Party (or any of its Affiliates) to the other Party, any of its Affiliates or any of their respective employees, agents or contractors, 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.

1.28. “**Control**” or “**Controlled**” means, with respect to any Know-How, Patent Right or other intellectual property right, subject to Section 8.10.4, 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 agreement or binding arrangement with any Third Party; *provided, however*, that any Know-How, Patent Right or other intellectual property right that is owned or licensed by an Acquirer of Protagonist or any Affiliate of such Acquirer (excluding any Affiliate that was an Affiliate of Protagonist 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 Protagonist for purposes of this

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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 Protagonist, 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 Protagonist, or (b) made, conceived or reduced to practice by the Acquirer or any such Affiliates through the use of the Protagonist Intellectual Property (to the extent such Protagonist Intellectual Property Covers the manufacture, use or sale of, or is necessary to manufacture, use or sell, a Licensed Compound or Licensed Product), Collaboration Know-How or Collaboration Patent Rights following the consummation of the Change of Control of Protagonist.

1.29. **“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 (or in the case of a pending patent application, if the claims of such patent application as then existing were issued).

1.30. **“CTA”** means (a) a clinical trial authorization application filed with a Regulatory Authority in any regulatory jurisdiction outside the U.S., the filing of which is necessary to commence or conduct clinical testing of a pharmaceutical or biologic product in humans in such jurisdiction; or (b) documentation issued by a Regulatory Authority that permits the conduct of clinical testing of a product in humans in a regulatory jurisdiction.

1.31. **“Data”** means any data or information used or developed to commence a Clinical Trial, any data or information developed as a result of a Clinical Trial, and all data and information resulting from CMC Development of a Licensed Compound or Licensed Product.

1.32. **“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 or biologic product. When used as a verb, **“Develop”** means to engage in Development activities.

1.33. **“Development Term”** means the period beginning on the Effective Date and ending on:

- (a) If Janssen does not make the First Opt-In Election, the date this Agreement terminates pursuant to Section 4.1.4;
- (b) If Janssen makes the First Opt-In Election, but does not make the Second Opt-In Election, the date this Agreement terminates pursuant to Section 4.2.4; or
- (c) If Janssen makes the Second Opt-In Election on or prior to the Phase 2B Completion Date, the Phase 2B Completion Date;

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(d) If Janssen makes the Second Opt-In Election after the Phase 2B Completion Date, the Opt-In Effective Date.

1.34. “**Diligent Efforts**” means, with respect to any Party’s performance of the Collaboration Activities during the Development Term, the carrying out of such activities in a prompt and timely manner using reasonable, good faith efforts and adequate and appropriate resources.

1.35. “**Drug Approval Application**” means: (a) a new drug application submitted to the FDA pursuant to Section 505(b) of the FDCA, 21 U.S.C. § 355(b) (an “**NDA**”); (b) a Biologics License Application submitted to the FDA pursuant to the Public Health Service Act, 42 U.S.C. §§ 262 - 263 (a “**BLA**”); or (c) 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), (b) or (c)), including all amendments and supplements thereto.

1.36. “**Drug Product**” means any formulation of Compound API or Licensed Product in final finished form, including packaging and labeling.

1.37. “**Effective Date**” means the first (1st) Business Day immediately following the date on which the Parties have actual knowledge that all applicable waiting periods under the HSR Act with respect to the transactions contemplated hereunder have expired or have been terminated. Upon the request of either Party, the Parties shall memorialize the Effective Date, as defined in the immediately preceding sentence, in a written document for the records.

1.38. “**EMA**” means the European Medicines Agency or any successor agency for the EU with responsibilities comparable to those of the European Medicines Agency.

1.39. “**EU**” means the countries of the European Economic Area, as it is constituted on the Execution Date and as it may be modified from time to time after the Execution Date.

1.40. “**Executive Officers**” means the [*] of Protagonist and the [*] of Janssen.

1.41. “**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.

1.42. “**FDCA**” means the U.S. Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.), as amended from time to time, and any regulations promulgated thereunder.

1.43. “**Field**” means all therapeutic, prophylactic and diagnostic uses in humans and animals.

1.44. “**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

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Parties (or their respective Affiliates, distributors or (sub)licensees), shall not constitute a First Commercial Sale.

1.45. “**FTE Rate**” means a rate of [*] per FTE 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); *provided, however*, that such rate shall be increased or decreased annually beginning on [*] by the percentage increase or decrease in the CPI between the last day of the most recently completed Calendar Year and December 31, 2016, plus [*] percent ([*]%). The FTE Rate is “fully burdened” and will cover employee salaries and such facilities and equipment and other materials and services, including ordinary laboratory consumables procured from distributors of relevant products as they may use.

1.46. “**Generic Product**” means, with respect to a Licensed Product in a country in the Territory, any product sold by a Third Party (including a “generic product”, “biogeneric”, “follow-on biologic”, “follow-on biological product”, “follow-on protein product”, “similar biological medicinal product” or “biosimilar product”) approved in such country by way of an abbreviated regulatory mechanism by the Regulatory Authority in such country that, in each case, meets the equivalency determination by the applicable Regulatory Authority (including a determination that the product is “comparable”, “interchangeable”, “bioequivalent”, “biosimilar” or other term of similar meaning, with respect to such Licensed Product), in each case, as is necessary to permit substitution of one product for another product under Applicable Law. A product shall not be considered to be a Generic Product if (a) Janssen or any of its Affiliates or sublicensees was involved in the Development of such product, or (b) such product is Commercialized by any Person who obtained such product in a chain of distribution that included Janssen or any of its Affiliates or sublicensees.

1.47. “**Good Clinical Practice**” or “**GCP**” means the current standards for clinical trials for pharmaceuticals, as set forth in the ICH guidelines and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required by the European Union and other organizations and Governmental Authorities in countries in which a pharmaceutical product is intended to be sold to the extent such standards are not less stringent than United States Good Clinical Practice.

1.48. “**Good Laboratory Practice**” or “**GLP**” means the current standards for laboratory activities for pharmaceuticals, as set forth in the FDA’s Good Laboratory Practice regulations or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development, as amended from time to time, and such standards of good laboratory practice as are required by the European Union and other organizations and Governmental Authorities in countries in which a pharmaceutical product is intended to be sold, to the extent such standards are not less stringent than United States Good Laboratory Practice.

1.49. “**Good Manufacturing Practice**” or “**GMP**” means the current quality assurance standards that ensure that pharmaceutical products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use as defined in 21 C.F.R. § 210 and 211, European Directive 2003/94/EC, Eudralex 4, Annex 16, and applicable United

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States, European Union, Canadian and ICH guidance or equivalent laws in other jurisdictions to the extent no less stringent.

1.50. “**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.

1.51. “**HSR Act**” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended from time to time, and any comparable Applicable Law in jurisdictions outside the U.S. related to the approval of transactions similar to those contemplated under this Agreement.

1.52. “**HSR Clearance Date**” means the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act.

1.53. “**HSR Filing**” means (a) filings by Janssen and Protagonist with the U.S. Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto, or (b) equivalent filings with relevant foreign authorities.

1.54. “**IND**” means an Investigational New Drug application as defined in the FDCA.

1.55. “**Indication**” means treatment of 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, and treatment of different signs or symptoms of the same disease shall not be treated as separate Indications. For example, treatment of mild to moderate Crohn’s disease is not a different Indication from treatment of moderate to severe Crohn’s disease.

1.56. “**Initiation**” means, with respect to a Clinical Trial, the dosing of the [*] subject in such Clinical Trial.

1.57. “**Initial Product**” means the Licensed Product containing the Initial Compound.

1.58. “**Janssen Parent**” means Johnson & Johnson.

1.59. “**Johnson & Johnson Universal Calendar**” means the universal calendar system used by Janssen Parent and its Affiliates for internal and external reporting purposes (a copy of which for the year 2017 is attached hereto as Schedule 1.59 and a copy of which prior to the beginning of each such year for succeeding years shall be provided to Protagonist upon request).

1.60. “**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

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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.

1.61. “**License Term**” means the period beginning on the Opt-In Effective Date and ending on the last day of the Term.

1.62. “**Licensed Compound**” means:

- (a) PTG-200, a GI restricted peptide with local IL23 receptor antagonist effect, as further described on Schedule 1.62 (the “**Initial Compound**”); and
- (b) any other peptide that is disclosed by any Protagonist IL23 Receptor Inhibitor Patent Rights and
 - (1) has an IC50 value of less than or equal to [*] nanomolar (i.e., [*]), as determined in the [*] described in Exhibit C; or
 - (2) has an affinity for IL23R less than or equal to [*]pM (i.e., [*]), as determined in the [*] described in Exhibit C.

1.63. “**Licensed Product**” means any pharmaceutical product or formulation containing a Licensed Compound.

1.64. “**Major European Countries**” means [*].

1.65. “**Major Market Countries**” means [*].

1.66. “**Manufacturing**” means any activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a pharmaceutical or biologic product directly or through one or more Third Parties. When used as a verb, “**Manufacture**” means to engage in Manufacturing activities.

1.67. “**Marketing Approval**” means any and all approvals (including supplements, amendments, pre- and post-approvals), licenses, registrations or authorizations of any Regulatory Authority that are necessary to market and/or sell a pharmaceutical or biologic product in a country or jurisdiction for one or more uses, including any pricing and reimbursement approvals that are necessary to conduct a launch of such product in such country or jurisdiction (even if such pricing and reimbursement approvals are not legally required to launch such product in such country or jurisdiction).

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1.68. “**Material Safety Issue**” means the occurrence of any significant safety-related event, incident or circumstance with respect to a Licensed Compound or Licensed Product that leads a Party to reasonably determine that the continued use of such Licensed Compound or Licensed Product by patients may result in patients being exposed to a product for which the risks outweigh the benefits. Examples of Material Safety Issues include the issuance of a clinical hold order (or similar requirement or recommendation) by a Regulatory Authority, where the clinical hold is not resolvable in the ordinary course, or an IRB requirement or recommendation to terminate or suspend a Clinical Trial.

1.69. “**Net Sales**” means the gross amounts invoiced on sales of a Licensed Product by Janssen, 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 U.S. 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, but not limited to, 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 or any other successor program;
- (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;

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- (g) any invoiced amounts that are not collected by Janssen or its Affiliates, including bad debts; and
- (h) any deductions in the context of payments that are due or collected significantly after invoice issuance.

All 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 sublicensees such that Licensed Product does not bear a disproportionate portion of such deductions. In no event will any particular amount identified above be deducted more than once in calculating Net Sales.

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 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 Trial or other scientific testing purposes, early access programs (such as to provide patients with such Licensed Product prior to Marketing 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 (for all financial terms pursuant to Article 7) 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 in such country when sold separately, and B is the weighted average sales price of the other active ingredient(s) or product(s) in the Combination Product in such country 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 in such country during the applicable reporting period, 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

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(by sales volume) of the Combination Product in such country. If neither the Licensed Product nor the other active ingredient(s) or product(s) were sold separately in such country 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 shall be used. 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 13).

1.70. “**New Indication**” means any Indication other than (a) UC (including pediatric indications for UC), (b) CD (including pediatric indications for CD) or (c) an Orphan Drug Indication.

1.71. “**Nondisclosure Agreement**” means the Confidential Disclosure Agreement between the Parties dated March 24, 2017.

1.72. “**Opt-In Effective Date**” means the date that Protagonist receives the Opt-In Exercise Fee.

1.73. “**Orphan Drug Indication**” means any Indication that affects fewer than 200,000 people in the U.S.

1.74. “**Patent Costs**” means any out-of-pocket costs and expenses incurred by a Party or its Affiliates in prosecuting and maintaining any Patent Rights.

1.75. “**Patent Proceeding**” means any opposition, re-issue, and re-examination, and any contested case, including inter-partes review, post-grant review, interference, derivation or similar proceedings.

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.

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1.78. “**Phase 1 Activities**” means the Phase 1 Clinical Trial of the Initial Product set forth in the initial Clinical Development Plan and any related Development activities set forth in the Clinical Development Plan.

1.79. “**Phase 1 Clinical Trial**” means, in reference to a clinical trial of a Licensed Product, (a) a trial that would satisfy the requirements for a Phase 1 study as defined in 21 C.F.R. § 312.21(a) or (b) a Phase 1 study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline).

1.80. “**Phase 1 Completion Date**” means the date of database lock for the Phase 1 Clinical Trial of the Initial Product set forth in the initial Clinical Development Plan.

1.81. “**Phase 1/2 Clinical Trial**” means, in reference to a clinical trial of a Licensed Product, that such trial combines both a Phase 1 Clinical Trial and a Phase 2 Clinical Trial of such Licensed Product into a single protocol, where the Phase 1 Clinical Trial portion is performed first to (a) establish initial safety, tolerability, pharmacokinetic and pharmacodynamic information for the Licensed Product as a monotherapy or in combination with another agent or (b) determine the maximum tolerable dose of such Licensed Product in subjects, and the Phase 2 Clinical Trial portion is performed second to further evaluate safety and/or efficacy of such Licensed Product as a monotherapy or in combination with another agent in subjects treated with a selected dose.

1.82. “**Phase 2 Activities**” means the CD Phase 2 Clinical Trial and any related Development activities set forth in the Clinical Development Plan.

1.83. “**Phase 2 Clinical Trial**” means, in reference to a clinical trial of a Licensed Product, (a) a trial that would satisfy the requirements for a Phase 2 study as defined in 21 C.F.R. § 312.21(b) or (b) a Phase 2 study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline). For purposes of Section 7.3.3, a Phase 1/2 Clinical Trial shall be deemed to be a Phase 2 Clinical Trial upon Initiation of the Phase 2 Clinical Trial portion of such Clinical Trial.

1.84. “**Phase 2 CMC Development Costs**” means the Collaboration CMC Costs incurred by a Party or any of its Affiliates with respect to the Collaboration CMC Activities for the Phase 2 Activities.

1.85. “**Phase 2 Development Costs**” means (a) Phase 2 Out-of-Pocket Costs and Expenses and (b) Phase 2 FTE Costs.

1.86. “**Phase 2 Development FTE**” means [*] hours of work devoted to or in direct support of the Phase 2 Activities under this Agreement by one or more qualified scientific, medical, manufacturing, technical and other employees, contractors or consultants of a Party or its Affiliates, as measured in accordance with such Party’s normal time allocation practices, *provided* that such employees, contractors or consultants shall not include personnel performing administrative and corporate functions (including human resources, finance, legal and investor relations).

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1.87. “**Phase 2 FTE Costs**” means, with respect to any period, the FTE Rate multiplied by the number of Phase 2 Development FTEs expended by a Party or any of its Affiliates during such period in the performance of Phase 2 Activities under this Agreement or the preparing, filing and maintaining of Regulatory Documentation (such as INDs and CTAs) for Licensed Products in support of Phase 2 Activities under this Agreement.

1.88. “**Phase 2 IND**” means, with respect to the CD Phase 2 Clinical Trial, (a) an IND if the protocol for such trial requires that an IND be filed with the FDA, or (b) the first CTA filed with the applicable Regulatory Authority if the protocol for such trial does not require that an IND be filed with the FDA.

1.89. “**Phase 2 Out-of-Pocket Costs and Expenses**” means amounts paid by either Party or any of its Affiliates (a) to Third Party vendors or contractors for services or materials provided by them directly in the performance of Phase 2 Activities under this Agreement, to the extent such services or materials apply directly to Phase 2 Activities under this Agreement, or the preparing, filing and maintaining of Regulatory Documentation (such as INDs and CTAs) for Licensed Products in support of Phase 2 Activities under this Agreement or (b) to the FDA or other Regulatory Authorities for filing fees for such Regulatory Documentation.

1.90. “**Phase 2/3 Clinical Trial**” means, in reference to a clinical trial of a Licensed Product, a Phase 2 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 Licensed Product or a similar clinical study prescribed by the FDA, with respect to the U.S., or other Regulatory Authority with respect to any other country in the Territory; and

(b) such trial is or becomes a registration trial sufficient for filing a Drug Approval Application for such Licensed Product, as evidenced by (i) an agreement with or statement from the FDA, with respect to the U.S., or other Regulatory Authority with respect to any other country in the Territory on a Special Protocol Assessment or equivalent, or (ii) other guidance or minutes issued by the FDA or such other Regulatory Authority for such registration trial.

1.91. “**Phase 2A Activities**” means the Phase 2A portion of the CD Phase 2 Clinical Trial, and any related Development activities set forth in the Clinical Development Plan.

1.92. “**Phase 2A Completion Date**” means the date on which the last patient in the Phase 2A portion of the CD Phase 2 Clinical Trial completes the last visit as described in the protocol for such Clinical Trial. For clarity, recruitment for the Phase 2B portion of the Phase 2 Clinical Trial shall commence before the Phase 2A Completion Date.

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- 1.93. “**Phase 2B Activities**” means the Phase 2B portion of the CD Phase 2 Clinical Trial, and any related Development activities set forth in the Clinical Development Plan.
- 1.94. “**Phase 2B Completion Date**” means the date of database lock for the CD Phase 2 Clinical Trial after the last patient in such Clinical Trial completes the last visit as described in the protocol for such Clinical Trial.
- 1.95. “**Phase 3 Clinical Trial**” means, in reference to a clinical trial of a Licensed Product, (a) a trial that would satisfy the requirements for a Phase 3 study as defined in 21 C.F.R. § 312.21(c) or (b) a Phase 3 study as defined in the ICH E8 Guideline (or, in either case, any amended or successor regulation or guideline). For purposes of Section 7.3.3, a Phase 2/3 Clinical Trial shall be deemed to be a Phase 3 Clinical Trial upon the date that such Phase 2/3 Clinical Trial first satisfies the criteria set forth in clause (b) of Section 1.90.
- 1.96. “**Protagonist-Controlled Patent Rights**” means (a) the Retained Patent Rights and (b) any Protagonist Patent Rights that Cover Protagonist Platform Know-How and do not Cover a Licensed Compound or Licensed Product.
- 1.97. “**Protagonist IL23 Receptor Inhibitor Patent Rights**” means the Patent Rights listed in Schedule 1.97, and any Patent Rights that are counterparts to or that have a valid priority claim to any of the patents and applications listed in Schedule 1.97, excluding the Retained Patent Rights.
- 1.98. “**Protagonist Intellectual Property**” means Protagonist Know-How and Protagonist Patent Rights, collectively.
- 1.99. “**Protagonist Know-How**” means any Know-How used in or otherwise relating to a Licensed Compound or Licensed Product or the Development, Manufacture and Commercialization of a Licensed Compound or Licensed Product that either (a) is Controlled by Protagonist or any of its Affiliates on the Execution Date or (b) comes into the Control of Protagonist or any of its Affiliates during the Term. For clarity, Protagonist Know-How shall include the Protagonist Collaboration Know-How, but excludes Know-How that relates solely to any Retained Compounds.
- 1.100. “**Protagonist Platform Know-How**” means any Know-How owned by or licensed to Protagonist that primarily relates to Protagonist’s core peptide technology platform which comprises the following: molecular design tools and structure of peptide scaffolds, computational screening and rank ordering of scaffolds, virtual libraries of constrained scaffolds and peptides, collectively known as Vectrix, random libraries and phage-display techniques, medicinal chemistry know-how, peptide and peptidomimetic chemistry know-how, oral stability assays and know-how, formulation know-how, and in vivo pharmacology tools, techniques and know-how pertaining to peptide oral stability, transport, and GI-restriction.
- 1.101. “**Protagonist Patent Right**” means (a) the Protagonist IL23 Receptor Inhibitor Patent Rights; (b) the Protagonist Collaboration Patent Rights; (c) Protagonist’s and its Affiliates’ interests in the Joint Collaboration Patent Rights; and (d) any Patent Right other than those

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described in clauses (a) through (c) that: (i) either (A) is Controlled by Protagonist or any of its Affiliates on the Execution Date or (B) comes into the Control of Protagonist or any of its Affiliates during the Term; and (ii) Covers any Licensed Compound, Licensed Product or Protagonist Know-How.

1.102. “**Public Health Service Act**” means the U.S. Public Health Service Act (42 U.S.C. §201 et seq.), as amended from time to time, and any regulations promulgated thereunder.

1.103. “**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 Licensed Compound or Licensed Product in any country or jurisdiction in the Territory for one or more uses.

1.104. “**Regulatory Authority**” means any Governmental Authority with authority over the Development, marketing and sale of a pharmaceutical or biologic product in a country, such as the FDA in the United States or EMA in the EU. Regulatory Authority also includes any non-governmental group licensed by an entity described in the preceding sentence to perform inspections, audits and/or reviews.

1.105. “**Regulatory Documentation**” means: (a) all applications for Regulatory Approval (including Drug Approval Applications); (b) all Regulatory Approvals, including INDs, CTAs 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)).

1.106. “**Regulatory Exclusivity Period**” means, with respect to a Licensed Product and a 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. If 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.

1.107. “**Relevant Factors**” means all relevant scientific, technical, operational, commercial, economic and other factors that may affect the Development, Marketing Approval, Manufacturing or Commercialization of a product, including (as applicable): [*].

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1.108. “**Retained Compound**” means any peptide that is disclosed by any Protagonist IL23 Receptor Inhibitor Patent Rights and that:

- (a) has an IC50 value of greater than [*] nanomolar (i.e., [*]), as determined in the [*] described in Exhibit C; and
- (b) has an affinity for IL23R greater than [*]pM (i.e., [*]), as determined in the [*] described in Exhibit C.

1.109. “**Royalty Term**” means, with respect to a Licensed Product and a 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 Protagonist Patent Right that Covers the composition of matter of such Licensed Product in such country; or (c) the expiration or termination of the Regulatory Exclusivity Period with respect to such Licensed Product in such country.

1.110. “**Tax**” or “**Taxes**” means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any penalties or interest thereon).

1.111. “**Territory**” means worldwide.

1.112. “**Third Party**” means any Person other than a Party or any of its Affiliates.

1.113. “**Third Party Blocking Intellectual Property Rights**” means intellectual property rights of a Third Party that Cover the manufacture, use or sale of, or are necessary to manufacture, use or sell, a Licensed Compound or a Licensed Product.

1.114. “**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.

1.115. “**UC**” means treatment of ulcerative colitis.

1.116. “**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 Governmental Authority of competent jurisdiction from which no appeal can be taken, or a decision of a Governmental Authority 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; *provided* that if such claim is later issued, it shall from the issuance date forward be deemed to be a Valid Claim.

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

Defined Term	Section
Agreement	Preamble
Alliance Manager	2.1.5
Anti-Corruption Laws	10.5.4
Anti-Kickback Laws	10.5.2(a)
Audited Site	3.6.1(i)
Bankruptcy Code	12.4.2(a)
BLA	1.35
Breaching Party	12.3.1
CAPA	3.6.1(g)
Clinical Supply Agreement	3.5.2
Co-Detailing Agreement	5.6.2(e)
Co-Detailing Option	5.6.2(b)
Co-Detailing Option Exercise Notice	5.6.2(c)
Collaboration Patent Right	8.2.1
Collaboration Records	3.6.3(a)
Competing Product	6.7.2(a)
Conducting Party	3.6.1(a)
CPR Mediation Procedure	13.2.1
Cost Records	7.7.1
CPR Rules	13.3.1
CREATE Act	8.3.7
Cure Period	12.3.1
Deadlocked Matter	2.1.4(c)(2)
Detail	5.6.2(a)(1)
Disclosing Party	9.1.1
Dispute	13.1
Execution Date	Preamble
Existing Protagonist Know-How	10.3.4
Existing Protagonist License Agreement	10.3.2
Existing Protagonist Patents	10.3.1
First Opt-In Election	4.1.2
First Opt-In Election Notice	4.1.2
First Opt-In Period	4.1.2
Fundamental Development Plan Change	2.1.4(c)(2)
IBD Indication	6.7.2(b)
Incumbent Board	1.11
Indemnified Party	11.2
Indemnifying Party	11.2
Initial Co-Detailing Plan	5.6.2(d)
Initial Compound	1.62
Insolvency Event	12.4.1

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IRB	3.6.1(c)
Janssen	Preamble
Janssen Collaboration Know-How	8.2.2
Janssen Collaboration Patent Right	8.2.1(a)
Janssen Indemnified Party	11.1.2
Joint Collaboration Patent Right	8.2.1(c)
JMC	2.1.2(a)
JSC	2.1.1(a)
Losses	11.1.1
Manufacturing Party	3.6.1(h)
MHRA	7.3.1
Milestone Event	7.3
Milestone Payment	7.3
NDA	1.35
Opt-In Exercise Fee	4.2.3(a)
Opt-In Maintenance Fee	4.1.3(a)
Party/Parties	Preamble
Patent Representative	8.1
Patent Term Restoration	8.6
Permitted Subcontract	3.6.2(c)
Phase 1 Data Package	3.3.2
Phase 2 CMC Development Budget	3.2.1(b)
Phase 2 Development Budget	3.2.1(a)
Phase 2 Data Package	4.2.1
Phase 2A Results	4.1.1
Primary Call	5.6.2(a)(2)
Protagonist	Preamble
Protagonist Collaboration Know-How	8.2.2
Protagonist Collaboration Patent Right	8.2.1(b)
Protagonist Indemnified Party	11.1.1
Receiving Party	9.1.1
Restricted Change of Control	5.6.2(a)(3)
Retained Patent Rights	8.3.5(a)
Royalty Records	7.7.1
Sales Milestone Event	7.4
Sales Milestone Payment	7.4
Second Opt-In Election	4.2.2
Second Opt-In Election Notice	4.2.2
Second Opt-In Period	4.2.2
Secondary Call	5.6.2(a)(4)
Segregate	6.7.2(c)
Specified Percentage	7.2.1
Subcommittee	2.1.2(b)
Subcontracting Party	3.6.2(b)
Term	12.1

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Terminating Party	12.3.1
Third Party Claim	11.1.1
Third Party Subcontractor	3.6.2(b)

Article 2
GOVERNANCE

2.1. **Joint Steering Committee.**

2.1.1. **Formation, Composition and Term of JSC.**

- (a) Within [*] after the Effective Date, the Parties will establish a joint steering committee (the “**JSC**”) to oversee and coordinate the Parties’ activities during the Development Term and, following the Opt-In Effective Date (except as described in Section 2.1.4(c)(4)), to serve solely as an information-sharing body in accordance with Section 5.3.2.
- (b) The JSC initially shall be composed of [*] members, [*] of whom shall be representatives appointed by Protagonist and [*] of whom shall be representatives appointed by Janssen, each with the requisite experience and seniority to enable such representative to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JSC. Neither Party shall appoint any representative to the JSC that is not an employee of such Party or one of its Affiliates without the prior written consent of the other Party, which consent shall not be unreasonably withheld. Each Party shall appoint one (1) of its representatives as co-chairperson of the JSC. The size of the JSC may be changed from time to time by written agreement of the Parties, *provided* that the JSC shall at all times include an equal number of representatives of each Party. Each Party may replace its JSC representatives at any time upon written notice to the other Party.
- (c) After the Development Term, the JSC shall have no oversight or decision-making authority and shall serve solely as an information-sharing body in accordance with Section 5.3.2. The JSC shall automatically dissolve when Janssen has no further reporting obligations under Section 5.3.2 (or such later time as agreed by the Parties).

2.1.2. **Subcommittees.**

- (a) The Parties shall establish a Joint Manufacturing Committee (“**JMC**”) promptly after establishing the JSC. The purpose of the JMC will be to oversee and coordinate the Parties’ performance of the Collaboration CMC Activities during the Development Term, to share information and facilitate the performance and execution of such activities, and to review and discuss potential changes to the CMC Development Plan and to Third Party manufacturers of clinical supplies for the Phase 1 Activities and Phase 2 Activities.

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(b) The JSC may, as necessary or appropriate and agreed to by the JSC, establish other subcommittees and delegate tasks within its authority as expressly provided for hereunder to such subcommittees (the JMC and each other subcommittee, a “**Subcommittee**”). Each Subcommittee shall operate in the same manner as the JSC, as described in Section 2.1.4, *provided* that no Subcommittee shall have any decision-making authority, but shall instead make recommendations to the JSC with respect to such matters within its authority.

(c) All Subcommittees shall automatically dissolve upon the end of the Development Term (or such later time as agreed by the Parties).

2.1.3. **Responsibilities of the JSC During Development Term.** The JSC shall oversee the Collaboration Activities during the Development Term. In particular, the JSC shall:

(a) review and approve proposed amendments to the Clinical Development Plan (including the Phase 2 Development Budget) and CMC Development Plan (including the Phase 2 CMC Development Budget) in accordance with Section 3.2.2;

(b) review and discuss the results of the Collaboration Activities;

(c) decide matters presented to it by any Subcommittee, in each case, that is within the scope of responsibilities delegated to the respective Subcommittee under this Agreement or by the JSC; and

(d) perform such other functions as expressly set forth in this Agreement or as mutually agreed upon by the Parties in writing.

2.1.4. **JSC Operations.**

(a) *Meetings.* During the Development Term, the JSC shall hold meetings at least [*] or as often as its members may determine. Thereafter, the JSC shall hold meetings at least [*]. JSC meetings may be held in person or by any means of telecommunications as the members deem necessary or appropriate, including telephone, video conference or similar means in which each participant can hear what is said, and be heard, by the other participants, *provided* that, unless otherwise agreed by the Parties the location of any in-person meetings shall alternate between a location chosen by Protagonist and a location chosen by Janssen. A quorum of the JSC shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. Employees or consultants of either Party who are performing Collaboration Activities or other Development or Manufacturing activities hereunder but are not members of JSC may attend meetings of the JSC relating to such activities, *provided* that (i) such attendees shall not vote or otherwise participate in the decision-making process of the JSC, (ii) such attendees shall be bound in writing by obligations of confidentiality and non-use equivalent to those set forth in Article 9 and (iii) a consultant of a Party

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may attend a meeting only with prior notice to and consent of the other Party, which shall not be unreasonably withheld. Except as provided in the prior sentence, individuals who are not members of the JSC may not attend a meeting of the JSC without the prior consent of both Parties, except that each Party's Alliance Manager may attend without such consent. Each Party shall be responsible for its own expenses of participating in the JSC and in any Subcommittee.

(b) *Agenda and Minutes.* Each Party shall have the right to propose agenda items and shall provide all appropriate information with respect to such proposed agenda items in advance of each JSC meeting. Each co-chairperson of the JSC, on an alternating basis, shall prepare and circulate to all members of the JSC for review draft minutes of each JSC meeting within thirty (30) days after such meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the JSC, *provided* that, if the Parties cannot agree as to the content of the minutes by the time of the next JSC meeting, such minutes shall be finalized to reflect any areas of disagreement. The minutes of each meeting of the JSC shall be Collaboration Information.

(c) *Decision-Making.*

(1) The JSC shall make decisions and take action (A) by consensus of the members present at a meeting at which a quorum exists, with each Party ensuring that its representatives make such decisions in good faith, and having a single vote irrespective of the number of representatives of such Party in attendance, or (B) by a written resolution signed by at least both co-chairpersons appointed by each Party.

(2) If the JSC does not reach consensus on any matter within its authority (a "**Deadlocked Matter**") within a period of [*] (or such other period as the Parties may agree in writing) after it has met and attempted to reach such consensus, then either Party may, by written notice to the other Party, refer the Deadlocked Matter to the Executive Officers; *provided, however*, that, if the Executive Officers do not reach agreement on such Deadlocked Matter within [*] after such Deadlocked Matter is referred to the Executive Officers, then, subject to Sections 2.1.4(c)(3) and 2.1.4(c)(4):

(i) Protagonist shall have the final decision-making right with respect to any Deadlocked Matter to the extent it relates to Phase 1 Activities or to Collaboration CMC Activities for the Phase 1 Activities, which decision shall be final and binding on the Parties;

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- (ii) During the period prior to the date when the JSC determines pursuant to Section 3.3.3 (or Protagonist determines pursuant to 2.1.4(c)(2)(iii) below) that the results from the Phase 1 Activities support continuation of preparation and conduct of the CD Phase 2 Clinical Trial, Protagonist shall have the final decision-making right with respect to any Deadlocked Matter to the extent it relates to Phase 2 Activities (but not Collaboration CMC Activities for the Phase 2 Activities), which decision shall be final and binding on the Parties; *provided, however*, that Protagonist may not exercise its final decision-making authority under this Section 2.1.4(c)(2)(ii) to make any Fundamental Development Plan Change or to approve or amend the Phase 2 Development Budget without Janssen's consent, which shall not be unreasonably withheld, delayed or conditioned;
- (iii) Protagonist shall have the final decision-making right with respect to any Deadlocked Matter to the extent it relates to whether the results from the Phase 1 Activities support continuation of preparation and conduct of the CD Phase 2 Clinical Trial, which decision shall be final and binding on the Parties; *provided, however*, that Protagonist may not exercise its final decision-making authority under this Section 2.1.4(c)(2)(iii) to make any Fundamental Development Plan Change or to approve or amend the Phase 2 Development Budget without Janssen's consent, which shall not be unreasonably withheld, conditioned or delayed;
- (iv) Janssen shall have the final decision-making right with respect to any Deadlocked Matter to the extent it relates to Collaboration CMC Activities for any Phase 3 Clinical Trial, which decision shall be final and binding on the Parties except that Janssen may not exercise its final decision-making authority under this Section 2.1.4(c)(2)(iv) to assign to Protagonist

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any such Collaboration CMC Activities that are not already assigned to Protagonist under the then-current CMC Development Plan having last been approved by both Parties, without Protagonist's consent; and

- (v) Neither Party shall have the final decision-making right with respect to any Deadlocked Matter which is other than as described in Sections 2.1.4(c)(2)(i) through (iv), including for example and without limitation, whether to effect any Fundamental Development Plan Change, and in such event the matter shall remain deadlocked and the status quo shall persist unless and until the Parties reach agreement on such matter; *provided, however*, that, to the extent the Deadlocked Matter is with respect to a Fundamental Development Plan Change, the Parties shall proceed under the then-current Clinical Development Plan (including the then-current Phase 2 Development Budget) having last been approved by both Parties.

For purposes of this Section, "**Fundamental Development Plan Change**" means any of the following changes with respect to then-current Clinical Development Plan having last been approved by both Parties: (i) [*], (ii) a change to [*] any Phase 2 Clinical Trial, (iii) a change to [*] any Phase 2 Clinical Trial, (iv) any material change to [*] any Phase 2 Clinical Trial, (v) any material change to [*] any Phase 2 Clinical Trial, and (vi) removal or modification of any Phase 2 Clinical Trial [*].

(3) Neither Party may exercise its final decision-making authority under Section 2.1.4(c)(2) with respect to a Deadlocked Matter to: (i) require or cause the other Party to take any action in violation of Applicable Law or that, in such other Party's reasonable determination, is a risk to patients or clinical trial subjects or is otherwise contrary to GCP and ethics or such other Party's compliance policies; or (ii) require or cause the other Party to bear any costs other than those set forth in then-current Phase 2 Development Budget or to commit additional employee resources to conduct Collaboration Activities.

(4) If the Opt-In Effective Date occurs before the end of the Development Term, then on and after the Opt-In Effective Date: (A) Protagonist will no longer have final decision-making authority with

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respect to Deadlocked Matters under Section 2.1.4(c)(2) or Section 3.8.1, and (B) any Deadlocked Matter shall remain deadlocked and the status quo shall persist unless and until the Parties reach agreement on such matter.

(d) *Authority.* The JSC shall have only such powers as are specifically delegated to it hereunder, and for clarity the JSC shall not have any authority or ability to: (i) resolve or conclude any disputes regarding a Party's performance or non-performance of its obligations under this Agreement; (ii) modify, amend or waive the terms or conditions of this Agreement; (iii) bind either Party to act or refrain from acting in any manner; or (iv) make any decision that, under the terms of this Agreement, requires Protagonist's or Janssen's consent, approval or agreement or the consent, approval or agreement of both Parties.

2.1.5. **Alliance Managers.** Each Party shall designate a single alliance manager for all of the Development Term activities contemplated under this Agreement ("**Alliance Manager**"). Such Alliance Managers will be responsible for the day-to-day worldwide coordination of the collaboration contemplated by this Agreement and will serve to facilitate communication between the Parties. Such Alliance Managers shall have experience and knowledge appropriate for managers with such project management responsibilities. Each Party may change its designated Alliance Manager from time to time upon notice to the other Party.

2.1.6. **Discontinuation of the JSC.** The activities to be performed by the JSC and its Subcommittees shall solely relate to governance under this Agreement, and are not intended to be or involve the delivery of services. The JSC and each Subcommittee shall continue to exist as provided in Section 2.1.1(c) or Section 2.1.2(c), as applicable, unless before such time the Parties mutually agree to disband such committee or Protagonist provides written notice to Janssen of its intention to disband and no longer participate in such committee. Once the Parties mutually agree or Protagonist has provided written notice to disband a committee, such committee shall have no further obligations under this Agreement and, thereafter, each Party shall designate a contact person for the exchange of information under this Agreement or such exchange of information shall be made through the Alliance Managers. In the event a committee is disbanded as provided in this Section 2.1.6, any decisions that are designated under this Agreement as being subject to the review or approval of such committee shall be made by mutual agreement of the Parties directly (other than any matter that was subject to the final decision-making authority of Janssen under Section 2.1.4(c)(2)(iv), which shall thereafter be made by Janssen directly), subject to the other terms and conditions of this Agreement.

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Article 3
ACTIVITIES DURING DEVELOPMENT TERM

3.1. **General.** During the Development Term, the Parties shall conduct the Collaboration Activities in accordance with this Article 3.

3.2. **Clinical Development Plan; CMC Development Plan.**

3.2.1. **Contents.**

(a) The Clinical Development Plan shall contain all Development activities (other than CMC Development activities) necessary to complete Development of the Initial Product for CD through the end of Phase 2. The Clinical Development Plan shall include a reasonably detailed description of such activities, a timeline for completion of such activities and the deliverables for such activities. The Clinical Development Plan shall include a budget for the Phase 2 Activities broken down by activity and by Calendar Year (the "**Phase 2 Development Budget**"). The initial Phase 2 Development Budget shall be approved by the JSC and shall be consistent with the Summary of the Phase 2 Clinical and CMC Development Budget attached hereto as Exhibit D. The JSC shall review and update the Phase 2 Development Budget in accordance with Section 3.2.2 not less frequently than [*] for the subsequent Calendar Year prior to [*] of the current year, until the completion of the Phase 2 Activities hereunder.

(b) The CMC Development Plan shall at all times contain the following CMC Development and Manufacturing activities with respect to the Initial Compound and Initial Product:

- (1) Compound API production and release testing for the conduct of the Phase 1 Activities, Phase 2A Activities and Phase 2B Activities, API stability, API optimization studies, and for formulation development studies for Phase 1, Phase 2A, Phase 2B and Phase 3 use;
- (2) Compound API solution phase synthesis process development;
- (3) Drug Product capsule development, production, and release testing, packaging and labeling for the Phase 1 Activities and Phase 2A Activities;
- (4) Drug Product tablet development for the Phase 2B Activities and/or Phase 3 Clinical Trials; and
- (5) Drug Product tablet production, and release testing, packaging and labeling, for the Phase 2B Activities.

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The CMC Development Plan may also include other CMC Development activities with respect to the Licensed Compounds and Licensed Products mutually agreed upon by the Parties. The CMC Development Plan shall include a reasonably detailed description of the activities set forth therein, a timeline for completion of such activities and the deliverables for such activities. The CMC Development Plan shall include a budget for the Collaboration CMC Activities for the Phase 2 Activities, broken down by activity and by Calendar Year (the “Phase 2 CMC Development Budget”). The initial Phase 2 CMC Development Budget shall be approved by the JSC and shall be consistent with the Summary of the Phase 2 Clinical and CMC Development Budget attached hereto as Exhibit D.

3.2.2. **Amendments.** From time to time during the Development Term, either Party may submit proposed amendments to the Clinical Development Plan to the JSC for review and approval, and either Party or the JMC may submit proposed amendments to the CMC Development Plan to the JSC for review and approval. The JSC shall consider each such proposed amendment at its next scheduled meeting. If the JSC approves such proposed amendment in accordance with Section 2.1.4(c), the Clinical Development Plan or CMC Development Plan, as applicable, shall be deemed amended to reflect such amendment and such amended Clinical Development Plan or CMC Development Plan, as applicable, shall become effective and supersede the previous Clinical Development Plan or CMC Development Plan, as applicable, as of the date of such approval. If the JSC does not approve such proposed amendment, such matter shall be subject to escalation as described in Section 2.1.4(c).

3.2.3. **Regulatory Matters during the Development Term.**

(a) Following the Effective Date, Protagonist shall prepare and submit to the appropriate Regulatory Authorities the INDs and CTAs necessary to conduct the Phase 1 Activities. Protagonist shall take all actions reasonably necessary to maintain such INDs and CTAs during the conduct of the Phase 1 Activities. Protagonist shall be responsible for all regulatory responsibilities relating to Licensed Compounds and Licensed Products during the conduct of the Phase 1 Activities as required by Applicable Laws, including safety reporting obligations to Regulatory Authorities, ethics committees and investigators, submission of the final clinical study report to a Regulatory Authority, and all other reporting and publication requirements under Applicable Law. Protagonist shall have the sole responsibility for, and sole authority with respect to, communications with any Regulatory Authority regarding Licensed Compounds and Licensed Products during the conduct of the Phase 1 Activities, *provided* that Janssen shall have the right to participate as a silent observer in all material meetings, conferences and discussions between Protagonist and any Regulatory Authorities pertaining to Licensed Compounds and Licensed Products, unless the Parties have agreed otherwise in advance of such meeting, conference or discussion. Protagonist shall provide Janssen with reasonable advance notice of all such meetings, conferences and discussions and advance copies of all related documents and other relevant

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information relating to such meetings, conferences and discussions. Protagonist shall provide Janssen with copies of any material Regulatory Documentation with respect to the Licensed Compounds and Licensed Products that Protagonist submits to any Regulatory Authority during the conduct of the Phase 1 Activities. In addition, in the event that Protagonist is notified of any material regulatory or other inquiries that relate to a Licensed Compound or Licensed Product during the conduct of the Phase 1 Activities, Protagonist shall promptly notify Janssen of such inquiries.

(b) Following the Phase 1 Completion Date, if the JSC determines pursuant to Section 3.3.3 (or Protagonist determines pursuant to Section 2.1.4(c)(2)(iii)) that the results from the Phase 1 Activities support continuation of preparation and conduct of the CD Phase 2 Clinical Trial and related Phase 2 Activities, Janssen shall prepare and file the INDs and CTAs for the CD Phase 2 Clinical Trial in accordance with Section 3.4.1. Janssen shall take all actions reasonably necessary to maintain such INDs and CTAs during the conduct of the Phase 2 Activities. Janssen shall be responsible for all regulatory responsibilities relating to Licensed Compounds and Licensed Products during the conduct of the Phase 2 Activities as required by Applicable Laws, including safety reporting obligations to Regulatory Authorities, ethics committees and investigators, submission of the final clinical study report to a Regulatory Authority, and all other reporting and publication requirements under Applicable Law. Janssen shall have the primary responsibility for, and primary authority with respect to, communications with any Regulatory Authority regarding Licensed Compounds and Licensed Products during the conduct of the Phase 2 Activities, *provided* that Protagonist shall have the right to fully participate in all material meetings, conferences and discussions between Janssen and any Regulatory Authorities pertaining to Licensed Compounds and Licensed Products. Janssen shall provide Protagonist with reasonable advance notice of all such meetings, conferences and discussions and advance copies of all related documents and other relevant information relating to such meetings, conferences and discussions. Janssen shall provide Protagonist with advance drafts of any material Regulatory Documentation with respect to the Licensed Compounds and Licensed Products that Janssen plans to submit to any Regulatory Authority during the conduct of the Phase 2 Activities. Protagonist may provide comments regarding such Regulatory Documentation prior to their submission, and Janssen shall incorporate such comments prior to submission to any Regulatory Authority. Notices and other materials to be given in advance pursuant to this Section shall be provided at least [*] in advance unless circumstances necessitate a short time period. In addition, in the event that either Party is notified of any material regulatory or other inquiries that relate to a Licensed Compound or Licensed Product during the conduct of the Phase 2 Activities, such Party shall promptly notify the other Party of such inquiries.

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3.3. **Phase 1 Activities.**

3.3.1. **Responsibility; Diligence.**

(a) Protagonist shall be solely responsible for conducting the Phase 1 Activities at its sole cost and expense. Protagonist shall use Diligent Efforts to conduct and complete the Phase 1 Activities in accordance with the Clinical Development Plan (including the timeline set forth therein). Protagonist shall have day-to-day operational control over the conduct of the Phase 1 Activities.

(b) Protagonist shall perform the Phase 1 Activities in accordance with the terms and conditions of this Agreement, in good scientific manner and in compliance with Applicable Law, including, as applicable, those relating to GLP, GCP, GMP, pharmacovigilance and safety reporting, and requirements for the protection of human subjects.

3.3.2. **Delivery of Data Package.** Following the Phase 1 Completion Date, Protagonist shall prepare and deliver to Janssen a data package with respect to the Phase 1 Activities that contains: (a) [*] from the Phase 1 Activities; (b) all [*] with respect to the Data relating to the Licensed Compounds and Licensed Products generated by or on behalf of Protagonist pursuant to the conduct of the Phase 1 Activities; and (c) the other documents and information described on Schedule 3.3.2 (the “**Phase 1 Data Package**”).

3.3.3. **Evaluation of Data Package; Decision to Proceed to Phase 2 Activities.** Following Janssen’s receipt of a complete Phase 1 Data Package pursuant to Section 3.3.2, the JSC shall meet to discuss such Phase 1 Data Package and determine whether the results from the Phase 1 Activities support continuation of preparation and conduct of the CD Phase 2 Clinical Trial and related Phase 2 Activities. If Janssen or Protagonist has reasonably determined that there is a Material Safety Issue with respect to the results of the Phase 1 Activities, Janssen or Protagonist shall describe such safety issue in detail during such JSC meeting. The JSC shall also discuss whether any amendments to the Phase 2 Activities in the Clinical Development Plan should be made due to the results from the Phase 1 Activities and/or to address Material Safety Issues raised by either Party, and any such amendments shall be approved by the JSC in accordance with Section 3.2.2.

3.3.4. **Clinical Study Report.** Protagonist shall use Diligent Efforts to complete the clinical study report for the Phase 1 Clinical Trial of the Initial Product set forth in the Clinical Development Plan as promptly as is practicable following the delivery of the Phase 1 Data Package, and shall deliver such clinical study report to Janssen promptly following its completion (and, in any event, no later than [*] after the Phase 1 Completion Date).

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3.4. **Phase 2 Activities.**

3.4.1. **Commencement of Phase 2 Activities.**

(a) If, following delivery of the Phase 1 Data Package, the JSC determines pursuant to Section 3.3.3 (or Protagonist determines pursuant to Section 2.1.4(c)(2)(iii)) that the results from the Phase 1 Activities support continuation of preparation and conduct of the CD Phase 2 Clinical Trial and related Phase 2 Activities, Protagonist shall use Diligent Efforts to provide to Janssen all data and information relating to the Initial Compound and Initial Product necessary to prepare the INDs and CTAs for the CD Phase 2 Clinical Trial as soon as practicable after such JSC determination. Janssen shall use Diligent Efforts to prepare and submit such INDs and CTAs to the applicable Regulatory Authorities as soon as practicable after Protagonist provides such necessary data and information. The Parties will use Diligent Efforts to complete such activities within [*] after the date on which the JSC (or Protagonist, as the case may be) makes such determination, and in any event Janssen shall file the Phase 2 IND within [*] of the Phase 1 Completion Date, it being understood that any delay in Protagonist's delivery to Janssen of the necessary data and information as required above will result in a day for day increase to such time period.

(b) Janssen shall use Diligent Efforts to initiate study site recruitment for the CD Phase 2 Clinical Trial within [*] after submission of the Phase 2 IND and thereafter shall use Diligent Efforts to continue such recruitment and conduct and complete such trial in accordance with the Clinical Development Plan, subject to Section 3.8. Notwithstanding the foregoing, if a Regulatory Authority requests or requires any changes to the Phase 2 Activities following submission of an IND or CTA in accordance with Section 3.4.1 (a), (i) the JSC shall develop and approve an amendment to the Clinical Development Plan to address such request or requirement in accordance with Section 3.2.2 and (ii) Janssen shall have no obligation to commence the CD Phase 2 Clinical Trial until the JSC approves such amendment.

3.4.2. **Technology Transfer.** Promptly following the date on which the JSC (or Protagonist) determines pursuant to Section 3.3.3 that the results from the Phase 1 Activities support continuation of preparation and conduct of the CD Phase 2 Clinical Trial and related Phase 2 Activities, Protagonist shall transfer or make available to Janssen copies of (i) all Protagonist Know-How that is necessary and (ii) all Protagonist Know-How (other than Protagonist Platform Know-How or Know-How that originates from any other Protagonist programs that are not targeting the IL23 receptor) that is specifically useful, for Janssen to conduct the Phase 2 Activities, to the extent not previously provided under this Agreement. In addition, upon Janssen's reasonable request, Protagonist shall promptly provide to Janssen (a) complete sets of any preclinical or clinical data generated by or on behalf of Protagonist with respect to any Licensed Compound or Licensed Product (including any such data generated by or on behalf of Protagonist pursuant to the conduct of the Phase 1 Activities) and (b) raw data tables with respect to the data described in clause (a), in each case ((a) and (b)), to the extent that such information was not previously provided by Protagonist to Janssen.

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3.4.3. **Responsibility; Diligence.**

- (a) Janssen shall be solely responsible for conducting the Phase 2 Activities. The costs and expenses of the Phase 2 Activities shall be shared by the Parties in accordance with Section 7.2. Janssen shall use Diligent Efforts to conduct and complete the Phase 2 Activities in accordance with the Clinical Development Plan (including the timeline set forth therein). Janssen shall have day-to-day operational control over the conduct of the Phase 2 Activities.
- (b) Janssen shall perform the Phase 2 Activities in accordance with the terms and conditions of this Agreement, in good scientific manner and in compliance with Applicable Law, including, as applicable, those relating to GLP, GCP, GMP, pharmacovigilance and safety reporting, and requirements for the protection of human subjects.

3.4.4. **Janssen Opt-In following Completion of the Phase 2A Activities.** Following the Phase 2A Completion Date, Janssen shall conduct an interim analysis of the Phase 2A Results in accordance with the Clinical Development Plan and determine whether to make the First Opt-In Election in accordance with Section 4.1. If Janssen makes the First Opt-In Election in accordance with Section 4.1.2, this Agreement shall continue in full force and effect as further described in Section 4.1.3. If Janssen does not make the First Opt-In Election in accordance with Section 4.1.2, this Agreement shall terminate in accordance with Section 4.1.4. For clarity, Janssen shall continue to conduct the Phase 2 Activities in accordance with the Clinical Development Plan while Janssen performs such interim analysis and makes its determination with respect to the First Opt-In Election.

3.4.5. **Janssen Opt-In following Completion of the Phase 2B Activities.** Following the Phase 2B Completion Date, Janssen shall determine whether to make the Second Opt-In Election in accordance with Section 4.2. If Janssen makes the Second Opt-In Election in accordance with Section 4.2.2, then this Agreement shall continue in full force and effect as further described in Section 4.2.3. If Janssen does not make the Second Opt-In Election in accordance with Section 4.2.2, then this Agreement shall terminate in accordance with Section 4.2.4.

3.4.6. **Clinical Study Report.** Janssen shall use Diligent Efforts to complete the clinical study report for the CD Phase 2 Clinical Trial as promptly as is practicable following the delivery of the Phase 2 Data Package, and shall deliver such clinical study report to Protagonist promptly following its completion.

3.5. **Collaboration CMC Activities.**

3.5.1. **Responsibility.** Each Party shall be responsible for conducting the Collaboration CMC Activities allocated to it in the CMC Development Plan. Each Party shall perform the CMC Collaboration Activities in accordance with the terms and conditions of this Agreement, in good scientific manner and in compliance with Applicable Law, including those relating to GMP. The JMC shall oversee the conduct of the Collaboration CMC

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Activities, and all decisions regarding the CMC Development Plan shall be discussed and reviewed by the JMC and approved by the JSC.

3.5.2. **Clinical Supply Agreement.** If the CMC Development Plan allocates responsibility for Manufacture and supply of Compound API or Drug Product for any Phase 2 Activities to Protagonist, the Parties shall negotiate in good faith and attempt to agree within [*] after the Effective Date upon a supply agreement for such supplies by Protagonist to Janssen at cost with no markup (the “**Clinical Supply Agreement**”) and a related quality agreement.

3.5.3. **Diligence.** Each Party shall use Diligent Efforts to conduct and complete the Collaboration CMC Activities allocated to it in the CMC Development Plan in accordance with the CMC Development Plan (including the timelines set forth therein). Each Party shall have day-to-day operational control over the Collaboration CMC Activities allocated to it in the CMC Development Plan.

3.5.4. **Costs.** With respect to the costs and expenses of the Collaboration CMC Activities:

(a) Protagonist shall be responsible for one hundred percent (100%) of such costs and expenses incurred with respect to Collaboration CMC Activities for the Phase 1 Activities, and shall reimburse Janssen for any such costs and expenses incurred by Janssen or any of its Affiliates in accordance with Section 7.2;

(b) the Parties shall share the costs and expenses incurred with respect to Collaboration CMC Activities for the Phase 2 Activities in accordance with Section 7.2; and

(c) Janssen shall be responsible for one hundred percent (100%) of such costs and expenses incurred with respect to Collaboration CMC Activities for Phase 3 Clinical Trials of Licensed Products, and shall reimburse Protagonist for any such costs and expenses incurred by Protagonist or any of its Affiliates in accordance with Section 7.2.

3.5.5. **Technology Transfer.** Upon Janssen’s request, Protagonist shall, and shall cause its Third Party manufacturer(s) to (subject to the terms of any applicable agreement(s) with such Third Party manufacturer(s)), transfer existing Manufacturing processes for Compound API and Drug Product to Janssen (or its designee) and to provide reasonable technical assistance to Janssen (or its designee), to the extent reasonably necessary to enable Janssen to perform the Collaboration CMC Activities allocated to Janssen in the CMC Development Plan.

3.6. **Conduct of Activities during Development Term.** The following provisions of this Section 3.6 shall apply with respect to the conduct of the Collaboration Activities during the Development Term.

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3.6.1. **Development Compliance Matters.**

(a) *Sponsorship.* The Party responsible for conducting a Clinical Trial of a Licensed Product in accordance with this Article 3 (the “**Conducting Party**”) shall be the sponsor of such Clinical Trial.

(b) *Notifications.* The Conducting Party shall notify the other Party as soon as reasonably practicable in the event that the Conducting Party becomes aware of any of the following with respect to the applicable Clinical Trial:

- (1) changes proposed to be made by the Conducting Party and/or that may be required by any Regulatory Authority;
- (2) safety or technical issue;
- (3) expected or actual delay, or any issue that may reasonably be expected to give rise to a delay; or
- (4) other substantive issue.

Following receipt of notice of any such event, the Parties shall promptly meet to discuss the circumstance and the Conducting Party shall inform the other Party of its intended action plan to remedy (where possible) the issue and/or mitigate the delay risk to successful completion of the applicable Clinical Trial. In determining an action plan, the Conducting Party shall take the other Party’s comments into consideration in good faith.

(c) *IRB.* The Conducting Party 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. The Conducting Party shall modify the protocol or the informed consent without the prior written agreement of the IRB.

(d) *Informed Consent and Patient Authorization.* The Conducting Party 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 (or for sites outside of the United States, the foreign equivalent), which authorization shall contain such provisions as are necessary for the other Party to have access to patient data to the extent reasonably necessary to exercise its rights and fulfill its obligations hereunder.

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(e) *Clinical Study Registration and Results Reporting.* The Conducting Party shall be responsible for registering such Clinical Trial in the appropriate clinical study registry and reporting Clinical Trial results as may be required under Applicable Law.

(f) *Samples.* The Conducting Party shall accept, to the extent permitted by Applicable Law, responsibility for the retention of documentation and storage of samples of Licensed Products according to Applicable Law (provided, with respect to Janssen as the Conducting Party, the necessary documentation and samples have been transferred by Protagonist pursuant to this Agreement).

(g) *Audits.* With respect to any facility or site at which a Party conducts any Phase 1 Activities or Phase 2 Activities, and subject to the terms of any agreement between such Party and any applicable Third Party Subcontractor with respect to any facility or site of such Third Party Subcontractor, the other Party shall have the right, at its own expense, upon reasonable written notice to such Party, and during normal business hours, to inspect such site and facility of such Party or to accompany such Party to inspect any Third Party Subcontractor site and any records relating thereto [*], to verify such Party's compliance with Applicable Law in carrying out its obligations under this Agreement, including those relating to GLP, GCP, 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 Phase 1 Activities or Phase 2 Activities, the audited Party shall submit to the auditing Party proposed Corrective and Preventative Actions (“CAPA”) within [*] after the auditing Party provides notice of such non-compliance. The auditing Party shall have the right to review and comment on such CAPA, which comments the audited Party shall consider in good faith. The audited Party shall use Diligent Efforts to implement such CAPA promptly after review and comment by the auditing Party.

(h) *Manufacturing Site Audits.* In addition to its rights under Section 3.6.1(g), each Party shall have the right to conduct an audit of the manufacturing sites where any Collaboration CMC Activities for the Phase 1 Activities and Phase 2 Activities are conducted by the other Party (the “**Manufacturing Party**”) or its Third Party Subcontractors, and subject to the terms of any agreement between the Manufacturing Party and the applicable Third Party Subcontractors. The Manufacturing Party shall facilitate the accommodation of such request with its Third Party Subcontractors. Following the completion of any such audit, the auditing Party may request the remediation of deficiencies that are not in compliance with GMP and identified during such audit. In the case of any critical observation relating to any Collaboration CMC Activities that the Manufacturing Party or its Third Party Subcontractor cannot or do not remediate in a timely

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manner, the auditing Party shall have the right to require the use of a different manufacturer for such Collaboration CMC Activities.

(i) *Audits by Regulatory Authorities.* Each Party shall cooperate in good faith with respect to Regulatory Authority inspections of any site or facility where Collaboration Activities are conducted pursuant to this Agreement by or on behalf of such Party, whether such site or facility is such Party's, an Affiliate's, or a subcontractor's (each, an "**Audited Site**"). Such Party shall inform the other Party as promptly as practicable and in any event within [*] of receiving notice of such a Regulatory Authority audit and shall provide daily updates to the other Party 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 Collaboration Activities, the audited Party shall submit to the other Party proposed CAPA within [*] after the audited Party, its Affiliate, or its subcontractor receives notification of such non-compliance from the relevant Regulatory Authority. The other Party shall have the right to review and comment on such CAPA, which comments the audited Party shall consider in good faith. The audited Party shall use Diligent Efforts to implement such CAPA promptly after review and comment by the other Party.

3.6.2. **Subcontracting.**

(a) Each Party may subcontract the performance of any Collaboration Activities to any of its Affiliates or any Third Party with prior written notice to the other 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. Notwithstanding the foregoing, any Third Party Subcontractor to be used by the Conducting Party to perform any Collaboration CMC Activities for the Phase 1 Activities and Phase 2 Activities must be approved in advance by the other Party, which approval shall not be unreasonably withheld. An initial list of Protagonist's Third Party subcontractors as of the Effective Date is set forth in Schedule 3.6.2. Following the Effective Date, the JSC, upon recommendation of the JMC, may amend Schedule 3.6.2 to add or remove subcontractors.

(b) With respect to any Collaboration Activities to be subcontracted to a Third Party (a "**Third Party Subcontractor**") by Protagonist 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) each such contract 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

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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 Licensed Compounds or Licensed Products.

(c) A Subcontracting Party will notify the other Party of the engagement or retention of any Third Party Subcontractor to conduct any Collaboration 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 3.6.2.

3.6.3. **Records; Data Requirements.**

(a) 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 Collaboration Activities (the “**Collaboration 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 Collaboration Records shall reflect all work done and results achieved in connection with the Collaboration Activities. Each Party shall retain, and cause its Affiliates and Third Party Subcontractors to retain, the Collaboration Records for at least [*] from the completion of the Collaboration Activities or such longer period as may be required by Applicable Law.

(b) Each Party shall comply with Janssen’s data policies set forth on Exhibit E with regard to Collaboration Records.

3.6.4. **Reports.** During the Development Term:

(a) each Party shall provide updates on its progress with respect to the conduct of the Phase 1 Activities and Phase 2 Activities, and a summary of the data and results from such activities, at each meeting of the JSC;

(b) each Party shall provide updates on its progress with respect to the conduct of Collaboration CMC Activities, and a summary of the data and results from such activities, at each meeting of the JMC;

(c) in addition to any such reports made to the JSC or JMC, each Party shall make its employees and consultants available for an in-person or telephonic meeting with the other Party at least [*] to discuss its progress with respect to the conduct of the Collaboration Activities; and

(d) each Party shall provide the other Party with access to the data and results from the Collaboration Activities upon such other Party’s reasonable request.

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3.7. **No Branding Activities.** During the Development Term, neither Party shall use or file for protection of any Trademarks or trade names for a Licensed Product.

3.8. **Material Safety Issues.**

3.8.1. If, during the Development Term, either Party determines that there is a Material Safety Issue, such Party shall promptly notify the other Party and the JSC shall promptly meet to discuss such Material Safety Issue and to seek to approve an appropriate course of action to address such Material Safety Issue (which may include delaying, modifying, suspending or terminating one or more of the Collaboration Activities). During the pendency of such discussion, each Party may suspend or delay any Collaboration Activity allocated to it under the Clinical Development Plan or CMC Development Plan to the extent such activity is affected by such Material Safety Issue. If the JSC approves a course of action to address such Material Safety Issue, then the Parties shall thereafter take all actions necessary to implement such course of action. If the JSC does not approve a course of action to address such Material Safety Issue within [*] after becoming aware of such Material Safety Issue, then either Party may refer such matter to the Executive Officers for discussion and attempted resolution. If the Executive Officers approve a course of action to address such Material Safety Issue, then the Parties shall thereafter take all actions necessary to implement such course of action. If the Executive Officers do not approve a course of action to address such Material Safety Issue within [*] after the matter is referred to them, then, notwithstanding Section 2.1.4(c)(2), Protagonist shall have the final decision-making authority to determine the appropriate course of action to address such Material Safety Issue and Protagonist's decision shall be final and binding on the Parties, subject to the limitations set forth in Section 2.1.4(c)(3); *provided, however*, Protagonist may not exercise its final decision-making authority to require Janssen to commence or continue any Collaboration Activity if Janssen determines, in good faith, that such Collaboration Activity should not be commenced or continued due to such Material Safety Issue and in such instance Protagonist would have the right to authorize a clinical research organization to conduct the particular activity on behalf of Protagonist.

3.8.2. If (a) a Material Safety Issue arises after the commencement of the CD Phase 2 Clinical Trial pursuant to Section 3.4.1(b), (b) such Material Safety Issue is not resolved by the Parties after completing the process set forth in Section 3.8.1, (c) such Material Safety Issue has existed for more than [*] and (d) Janssen has not used Diligent Efforts to resolve such Material Safety Issue, and has not conducted any material Development activities pursuant to the Clinical Development Plan or CMC Development Plan, for more than [*], then Protagonist's obligations and restrictions under Section 6.7 shall expire on the first date that all conditions set forth in clauses (a) through (d) are satisfied and Section 6.7 shall be of no further force or effect after such date.

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Article 4
OPT-IN RIGHTS

4.1. First Opt-In.

4.1.1. **Delivery of Phase 2A Results.** Janssen shall deliver to Protagonist the top-line results from the Phase 2A Activities within [*] after they become available to Janssen, which results shall include the primary and second endpoint, as well as available safety and exposure data, from the interim analysis cohort (approximately [*]) (the “**Phase 2A Results**”).

4.1.2. **First Opt-In Election.** Janssen may, at its sole discretion, elect to maintain its rights under this Agreement through the expiration of the Second Opt-In Period by providing Protagonist with a written notice of such election (the “**First Opt-In Election Notice**”) at any time during the period beginning on the Effective Date and ending [*] after the Phase 2A Completion Date; *provided, however,* that if Janssen is stayed from making such election after the Phase 2A Completion Date by the filing of a petition by Protagonist under the Bankruptcy Code or otherwise, such period shall expire on the date that is [*] after the lifting or expiration of such stay (the “**First Opt-In Period**”). If Janssen provides a First Opt-In Election Notice on or prior to the expiration of the First Opt-In Period, Janssen shall be deemed to have made the “**First Opt-In Election**” on the date that the First Opt-In Election Notice is deemed given in accordance with Section 14.10.

4.1.3. **Effect of First Opt-In Election.** If Janssen makes the First Opt-In Election, then the provisions of this Section 4.1.3 shall apply.

(a) Protagonist shall invoice Janssen for, and Janssen shall pay to Protagonist within [*] after receipt of such invoice, a one-time, non-creditable, non-refundable fee equal to one hundred twenty-five million dollars (\$125,000,000) (the “**Opt-In Maintenance Fee**”); and

(b) this Agreement shall remain in full force and effect until the expiration of the Second Opt-In Period, unless earlier terminated in accordance with Article 12.

4.1.4. **Effect of Failure to Make the First Opt-In Election.**

(a) If Janssen does not provide a First Opt-In Election Notice on or prior to the expiration of the First Opt-In Period, then this Agreement shall terminate in its entirety upon the expiration of the First Opt-In Period without any further action on the part of either Party and Section 12.6 shall apply.

(b) If Janssen provides a First Opt-In Election Notice on or prior to the expiration of the First Opt-In Period but does not pay the Opt-In Maintenance Fee within [*] after receipt of an invoice from Protagonist pursuant to Section 4.1.3(a), then this Agreement shall terminate upon the day immediately after the

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last day of such [*] period without any further action on the part of either Party and Section 12.6 shall apply.

4.2. **Second Opt-In.**

4.2.1. **Delivery of Phase 2 Data Package.** As soon as possible following the Phase 2B Completion Date, but no later than [*] after such date, Janssen shall deliver to Protagonist a data package with respect to the Phase 2 Activities that contains: (a) a high-level summary of the available results from the Phase 2 Activities; and (b) all available safety and efficacy analyses conducted with respect to the Data relating to the Licensed Compounds and Licensed Products generated by or on behalf of Janssen in the course of performing the Phase 2 Activities (the “**Phase 2 Data Package**”).

4.2.2. **Second Opt-In Election.** Janssen may, at its sole discretion, elect to maintain its rights under this Agreement beyond the Second Opt-In Period by providing Protagonist with a written notice of such election (the “**Second Opt-In Election Notice**”) at any time during the period beginning on the date on which it timely pays the Opt-In Maintenance Fee and ending [*] after the Phase 2B Completion Date; *provided, however*, that if Janssen is stayed from making such election after the Phase 2B Completion Date by the filing of a petition by Protagonist under the Bankruptcy Code or otherwise, such period shall expire on the date that is [*] after the lifting or expiration of such stay (the “**Second Opt-In Period**”). If Janssen provides a Second Opt-In Election Notice on or prior to the expiration of the Second Opt-In Period, Janssen shall be deemed to have made the “**Second Opt-In Election**” on the date that the Second Opt-In Election Notice is deemed given in accordance with Section 14.10.

4.2.3. **Effect of Second Opt-In Election.** If Janssen makes the Second Opt-In Election, then the provisions of this Section 4.2.3 shall apply.

- (a) Protagonist shall invoice Janssen for, and Janssen shall pay to Protagonist within [*] after receipt of such invoice, a one-time, non-creditable, non-refundable fee equal to two hundred million dollars (\$200,000,000) (the “**Opt-In Exercise Fee**”);
- (b) Article 5 shall take effect on the Opt-In Effective Date; and
- (c) the restriction set forth in Section 6.1.2 shall terminate on the Opt-In Effective Date; and
- (d) the License Term shall commence on the Opt-In Effective Date and this Agreement shall remain in full force and effect until the expiration of the Term, unless earlier terminated in accordance with Article 12.

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4.2.4. **Effect of Failure to Make the Second Opt-In Election.**

(a) If Janssen does not provide a Second Opt-In Election Notice on or prior to the expiration of the Second Opt-In Period, then this Agreement shall terminate in its entirety upon the expiration of the Second Opt-In Period without any further action on the part of either Party and Section 12.6 shall apply.

(b) If Janssen provides a Second Opt-In Election Notice on or prior to the expiration of the Second Opt-In Period but does not pay the Opt-In Exercise Fee within [*] after receipt of an invoice from Protagonist pursuant to Section 4.2.3(a), then this Agreement shall terminate upon the day immediately after the last day of such [*] period without any further action on the part of either Party and Section 12.6 shall apply.

**Article 5
ACTIVITIES DURING LICENSE TERM**

5.1. **General.**

5.1.1. This Article 5 shall take effect on the Opt-In Effective Date.

5.1.2. During the License Term, Janssen shall conduct Development, Manufacture and Commercialization of the Licensed Compounds and Licensed Products in accordance with this Article 5; *provided, however*, if the Opt-In Effective Date occurs prior to the Phase 2B Completion Date, the terms of Article 3 shall continue to apply to the Collaboration Activities for the remainder of the Development Term.

5.2. **Transition; Technology Transfer.**

5.2.1. To facilitate an orderly transition of the Development and Manufacture of the Licensed Compounds and Licensed Products from Protagonist to Janssen:

(a) promptly following the Opt-In Effective Date, Protagonist shall transfer to Janssen, and hereby assigns to Janssen all its right, title and interest in, to and under, all INDs, CTAs, safety databases and other Regulatory Documentation with respect to the Licensed Compounds and Licensed Products then held by Protagonist, its Affiliates and Third Party Subcontractors; and

(b) upon Janssen's request, Protagonist shall, and shall cause its Third Party manufacturer(s) (subject to the terms of any applicable agreement(s) with such Third Party Manufacturer(s)), to transfer existing Manufacturing processes for the Compound API and Licensed Products to Janssen (or its designee) and to provide reasonable technical assistance to Janssen (or its designee) in establishing Manufacturing processes for the Licensed Compounds and Licensed Products for a period of up to [*] following the Opt-In Effective Date.

5.2.2. Protagonist will transfer any other information in Protagonist's control reasonably requested by Janssen (e.g., assays) in order to Develop and Manufacture the Licensed

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Compounds and Licensed Products. Upon Janssen's request during the License Term, Protagonist shall promptly provide to Janssen (a) complete sets of any preclinical or clinical data generated by or on behalf of Protagonist with respect to any Licensed Compound or Licensed Product, (b) raw data tables with respect to the data described in clause (a), (c) CMC data or information generated by or on behalf of Protagonist with respect to any Licensed Compound or Licensed Product or (d) any other Protagonist Know-How that is necessary, and any other Protagonist Know-How (other than Protagonist Platform Know-How or Know-How that originates from any other Protagonist programs that are not targeting the IL23 receptor) that is specifically useful, for the Development, Manufacture or Commercialization of Licensed Compounds and Licensed Products, in each case ((a) - (d)), to the extent that such information was not previously provided by Protagonist to Janssen.

5.3. **Development.**

5.3.1. **Responsibility; Diligence.** Janssen shall have the sole right and authority, at its sole cost and expense (other than with respect to the Collaboration Activities), to Develop Licensed Compounds and Licensed Products in the Field in the Territory. Janssen shall use Commercially Reasonable Efforts to Develop and obtain Marketing Approval for one (1) Licensed Product for each of CD and UC (which may be the same Licensed Product) in each of the Major Market Countries. Janssen shall conduct all Development of Licensed Compounds and Licensed Products in accordance with the terms and conditions of this Agreement, in good scientific manner and in compliance with Applicable Law including, as applicable, those relating to GLP, GCP, pharmacovigilance and safety reporting, and requirements for the protection of human subjects.

5.3.2. **Reports.** Janssen shall provide Protagonist, through the JSC, with an update (in the form of a report or presentation at a meeting of the JSC) of its progress and high-level summaries of its plans with respect to the Development of Licensed Compounds and Licensed Products in the Field in the Territory until the receipt of Marketing Approval for a Licensed Product for each of CD and UC in each of the Major Market Countries. Upon request, Janssen shall provide Protagonist with a copy of all materials presented at such JSC meetings.

5.4. **Regulatory.** Janssen shall have the sole right and authority, at its sole cost and expense, to seek to obtain and maintain Regulatory Approvals for the Licensed Compounds and Licensed Products in the Field in the Territory and to conduct all related regulatory matters, including communications with any Regulatory Authorities relating to the Licensed Compounds and Licensed Products. Upon Janssen's reasonable request, Protagonist shall provide reasonable assistance as necessary for Janssen to file Drug Approval Applications and obtain and maintain Regulatory Approvals with respect to the Licensed Compounds and Licensed Products, up to [*].

5.5. **Manufacturing.** Janssen shall have the sole right and authority, 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

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conditions of this Agreement and in compliance with Applicable Law, including those relating to GMP.

5.6. **Commercialization.**

5.6.1. **Responsibility; Diligence.** Subject to Section 5.6.2, Janssen shall have the sole right and authority, at its sole cost and expense, to Commercialize the Licensed Compounds and Licensed Products in the Field in the Territory. Janssen shall use Commercially Reasonable Efforts to Commercialize each Licensed Product in each of the Major Market Countries following receipt of Marketing Approval of such Licensed Product in the applicable country. Janssen shall conduct all such Commercialization in accordance with the terms and conditions of this Agreement and in compliance with Applicable Law.

5.6.2. **Protagonist Co-Detailing Option.**

(a) *Definitions.*

(1) **“Detail”** means one (1) Primary Call or two (2) Secondary Calls. E-details, sample drops (if applicable) and reminder details shall not constitute a Detail. With regard to presentations made at conventions or similar gatherings, Details shall include that number of Details represented by the members of the target audience in attendance. For the avoidance of doubt, Details may occur in group situations if the definition of a Detail is met.

(2) **“Primary Call”** means a one-on-one in-person contact in which a sales representative makes a presentation, including selling message and features and benefits of a pharmaceutical or biologic product to a healthcare professional having prescribing authority within the target audience, during which contact such product is [*].

(3) **“Restricted Change of Control”** means, with respect to Protagonist, a Change of Control in which the Acquirer: (A) has, as of the time of such Change of Control a field sales force in the United States that promotes any pharmaceutical product for any IBD Indication (as defined in Section 6.7.2), (B) has entered into or become the subject of a corporate integrity agreement, settlement or order with or of the Office of Inspector General, U.S. Department of Health and Human Services, or another Governmental Authority, relating to marketing or commercialization of pharmaceutical products, (C) is the subject of a bona fide investigation or proceeding with the Office of Inspector General, U.S. Department of Health and Human Services, or another Governmental Authority, with respect to the marketing or commercialization of pharmaceutical products or (D) is engaged in significant litigation or other significant legal dispute with Janssen or any of its Affiliates, as evidenced by written

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correspondence outlining the issues in such dispute, ongoing alternative dispute resolution proceedings or an active court case.

(4) “**Secondary Call**” means a one-on-one in-person contact in which a sales representative makes a presentation, including selling message and features and benefits of a pharmaceutical or biologic product to a healthcare professional having prescribing authority within the target audience, in which such product is [*].

(b) *Co-Detailing Option.* Janssen hereby grants Protagonist an option to provide, at Protagonist’s election, up to thirty percent (30%) of the Details for each Licensed Product (other than Combination Products) in the U.S. for all approved Indications, as further described in this Section 5.6.2 (the “**Co-Detailing Option**”). Notwithstanding the foregoing, if Protagonist does not exercise the Co-Detailing Option with respect to the first Licensed Product for which Janssen delivers top-line results in accordance with Section 5.6.2(c), then the Co-Detailing Option shall not apply to any future Licensed Products and this Section 5.6.2 shall become null and void. If Protagonist exercises the Co-Detailing Option with respect to two or more Licensed Products, Protagonist shall not have the right to provide more than thirty percent (30%) of the aggregate number of Details for all such Licensed Products nor more than thirty percent (30%) of the Details for any such Licensed Product. Notwithstanding the foregoing, Janssen shall have the right, upon [*] written notice where such Co-Detailing Option has not as of such time been exercised, or upon [*] written notice where such option has as of such time been exercised by Protagonist, to terminate the Co-Detailing Option and Protagonist’s rights under this Section 5.6.2 in the event of the occurrence of a Restricted Change of Control of Protagonist or an assignment of this Agreement in its entirety by Protagonist (other than an assignment to an Affiliate of Protagonist), unless Janssen otherwise consents, which consent may be withheld in Janssen’s sole discretion.

(c) *Exercise of Option.* Protagonist may, in its sole discretion, exercise the Co-Detailing Option with respect to a Licensed Product by delivering written notice thereof to Janssen (the “**Co-Detailing Option Exercise Notice**”) within [*] after receipt of written notice from Janssen that the top-line results of the second Phase 3 Clinical Trial of such Licensed Product for the initial Indication for which such event occurs have become available to Janssen if two Phase 3 Clinical Trials of such Licensed Product are conducted, and within [*] after receipt of written notice from Janssen that the top-line results of the first Phase 3 Clinical Trial of such Licensed Product have become available to Janssen if following the conduct of the first Phase 3 Clinical Trial Janssen determines in its reasonable discretion that a second Phase 3 Clinical Trial is not necessary to proceed with filing of a Drug Approval Application for such Licensed Product. Janssen shall provide such results to Protagonist promptly following the occurrence thereof.

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(d) *Co-Detailing Plan.* If Protagonist provides a Co-Detailing Option Exercise Notice with respect to a Licensed Product, Janssen shall prepare and provide to Protagonist for its review and comment Janssen's initial written plan for the Detailing of and allocation of calls for such Licensed Product in the U.S. (the "**Initial Co-Detailing Plan**") in the ordinary course of its U.S. Commercialization planning process. The Parties shall discuss, and Janssen shall consider in good faith Protagonist's comments on, the Initial Co-Detailing Plan before Janssen finalizes such plan. For clarity, this Section 5.6.2(d) does not limit or modify Janssen's sole authority to Commercialize such Licensed Product pursuant to Section 5.6.1.

(e) *Terms of Co-Detailing.* Promptly following Janssen's receipt of the Co-Detailing Option Exercise Notice for the first Licensed Product, the Parties shall negotiate in good faith to enter into a separate co-detailing agreement with respect to the co-detailing of such Licensed Product (and any additional Licensed Products for which Protagonist exercises the Co-Detailing Option) in the U.S. on commercially reasonable terms (the "**Co-Detailing Agreement**"), which would provide for a working group or other administrative body to be established by the Parties to serve solely as an information-sharing body with respect to each Party's detailing activities, and not as an oversight or decision-making body. In addition to such usual and customary terms that are typically found within contract sales force agreements, the Co-Detailing Agreement shall include the terms set forth below in this Section 5.6.2(e).

(1) Protagonist would contribute a mutually agreed percentage of Janssen's planned Details for each such Licensed Product in the U.S. for each Calendar Year (*provided* that such percentage shall not be less than [*] and shall not exceed thirty percent (30%) without Protagonist's written consent), as set forth in Janssen's call plan for such Calendar Year. Protagonist would employ a number of sales representatives sufficient to provide the agreed percentage of Details for each such Licensed Product in the U.S. for each Calendar Year.

(2) Following consultation through the working group or other administrative body established under the Co-Detailing Agreement, Janssen would have the right to allocate the planned Details for each such Licensed Product in the U.S. for each Calendar Year between the Parties in a manner consistent with the allocation described in clause (1) of this Section 5.6.2(e), *provided* that, unless the Parties agree otherwise, Protagonist would be allocated Details to healthcare professionals [*] for such Licensed Product in the U.S. The Parties would coordinate their detailing activities for such Licensed Products in the U.S. in accordance with mutually agreed procedures.

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- (3) Janssen would reimburse Protagonist for the Details of each such Licensed Product in the U.S. performed by Protagonist at a mutually agreed cost per primary detailing equivalent, which shall be agreed between the Parties acting reasonably and in good faith and [*].
- (4) All Protagonist sales representatives who would Detail any Licensed Product in the U.S. would be required to [*] such Licensed Product in the U.S.
- (5) Protagonist would compensate its sales representatives who detail each such Licensed Product in the U.S. using a sales compensation structure [*] such Licensed Product in the U.S.
- (6) Each sales representative who details any Licensed Product in the U.S. on behalf of Protagonist would be required to [*].
- (7) Protagonist's sales representatives performing Details of a Licensed Product in the U.S. would be required to comply with Applicable Law and all of Janssen's reasonable instructions, quality standards, policies and guidelines which relate to the Commercialization of such Licensed Product and of which Protagonist has been given sufficient written notice. Protagonist would establish a compliance program and appoint a compliance officer to ensure that Protagonist's detailing of such Licensed Product is in compliance with Applicable Law and such Janssen instructions, quality standards, policies and guidelines. Janssen would have the right to audit Protagonist's records regarding performance under the Co-Detailing Agreement, solely for the purpose of determining Protagonist's compliance with the Co-Detailing Agreement.
- (8) Janssen would have the right to terminate the Co-Detailing Agreement immediately by written notice if (i) Protagonist fails to contribute at least [*] percent ([*]%) of the Details for such Licensed Products in the U.S. for a Calendar Quarter that Protagonist is obligated to provide under the Co-Detailing Agreement and fails to remedy such shortfall within [*] after receiving written notice of such shortfall from Janssen or (ii) Protagonist materially breaches the Co-Detailing Agreement and fails to cure such breach within [*] after receiving written notice of such breach from Janssen. The Co-Detailing Agreement would be subordinate to and coterminous with this Agreement.
- (9) The Co-Detailing Agreement would not be assignable by Protagonist without the consent of Janssen, which consent shall not be unreasonably withheld, conditioned, or delayed with respect to assignment to an Affiliate of Protagonist. The Co-Detailing Agreement would terminate in the event of the occurrence of a Restricted Change of Control

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of Protagonist if Janssen terminates Protagonist's rights as set forth in Section 5.6.2(b).

(10) Protagonist would have the right to terminate its obligations under the Co-Detailing Agreement on a Licensed Product-by-Licensed Product basis upon [*] prior written notice (or sooner, at Janssen's election).

Article 6 LICENSE GRANTS

6.1. License Grants to Janssen.

6.1.1. Subject to the terms and conditions of this Agreement, Protagonist hereby grants, on behalf of itself and its Affiliates, to Janssen an exclusive (even as to Protagonist, except as provided in Section 6.2), sublicensable (solely as provided in Section 6.3), royalty-bearing license under the Protagonist Intellectual Property to Develop, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported, and otherwise exploit, Manufacture and Commercialize Licensed Compounds and Licensed Products in the Field in the Territory.

6.1.2. Prior to the Opt-In Effective Date, neither Party shall conduct any Development, Manufacture or Commercialization of the Licensed Compounds or Licensed Products except pursuant to the Clinical Development Plan and CMC Development Plan or as otherwise expressly permitted by this Agreement.

6.1.3. Each Party hereby grants, on behalf of itself and its Affiliates, to the other Party a non-exclusive, perpetual, irrevocable, world-wide, royalty-free license to use internally for its or its Affiliates' ordinary course of business during or after the Term any Confidential Information or Know-How disclosed to it by the other Party solely to the extent such Confidential Information or Know-How has been retained in intangible form in the unaided memory of such Party's employees who have had access thereto pursuant to the terms of this Agreement; *provided* that (a) such Party and its Affiliates shall not disclose any Confidential Information in violation of this Agreement; and (b) such employees did not intentionally memorize such Confidential Information or Know-How.

6.2. Protagonist Retained Rights.

6.2.1. Notwithstanding the rights granted to Janssen in Section 6.1, Protagonist hereby expressly retains the right to practice the Protagonist Intellectual Property in the Field in the Territory solely as necessary to exercise its rights and perform its obligations under this Agreement.

6.2.2. Protagonist hereby expressly retains all rights under the Protagonist Intellectual Property other than the rights under the Protagonist Intellectual Property granted to Janssen pursuant to Section 6.1 or elsewhere in this Agreement, including, without

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limitation, the right to research, develop, make and have made, and commercialize Retained Compounds under the Retained Patent Rights.

6.2.3. Notwithstanding Section 6.2.2, Protagonist's right to further research, develop, make and have made, and commercialize any Retained Compound shall not include the right to research, develop, make and have made, or commercialize such Retained Compound based upon its utility as a therapeutic agent that modulates the IL23 receptor.

6.3. **Sublicensing.**

6.3.1. **Development Term Sublicensing.** Prior to the Opt-In Effective Date, except as set forth in Section 3.6.2, Janssen may not sublicense to any Third Party any of the rights granted to it by Protagonist under Section 6.1.1 without the prior written consent of Protagonist, which consent shall not be unreasonably withheld by Protagonist. Janssen may grant sublicenses to one or more Affiliates without the consent of Protagonist.

6.3.2. **License Term Sublicensing.** During the License Term, Janssen may grant and authorize sublicenses of any of the rights granted to it by Protagonist under Section 6.1.1 without the consent of Protagonist to one or more of its Affiliates or to one or more Third Parties through multiple tiers. Each sublicense shall be pursuant to a written agreement that is subject to and consistent with the terms and conditions of this Agreement. Janssen shall remain directly responsible and fully liable to Protagonist for the performance of each sublicensee in accordance with this Agreement. Janssen shall provide to Protagonist a copy of each sublicense agreement within [*] following the execution thereof, *provided* that Janssen shall be permitted to redact commercially sensitive terms to the extent such terms are not necessary for Protagonist to confirm its rights hereunder.

6.4. **License Grant to Protagonist.** Subject to the terms and conditions of this Agreement, Janssen, on behalf of itself and its Affiliates, hereby grants to Protagonist a limited-term, non-exclusive license under the Janssen Collaboration Know-How and Janssen Collaboration Patent Rights solely as necessary to perform its obligations under this Agreement.

6.5. **No Conflicting Licenses.** During the Term, neither Protagonist nor any of its Affiliates shall grant any right with respect to any Licensed Compound or Licensed Product to any Third Party that would impair or conflict in any way with any of the rights granted to Janssen under this Article 6 or any other provision of this Agreement.

6.6. **No Implied Licenses.** Neither Party grants to the other Party any rights or licenses in or to any intellectual property, whether by implication, estoppel, or otherwise, other than the rights and licenses that are expressly granted under this Agreement.

6.7. **Exclusivity.**

6.7.1. During the period beginning on the Effective Date and ending upon the Phase 2B Completion Date, neither Protagonist nor any of its Affiliates shall (i) Develop (including research), Manufacture, make, have made, use, have used, Commercialize, import, have

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imported, sell, have sold, offer for sale or have offered for sale any Competing Product for any IBD Indication; or (ii) collaborate with, license, enable or otherwise authorize or grant any rights to any Third Party to do any of the activities described in clauses (i), or enter into any agreement, amendment to an existing agreement or option to do any of the activities described in clause (i), except in either case (clause (i) or (ii)) to the extent necessary to perform Protagonist's obligations under this Agreement. The restrictions set forth in this Section 6.7 shall not apply to an Acquirer of Protagonist, *provided* that such Acquirer Segregates any activities that would otherwise be prohibited by this Section 6.7.

6.7.2. For purposes of this Section 6.7:

- (a) “**Competing Product**” means any product comprising a peptide that blocks, inhibits, or neutralizes an interleukin-23 receptor and (i) has an IC50 value of less than or equal to [*] nanomolar, as determined in the [*] described in Exhibit C or (ii) has an affinity for IL23R less than or equal to [*] pM, as determined by the [*] described in Exhibit C;
- (b) “**IBD Indication**” means any chronic intestinal disease that is characterized by inflammation of the bowel, including UC and CD; and
- (c) “**Segregate**” means, with respect to an activity, to use reasonable, good faith efforts to segregate such activity from the Development, Manufacturing and Commercialization of Licensed Compounds and Licensed Products under this Agreement, including using such efforts to ensure that: (i) no personnel involved in performing such activity on behalf of the Acquirer have access to non-public plans or information relating to the Development, Manufacturing and Commercialization of Licensed Compounds and Licensed Products under this Agreement; and (ii) no personnel involved in performing the Development, Manufacturing and Commercialization of Licensed Compounds and Licensed Products under this Agreement have access to non-public plans or information relating to such activity of the Acquirer.

Article 7 FINANCIAL TERMS

7.1. **Upfront Payment.** On or after the Effective Date, Protagonist shall submit an invoice to Janssen for Fifty Million Dollars (\$50,000,000) as a one-time, non-refundable, non-creditable upfront payment in partial consideration of the license and rights granted by Protagonist to Janssen under this Agreement. Such invoice shall be due and payable within [*] after receipt of such invoice by Janssen.

7.2. **Cost Sharing and Reimbursement.**

7.2.1. Protagonist shall be responsible for twenty percent (20%) and Janssen shall be responsible for eighty percent (80%) of Phase 2 Development Costs and Phase 2 CMC Development Costs (with respect to a Party, such percentage is referred to as its

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“**Specified Percentage**”). Protagonist shall be responsible for one hundred percent (100%) of the Collaboration CMC Costs for the Phase 1 Activities incurred by either Party or any of their Affiliates, and Janssen shall be responsible for one hundred percent (100%) of the Collaboration CMC Costs for any Phase 3 Clinical Trial(s) incurred by either Party or any of their Affiliates.

7.2.2. Within [*] after the end of each Calendar Quarter during which either Party incurs any Phase 2 Development Costs, any Phase 2 CMC Development Costs or any Collaboration CMC Costs for which the other Party is responsible pursuant to Section 7.2.1, each Party will provide a written report to the other Party setting forth in reasonable detail such Phase 2 Development Costs, Phase 2 CMC Development Costs and Collaboration CMC Costs incurred by it and its Affiliates during such Calendar Quarter.

7.2.3. The Party that incurs more than its Specified Percentage of Phase 2 Development Costs or Phase 2 CMC Development Costs in a Calendar Quarter shall, within [*] after delivery of the reports for such Calendar Quarter, invoice the other Party an amount sufficient to reconcile to the Specified Percentage of Phase 2 Development Costs or Phase 2 CMC Development Costs, as applicable. If a Party incurs Collaboration CMC Costs for which the other Party is responsible pursuant to Section 7.2.1 in such Calendar Quarter, such Party shall, within [*] after delivery of the reports for such Calendar Quarter, invoice the other Party for such Collaboration CMC Costs. Such invoices, if undisputed, shall be payable (a) within [*] after receipt or, (b) if disputed by the Party receiving such invoice, within [*] after resolution of such dispute and, if such dispute is resolved against the invoicing Party, receipt of a correct invoice.

7.2.4. Notwithstanding the foregoing:

(a) in the event a Party performing Phase 2 Activities for which it is responsible under the Clinical Development Plan incurs more than [*] percent ([*]%) of aggregate Phase 2 Development Costs budgeted for such activities in the Phase 2 Development Budget, the other Party shall not be obligated to bear its Specified Percentage of such excess Phase 2 Development Costs, except: (a) if the JSC approves such excess Phase 2 Development Costs (either before or after they are incurred); or (b) to the extent such excess Phase 2 Development Costs are attributable to (i) a change in Applicable Law, (ii) a force majeure event, (iii) variation in actual patient enrollment from projected patient enrollment, (iv) a change to a Clinical Trial protocol required or requested by any Regulatory Authority, or (v) unanticipated increases in the cost of raw materials; and

(b) in the event a Party performing Collaboration CMC Activities for the Phase 2 Activities for which it is responsible under the CMC Development Plan incurs more than [*] percent ([*]%) of aggregate Phase 2 CMC Development Costs budgeted for such activities in the Phase 2 CMC Development Budget, the other Party shall not be obligated to bear its Specified Percentage of such excess Phase 2 CMC Development Costs, except: (a) if the JSC approves such excess

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Phase 2 CMC Development Costs (either before or after they are incurred); or (b) to the extent such excess Phase 2 Development Costs are attributable to (i) a change in Applicable Law, (ii) a force majeure event, or (iii) unanticipated increases in the cost of raw materials.

7.2.5. Any disputes with respect to the amounts set forth in a report or invoice delivered under this Section 7.2 that are not resolved by the Parties within [*] after such dispute is first raised shall be referred to the JSC for attempted resolution. If the JSC does not resolve such dispute within [*], the Parties shall mutually select and engage an independent Third Party accounting firm that has no auditing or other financial relationship with either Party or any of its Affiliates to resolve such matter. Such accounting firm shall, as soon as reasonably practicable after such firm is engaged, deliver a report to each Party with its analysis and determination of such matter. Such determination shall be final and binding on the Parties. The costs of such firm's services shall be shared equally by the Parties.

7.2.6. The audit rights set forth in Section 7.7 shall apply to any payment made pursuant to this Section 7.2.

7.2.7. Neither Party will double charge the other Party for any FTE Costs or other costs or expenses subject to reimbursement under this Section 7.2.

7.3. **Development and Approval Milestones.** Janssen will notify Protagonist in writing within [*] after the first achievement by Janssen or any of its Affiliates or sublicensees of any of the milestone events set forth in a table below in Sections 7.3.1, 7.3.2 and 7.3.3 (each, a "**Milestone Event**"). In consideration of the rights and licenses granted to Janssen hereunder, Janssen shall pay to Protagonist the applicable milestone payment set forth in the tables below (each, a "**Milestone Payment**") within [*] after receipt of an invoice from Protagonist with respect to achievement of each Milestone Event that occurs prior to or on the Opt-In Effective Date and [*] after receipt of an invoice from Protagonist with respect to achievement of each Milestone Event that occurs after the Opt-In Effective Date. Each Milestone Payment shall be payable only once, even if the corresponding Milestone Event occurs more than once or with respect to more than one Licensed Product or (for Milestone Events set forth in in the table in Section 7.3.3) with respect to more than one New Indication. Each Milestone Payment shall be non-refundable and non-creditable.

7.3.1. **Development and Approval Milestone Events in CD:**

Milestone Event	Milestone Payment	
[*]	US\$	[*]
[*] a Licensed Product for use in CD	US\$	[*]
[*] a Licensed Product for use in CD [*]	US\$	[*]
[*] a Licensed Product for use in CD	US\$	[*]
[*] a Licensed Product for use in CD	US\$	[*]
[*] a Licensed Product for use in CD	US\$	[*]

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7.3.2. Development and Approval Milestone Events in UC:

Milestone Event	Milestone Payment	
[*] a Licensed Product for use in UC	US\$	[*]
[*] a Licensed Product for use in UC [*]	US\$	[*]
[*] a Licensed Product for use in UC	US\$	[*]
[*] a Licensed Product for use in UC	US\$	[*]
[*] a Licensed Product for use in UC	US\$	[*]

7.3.3. Development and Approval Milestone Events in New Indication:

Milestone Event	Milestone Payment	
A. [*] a Licensed Product for a New Indication	US\$	[*]
B. [*] a Licensed Product for a New Indication	US\$	[*]
C. [*] a Licensed Product for use in a New Indication	US\$	[*]
D. [*] a Licensed Product for use in a New Indication [*]	US\$	[*]
E. [*] a Licensed Product for use in a New Indication	US\$	[*]
F. [*] a Licensed Product for use in a New Indication	US\$	[*]
G. [*] a Licensed Product for use in a New Indication	US\$	[*]

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With respect to the Milestone Events set forth in the table above in this Section 7.3.3: (a) if for any reason Milestone A does not occur before the occurrence of Milestone B, then Milestone A shall be deemed to occur concurrently with the occurrence of Milestone B; and (b) if for any reason Milestone B does not occur before the first to occur of Milestone C and Milestone D, then Milestone B shall be deemed to occur concurrently with the occurrence of the first to occur of Milestone C and Milestone D.

7.4. **Sales Milestones.** Janssen will notify Protagonist in the applicable royalty report delivered pursuant to Section 7.5.4 the first time the aggregate Net Sales of Licensed Products in any Calendar Year by Janssen, its Affiliates and its sublicensees in the Territory exceed the amounts set forth in the following table (each, a “Sales Milestone Event”). In partial consideration of the rights and licenses granted to Janssen hereunder, Janssen shall pay to Protagonist the applicable milestone payment set forth in the table below (each, a “Sales Milestone Payment”) within [*] after receipt of an invoice from Protagonist with respect to achievement of each Sales Milestone Event. Each Milestone Payment shall be non-refundable and non-creditable.

Annual Aggregate Net Sales in the Territory Milestone Event	Sales Milestone Payment
Upon the first occasion that annual aggregate Net Sales of Licensed Products in the Territory in a Calendar Year exceeds US\$[*]	US\$ [*]
Upon the first occasion that annual aggregate Net Sales of Licensed Products in the Territory in a Calendar Year exceeds US\$[*]	US\$ [*]
Upon the first occasion that annual aggregate Net Sales of Licensed Products in the Territory in a Calendar Year exceeds US\$[*]	US\$ [*]
Upon the first occasion that annual aggregate Net Sales of Licensed Products in the Territory in a Calendar Year exceeds US\$[*]	US\$ [*]

7.5. **Royalties.**

7.5.1. **Royalty Rates.** In partial consideration of the licenses and rights granted by Protagonist to Janssen under this Agreement, Janssen shall pay to Protagonist royalties on the aggregate Net Sales of each Licensed Product by Janssen, its Affiliates and sublicensees in each country in the Territory during each Calendar Year of the Royalty Term for such Licensed Product in such country at the rates set forth in the table below.

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Annual Aggregate Net Sales of such Licensed Product in the Territory	Royalty Rate
For that portion of annual Net Sales of such Licensed Product in the Territory in such Calendar Year less than [*] Dollars (US\$[*])	10%
For that portion of annual Net Sales of such Licensed Product in the Territory in such Calendar Year greater than or equal to [*] Dollars (US\$[*]) and less than [*] Dollars (US\$[*])	[*]%
For that portion of annual Net Sales of such Licensed Product in the Territory in such Calendar Year greater than or equal to [*] Dollars (US\$[*])	[*]%

By way of example, if annual Net Sales of a Licensed Product in the Territory during such Calendar Year were \$[*], the royalties due with respect to such Licensed Product would equal the sum of (a) 10% of [*], (b) [*] and (c) [*].

7.5.2. Royalty Reductions.

- (a) Janssen shall have the right to deduct, from the royalties due to Protagonist pursuant to Section 7.5.1 with respect to a Licensed Product during a Calendar Quarter, [*] percent ([*]%) of the aggregate payments made by Janssen or its Affiliate or sublicensee to such Third Party(ies) that are specifically made as consideration for a license under Third Party Blocking Intellectual Property Rights with respect to such Licensed Product during such Calendar Quarter, *provided* that if any agreement with such Third Party includes rights to additional intellectual property other than such intellectual property rights or covers products other than such Licensed Product, any such payment shall be equitably allocated by Janssen in good faith among all products and programs to which such agreement applies. Janssen shall provide documentation of such allocation to Protagonist, and any dispute regarding such allocation shall be subject to resolution under Article 13.
- (b) On a country-by-country and Licensed Product-by-Licensed Product basis, the royalties due to Protagonist pursuant to Section 7.5.1 shall be reduced during the Royalty Term for such Licensed Product in such country to [*] percent ([*]%) of the amount otherwise payable from and after the date that there is no Valid Claim of any Protagonist Patent Right that Covers the composition of matter of such Licensed Product in such country. Such reduced royalty rate will be applied to the sales of the applicable Licensed Product beginning with the Calendar Quarter immediately following the Calendar Quarter during which such event first

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occurs and will remain in effect unless and until the event set forth in Section 7.5.2(c).

(c) If, after the date upon which there is no Valid Claim of any Protagonist Patent Right that Covers the composition of matter of a Licensed Product sold by Janssen (directly or through an Affiliate or Third Party sublicensee) in a particular country, one or more Generic Products is sold by a Third Party in such country, the royalty rates provided in Section 7.5.1 for such Licensed Product shall be reduced in such country by [*] percent ([*]%) for the remainder of the Royalty Term for such Licensed Product in such country.

(d) Notwithstanding the foregoing, in no event shall the total deductions under Sections 7.5.2(a), 7.5.2(b), and 7.5.2(c) reduce the royalties payable to Protagonist under Section 7.5.1 with respect to a given Licensed Product in a given country in any Calendar Quarter by more than [*] percent ([*]%); *provided, however*, that to the extent Janssen cannot deduct any amounts because of this Section 7.5.2(d), Janssen may deduct such amounts from royalties payable in future Calendar Quarters, subject to this Section 7.5.2(d).

7.5.3. Royalty Term Expiration. Upon the expiration of the Royalty Term with respect to a Licensed Product in a country in the Territory, Protagonist hereby grants to Janssen a perpetual, irrevocable, non-exclusive, fully-paid and royalty-free right and license, with the right to grant sublicenses, under the Protagonist Intellectual Property to Develop, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported, and otherwise exploit, Manufacture and Commercialize such Licensed Product in the Field in such country. For clarity, after the Royalty Term expires with respect to a Licensed Product in a country, the calculation of annual Net Sales of such Licensed Product in the Territory shall exclude sales of such Licensed Product in such country.

7.5.4. Royalty Reports and Payments. Commencing with the First Commercial Sale of a Licensed Product by Janssen or its Affiliates or sublicensees, (a) within [*] after the end of each Calendar Quarter, Janssen shall make preliminary written reports to Protagonist stating in each such report, by Licensed Product, the estimated aggregate Net Sales in U.S. Dollars of Licensed Products sold in the Territory during such Calendar Quarter by Janssen and its Affiliates and sublicensees, and (b) within [*] after the end of each Calendar Quarter Janssen shall make final written reports to Protagonist stating in each such report, by Licensed Product and by region (which regions shall be the U.S., Canada, Japan, the Major European Countries and all other countries in the Territory), the aggregate Net Sales in U.S. Dollars of Licensed Products sold during such Calendar Quarter by Janssen and its Affiliates and sublicensees. The final report shall also show (a) the calculation of the royalty payments due to Protagonist on such Net Sales ([*]), (b) the amount of taxes, if any, withheld to comply with Applicable Laws, and (c) the exchange rates used in calculating the payments due Protagonist, which exchange rates shall comply with Section 7.6.2. Simultaneously with the delivery of each such final

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report, Janssen shall pay to Protagonist the total royalties, if any, due to Protagonist for the period of such report. If no royalties are due, Janssen shall so report. All preliminary and final reports delivered by Janssen under this Section 7.5.4 shall be Confidential Information of Janssen.

7.5.5. Royalty Conditions. All royalties due to Protagonist pursuant to Section 7.5.1 are subject to the following conditions: (a) only one royalty shall be due with respect to the same unit of Licensed Product; (b) no royalties shall be due upon the sale or other transfer among Janssen or its Affiliates, but in such cases the royalty shall be due and calculated upon Janssen's or its Affiliate's Net Sales to the first independent Third Party, and distributors of Janssen selling Licensed Product that are not Affiliates of Janssen will not, for this purpose, be deemed to be sublicensees of Janssen and shall instead be considered as independent Third Parties; and (c) no royalties shall be due upon free samples, donations, patient assistance, test marketing programs or other similar programs or studies.

7.6. Payment Terms.

7.6.1. 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.

7.6.2. 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 [*].

7.6.3. 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 [*] or the maximum rate allowable by Applicable Law, whichever is lower.

7.7. Records; Inspection.

7.7.1. Each Party shall keep (and cause its Affiliates, (sub)licensees and Third Party Subcontractors to keep) complete, true and accurate books of account and records for the purpose of determining the Phase 2 Development Costs and Collaboration CMC Costs shared or reimbursed by the Parties under Section 7.2 (the "**Cost Records**"); and Janssen shall keep (and cause its Affiliates, sublicensees and Third Party Subcontractors to keep) complete, true and accurate books of account and records for the purpose of determining royalties and Sales Milestone Payments payable by Janssen to Protagonist under Sections 7.4 and 7.5 (the "**Royalty Records**").

7.7.2. Each Party shall retain its Cost Records and Royalty Records for at least [*] following the end of the Calendar Year to which they pertain. Each Party shall, and shall cause its Affiliates and (sub)licensees to, make the Cost Records and Royalty Records available for inspection by an independent public accounting firm of national prominence

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selected by the other Party, and reasonably acceptable to the audited Party, during normal business hours, as may be reasonably necessary for the sole purpose of verifying the cost and royalty reports and payments delivered by the Parties pursuant to Sections 7.2, 7.4 and 7.5 during the preceding [*]. The records for a given Calendar Year shall be subject to audit no more than [*]. Such independent public accounting firm shall execute a reasonable confidentiality agreement with the audited Party prior to commencing any such inspection. Such inspections shall be made no more than [*] at reasonable times and on reasonable notice.

7.7.3. Following completion of an inspection pursuant to Section 7.7.2, the independent public accounting firm shall, prior to distribution to the auditing Party, share its report with the audited Party. If the audited Party provides the independent public accounting firm with justifying remarks for inclusion in the report, the independent public accounting firm shall incorporate such remarks into its report prior to sharing the conclusions of such independent public accounting firm with the auditing Party. The final audit report shall be shared with both Parties at the same time and shall specify (a) whether any royalties paid by the audited Party during the audited period were correct and, if incorrect, the amount of any underpayment or overpayment and (b) whether any Phase 2 Development Costs or Collaboration CMC Costs reported by the audited Party during the audited period were correct and, if incorrect, the difference between the reported amounts and the amounts actually incurred. The audit report shall only contain the information relevant to support the statement as to whether the royalties paid or costs reported to the auditing Party were calculated accurately and shall not include any confidential information (or additional information that is ordinarily not included in the royalty or cost reports delivered pursuant to this Agreement) disclosed to the independent public accounting firm during the course of the audit.

7.7.4. The auditing Party shall bear the costs and expenses of any inspection conducted under this Section 7.7 unless such inspection reveals (a) an over-reporting of Phase 2 Development Costs and/or Collaboration CMC Costs by the audited Party of more than [*] percent ([*]%) of the actual Phase 2 Development Costs or Collaboration CMC Costs, as applicable, incurred by the audited Party during the audited period or (b) an underpayment of royalties payable pursuant to Section 7.5 by the audited Party of more than [*] percent ([*]%) of the amount payable for the audited period, in which case ((a) or (b)) the audited Party shall bear the costs and expenses of such inspection.

7.7.5. If such inspection reveals an over-reporting of Phase 2 Development Costs and/or Collaboration CMC Costs by the audited Party pursuant to Section 7.2, then the auditing Party shall conduct the applicable calculation pursuant to Section 7.2.3 and invoice the audited Party for the difference between the amount paid pursuant to Section 7.2.3 and the amount due as a result of the corrected calculation. The audited Party shall pay such invoice within [*] after receipt thereof.

7.7.6. If such inspection reveals an overpayment of royalties by the audited Party pursuant to Section 7.5, then the audited Party shall invoice the auditing Party for the

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amount of the overpayment and the auditing Party shall pay such invoice within [*] after receipt thereof, *provided* that the auditing Party may elect to offset such amounts against future royalties payable by the audited Party. If such inspection reveals an underpayment of royalties by the audited Party pursuant to Section 7.5, then the auditing Party shall invoice the audited Party for the amount of the underpayment and the audited Party shall pay such invoice within [*] after receipt thereof.

7.7.7. If the audited Party disagrees with the findings of the audit report, the Parties will meet to attempt to mutually agree upon a resolution to the dispute. If such resolution cannot be reached, such disagreement shall be subject to the dispute resolution procedures set forth in Article 13.

7.8. **Taxes.**

7.8.1. Each Party shall make all payments 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; *provided, however*, that the paying Party shall use reasonable, good faith efforts to give the recipient Party advance notice of its intention to make such deduction or withholding. Any Tax required to be withheld on amounts payable under this Agreement will be timely paid by the paying Party on behalf of the recipient Party to the appropriate Governmental Authority, and the paying Party will furnish the recipient Party with proof of payment of such Tax as well as any official receipts issued by the applicable Governmental Authority or other evidence as is reasonably requested to establish that such Taxes have been paid. Any such Tax required to be withheld will be an expense of and borne by the recipient Party.

7.8.2. The paying Party shall pay all value added, transfer, sales, use, stamp, or similar Taxes (“**Transfer Taxes**”) required to be paid in connection with any payment made to the other Party under this Agreement.

7.8.3. The Parties shall cooperate with respect to all documentation required by any taxing authority or reasonably requested to secure a reduction in the rate of applicable withholding taxes, and the Parties shall provide reasonable mutual assistance with respect to any claim of refund or exemption from Taxes under any relevant agreement or treaty. On or before the Effective Date, Protagonist will deliver to Janssen an accurate and complete Internal Revenue Service Form W-9.

Article 8
INTELLECTUAL PROPERTY

8.1. **Reporting of Collaboration 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 Collaboration Invention.

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8.2. **Ownership of Collaboration Inventions, Patent Rights and Know-How.**

8.2.1. **Collaboration Inventions and Collaboration Patent Rights.** Ownership in the Territory of Collaboration Inventions and Patent Rights filed after the Effective Date claiming one or more Collaboration Inventions (each, a “**Collaboration Patent Right**”) shall be allocated in accordance with inventorship as determined pursuant to principles of United States patent law as follows:

- (a) each Collaboration Invention invented solely by one or more employees or agents of Janssen (or its Affiliates or Third Party Subcontractors) and each Collaboration Patent Right to the extent claiming one or more of such Collaboration Inventions shall be owned solely by Janssen (a “**Janssen Collaboration Patent Right**”);
- (b) each Collaboration Invention invented solely by one or more employees or agents of Protagonist (or its Affiliates or Third Party Subcontractors) and each Collaboration Patent Right to the extent claiming one or more of such Collaboration Inventions shall be owned solely by Protagonist (a “**Protagonist Collaboration Patent Right**”); and
- (c) each Collaboration 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 Protagonist (or its Affiliates or Third Party Subcontractors) and each Collaboration Patent Right to the extent claiming one or more of such Collaboration Inventions shall be owned jointly by the Parties (a “**Joint Collaboration Patent Right**”).

For purposes of this Agreement, except as set forth in Section 9.1, Collaboration Know-How which is the basis for a Collaboration Invention upon the filing of a Collaboration Patent Right therefor will be the Confidential Information of the owner(s) of such Collaboration Patent Right.

8.2.2. **Other Collaboration Know-How.** Subject to Section 9.1, any Collaboration Know-How generated by Janssen’s or its Affiliates’ or Third Party Subcontractors’ employees or agents that is not otherwise allocated pursuant to Section 8.2.1 will be the Confidential Information of Janssen (“**Janssen Collaboration Know-How**”). Subject to Section 9.1, any other Collaboration Know-How generated by Protagonist’s or its Affiliates’ or Third Party Subcontractors’ employees or agents that is not otherwise allocated pursuant to Section 8.2.1 will be the Confidential Information of Protagonist (“**Protagonist Collaboration Know-How**”).

8.2.3. **Confirmatory Assignments; Inventor Compensation.** Each Party shall take all reasonable actions requested by the other Party responsible for prosecuting any Collaboration Patent Right to perfect or separately document the other Party’s ownership interest rights in such Collaboration Patent Right 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

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Third Party Subcontractors, or any of their employees, or agents, for the execution of any assignments or other papers pursuant to this Section 8.2.3. For clarity, each Party (directly or through its applicable Affiliate or Third Party Subcontractor) shall be solely responsible for any compensation directly due to its and its Affiliates' and Third Party Subcontractors' employees and agents (a) in connection with the assignment of their respective rights to any Collaboration Inventions and associated Collaboration Patent Rights pursuant to this Agreement, or (b) the exploitation by any Party or its Affiliates or Third Party sublicensees hereunder of any such Collaboration Inventions or associated Collaboration Patent Rights with respect to Licensed Compounds or Licensed Products, including in each case any required by operation of Applicable Law on account of any Commercialization of any such Collaboration Inventions with respect to Licensed Compounds or Licensed Products hereunder.

8.2.4. **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 Collaboration Inventions and Collaboration Patent Rights that are owned jointly by the Parties pursuant to Section 8.2.1, each Party shall have the right to practice and exploit such Collaboration Inventions and Collaboration Patents, with full rights to license its interest therein 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.

8.3. **Prosecution of Collaboration and Joint Patent Rights.**

8.3.1. **Communications.** Each Party shall use reasonable efforts to handle all communications between the Parties under this Section 8.3 through their Patent Representatives and keep such communications in strict confidence to protect their attorney-client privileged status in accordance with Section 9.10.

8.3.2. **Filing, Prosecution and Maintenance of Janssen Collaboration Patent Rights and Joint Collaboration Patent Rights Prior to the Opt-In Effective Date.**

(a) Prior to the Opt-In Effective Date, Janssen shall be responsible for prosecuting or causing to be prosecuted in the United States and in foreign countries Janssen Collaboration Patent Rights and Joint Collaboration Patent Rights, at [*].

(b) Within [*] after the filing of an application within the Janssen Collaboration Patent Rights or Joint Collaboration Patent Rights, Janssen shall provide Protagonist with a written report indicating in which countries/regions Janssen will file a corresponding international application. Protagonist shall then notify Janssen within [*] of such notice in which additional countries/regions Protagonist would desire Janssen to file a corresponding international application. If Janssen does not desire to file such an international application in the additional countries/regions requested by Protagonist, Janssen shall so notify Protagonist and

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then Protagonist shall have the option to request that Janssen file such international application in such country(s)/region(s). Janssen shall file such international application in such country(s)/region(s), and Protagonist shall reimburse Janssen for [*] Patent Costs with respect to such requested international patent application(s). Protagonist, however, shall have the right to discontinue reimbursement of Patent Costs for such requested international patent application(s), upon [*] written notice to Janssen; *provided, however*, that [*]. If Protagonist discontinues reimbursement of the Patent Costs with respect to such requested international patent application(s), such requested international patent application(s) shall no longer be considered to be within the Janssen Collaboration Patent Rights or Joint Collaboration Patent Rights, as applicable, except for purposes of the license granted to Protagonist pursuant to 12.6.1(g).

(c) Janssen shall provide to Protagonist: (i) copies of or access to all relevant patent applications included in Janssen Collaboration Patent Rights and Joint Collaboration Patent Rights for which Janssen is responsible for prosecuting; (ii) [*]; and (iii) copies of or access to all correspondence to and from the U.S. Patent and Trademark Office and foreign patent offices for such applications.

(d) Protagonist shall have the right to consult with Janssen regarding the content of the patent applications included in Janssen Collaboration Patent Rights and Joint Collaboration Patent Rights, [*] and correspondence, and to comment thereon to Janssen, or at Janssen's request, to Janssen's designated outside counsel. Janssen shall reasonably [*] in good faith all such comments offered by Protagonist; *provided, however*, that all final decisions respecting conduct of the prosecution of said patent applications shall rest solely in the discretion of Janssen with respect to Janssen Collaboration Patents, and with Protagonist with respect to Joint Collaboration Patent Rights.

8.3.3. Filing, Prosecution and Maintenance of Protagonist Patent Rights (other than Joint Collaboration Patent Rights) prior to Opt-In Effective Date.

(a) Prior to the Opt-In Effective Date, Protagonist shall be responsible for prosecuting or causing to be prosecuted in the United States and in foreign countries the Protagonist Patent Rights other than the Joint Collaboration Patent Rights, at [*] as provided in Section 8.3.5.

(b) Within [*] after the filing of an application within such Protagonist Patent Rights, Protagonist shall provide Janssen with a written report indicating in which countries/regions Protagonist will file a corresponding international application. Janssen shall then notify Protagonist within [*] of such notice in which additional countries/regions Janssen would desire Protagonist to file a corresponding international application. If Protagonist does not desire to file any such additional international application in a country/region requested by Janssen, Protagonist shall so notify Janssen and then Janssen shall have the option to request that Protagonist file such international application in such

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country(s)/region(s). Protagonist shall file such international application in such country(s)/region(s), and Janssen shall reimburse Protagonist for [*] Patent Costs with respect to such requested international patent application(s). Janssen, however, shall have the right to discontinue reimbursement of the Patent Costs for such requested international patent application(s), upon [*] written notice to Protagonist; *provided, however*, that Janssen shall remain responsible for reimbursement of such Patent Costs during such [*] notice period. If Janssen discontinues reimbursement of the Patent Costs with respect to such requested international patent application(s), such requested international patent application(s) shall no longer be considered to be within the Protagonist Patent Rights.

(c) Protagonist agrees to provide to Janssen: (i) copies of or access to all relevant patent applications included in the Protagonist Patent Rights for which Protagonist is responsible for prosecuting; (ii) [*]; and (iii) copies of or access to all correspondence to and from the U.S. Patent and Trademark Office and foreign patent offices for such applications.

(d) Janssen shall have the right to consult with Protagonist regarding the content of the patent applications included in Protagonist Patent Rights, [*] and correspondence, and to comment thereon to Protagonist, or at Protagonist's request, to Protagonist's designated outside counsel. Protagonist shall reasonably consider in good faith all such comments offered by Janssen; *provided, however*, that all final decisions respecting conduct of the prosecution of said patent applications shall rest solely in the discretion of Protagonist. Without limiting the foregoing, prior to the Opt-In Effective Date, Janssen may request a patent strategy meeting with Protagonist. Protagonist agrees to reasonably [*] in good faith all of Janssen's comments at such meeting regarding the patent strategy with respect to the Protagonist IL23 Receptor Inhibitor Patent Rights. Any Patent Costs associated with subsequent actions requested by Janssen at such meeting shall be at Janssen's expense.

8.3.4. Filing, Prosecution and Maintenance of Protagonist Patent Rights (other than the Protagonist-Controlled Patent Rights), Janssen Collaboration Patent Rights and Joint Collaboration Patent Rights after Opt-In Effective Date.

(a) On and after the Opt-In Effective Date, Janssen shall have the sole right to prosecute or cause to be prosecuted in the United States and in foreign countries the Protagonist Patent Rights (other than the Protagonist-Controlled Patent Rights), Janssen Collaboration Patent Rights and Joint Collaboration Patent Rights, at Janssen's sole expense, and in Janssen's good faith discretion. Such right includes the right to initiate a re-issue or reexamination of any of the Protagonist Patent Rights.

(b) Upon Protagonist's reasonable request, Janssen shall provide to Protagonist: (i) notice of and copies of or access to all significant patent filings with respect to the

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Protagonist Patent Rights (other than the Protagonist-Controlled Patent Rights) and Joint Collaboration Patent Rights [*], and (ii) copies of or access to all correspondence to and from the U.S. Patent and Trademark Office and foreign patent offices for such applications.

8.3.5. Filing, Prosecution and Maintenance of Retained Patent Rights and Other Protagonist-Controlled Patent Rights.

- (a) Each Party understands and acknowledges that the Protagonist IL23 Receptor Inhibitor Patent Rights as of the Execution Date Cover both Licensed Compounds and Retained Compounds. After the Execution Date, Protagonist shall have the right to file and prosecute any divisional, continuation and continuation-in-part application(s) claiming priority to any of the Protagonist IL23 Receptor Inhibitor Patent Rights, but only so long as any such divisional, continuation and continuation-in-part application(s) do not include any claim that Covers any Licensed Compound or Licensed Product (such divisionals, continuations and continuation-in-parts, the “**Retained Patent Rights**”).
- (b) Protagonist shall have the sole right to prosecute or cause to be prosecuted in the United States and in foreign countries the Retained Patent Rights, at Protagonist’s sole expense. On and after the Opt-In Effective Date, Protagonist shall have the sole right to prosecute or cause to be prosecuted in the United States and in foreign countries any other Protagonist-Controlled Patent Rights, at Protagonist’s sole expense.
- (c) Protagonist agrees to provide to Janssen: (i) copies of or access to all relevant patent applications included in the Protagonist-Controlled Patent Rights; and (ii) copies of or access to all correspondence to and from the U.S. Patent and Trademark Office and foreign patent offices for such applications.
- (d) Janssen shall have the right to consult with Protagonist regarding the content of patent applications included in the Protagonist-Controlled Patent Rights, and to comment thereon to Protagonist, or at Protagonist’s request, to Protagonist’s designated outside counsel. Protagonist shall reasonably [*] in good faith all such comments offered by Janssen; *provided, however*, that all final decisions respecting conduct of the prosecution of said patent applications shall rest solely in the discretion of Protagonist, so long as such decisions do not adversely impact the Protagonist IL23 Receptor Inhibitor Patent Rights.

8.3.6. Option to Prosecute and Maintain Patent Rights. Either Party may cease prosecution and/or maintenance of any Patent Rights that such Party is responsible for prosecuting pursuant to this Section 8.3 on a country-by-country basis in the Territory by providing the other Party written notice reasonably in advance, i.e., approximately [*] before such due date. If the responsible Party elects to cease prosecution or maintenance of the relevant Patent Rights in a country, the other Party, at its sole discretion and cost, may continue prosecution or maintenance of such Patent Rights and in such country. If

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the other Party elects to continue prosecution or maintenance or elects to file additional applications following the responsible Party's election to cease prosecution or maintenance pursuant to this Section 8.3.6, the responsible Party shall transfer the applicable patent files to such other Party or its designee and execute such documents and perform such acts at the responsible Party's expense as may be reasonably necessary to allow the other Party to initiate or continue such filing, prosecution or maintenance at the other Party's sole expense. If Janssen ceases the prosecution and/or maintenance of any Protagonist Patent Right or Joint Patent Right that Janssen is responsible for prosecuting pursuant to this Section 8.3, then such Patent Rights shall thereafter be excluded from the Protagonist Patent Rights. Notwithstanding the foregoing, Janssen shall have no rights to prosecute or maintain, and this Section 8.3.6 shall not apply, to any Protagonist-Controlled Patent Rights.

8.3.7. **CREATE Act.** The Parties acknowledge that Collaboration Inventions 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 of the Licensed Compounds and Licensed Products, to constitute a qualifying written Joint Research Agreement.

8.4. **Interference, Opposition, Re-examination and Re-issue.**

8.4.1. Each Party shall inform the other Party promptly (and, in any case, within thirty (30) days) of learning of any request for, or filing or declaration of, any Patent Proceeding relating to Protagonist Patent Rights or Collaboration Patent Rights for which such Party is responsible. The Parties shall thereafter consult and cooperate fully to determine a course of action with respect to any such Patent Proceeding. Except with respect to Janssen Collaboration Patent Rights following the Opt-In Effective Date, each Party has the right to review any submission, within reason, to be made in connection with the Patent Proceeding of the other Party and has the right to provide reasonable comments on any such submission related to Protagonist Patent Rights and Joint Collaboration Patent Rights, *provided* that such comments shall not be unreasonably withheld or delayed and the responsible Party will consider such comments in good faith.

8.4.2. Prior to the Opt-In Effective Date, Protagonist shall have the first right, but not the obligation, to defend any Patent Proceeding relating to Protagonist Patent Rights or Joint Collaboration Patent Rights at its own expense; if Protagonist elects not to defend any such Patent Proceeding then Janssen shall have the right, but not the obligation, to defend such Patent Proceeding (other than any proceeding relating to the Protagonist-Controlled Patent Rights) at its own expense and in the name of Protagonist and Janssen (or just Protagonist or just Janssen, if the laws of the jurisdiction so dictate). Prior to the Opt-In Effective Date, Janssen shall have the first right, but not the obligation, to defend

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any Patent Proceeding relating to Janssen Collaboration Patent Rights at its own expense; if Janssen elects not to defend any such Patent Proceeding then Protagonist shall have the right, but not the obligation, to defend such Patent Proceeding at its own expense and in the name of Protagonist and Janssen (or just Protagonist or just Janssen, if the laws of the jurisdiction so dictate).

8.4.3. Following the Opt-In Effective Date and for the remainder of the Term, (a) Janssen shall have the sole right, but not the obligation, to defend any Patent Proceeding relating to Janssen Collaboration Patent Rights at its own expense, and (b) Janssen shall have the first right, but not the obligation, to defend any Patent Proceeding relating to the Protagonist Patent Rights (other than the Protagonist-Controlled Patent Rights) or Joint Collaboration Patent Rights at its own expense and in the name of Protagonist and Janssen (or just Protagonist or just Janssen, if the laws of the jurisdiction so dictate). If Janssen elects not to defend any such Patent Proceeding described in subclause (b) of this Section 8.4.3, then Protagonist shall have the right, but not the obligation, to defend such Patent Proceeding at its own expense and in the name of Protagonist and Janssen (or just Protagonist or just Janssen, if the laws of the jurisdiction so dictate).

8.4.4. Each Party shall provide the other Party with written notice [*] (a) prior to initiating any Patent Proceeding relating to Protagonist Patent Rights or Collaboration Patent Rights for which such Party is responsible pursuant to this Agreement, and (b) if such Party elects not to defend such Patent proceeding. Any notice under subclause (b) of this Section 8.4.4 shall be made [*] any filing, administrative or other applicable deadline to reasonably allow the other Party to exercise its rights under Section 8.4.2 or 8.4.3, as applicable.

8.4.5. In connection with any Patent Proceeding relating to Protagonist Patent Rights or Collaboration Patent Rights, the Parties shall cooperate fully and shall provide each other with any information or assistance that either may reasonably request. Each Party shall

keep the other Party informed of developments in any such action or proceeding, including, to the extent permissible by law, consultation regarding any settlement, the status of any settlement negotiations and the terms of any related offer.

8.5. **Enforcement and Defense.**

8.5.1. Each Party shall promptly give the other Party notice of (a) any infringement of Protagonist Patent Rights or Collaboration Patent Rights, or (b) any misappropriation or misuse of Protagonist Know-How or Collaboration Know-How, which may come to such Party's attention. The Parties shall thereafter cooperate to determine a course of action to terminate any such infringement of Protagonist Patent Rights or Joint Collaboration Patent Rights or any such misappropriation or misuse of Protagonist Know-How or Collaboration Know-How.

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8.5.2. Prior to the Opt-In Effective Date:

(a) Protagonist shall have the right, but not the obligation, to initiate and prosecute any such legal action, or to control the defense of any declaratory judgment action relating to the Protagonist Patent Rights (other than Joint Collaboration Patent Rights) or any Protagonist Know-How at its own expense. The costs of any legal action commenced or the defense of any declaratory judgment shall be borne by Protagonist. Protagonist shall promptly inform Janssen if it elects not to exercise such right with respect to Protagonist Patent Rights and Janssen shall thereafter have the right at its sole cost to either initiate and prosecute such action or to control the defense of such declaratory judgment action (other than with respect to any Protagonist-Controlled Patent Rights) in the name of Protagonist and, if necessary, Janssen. Each Party shall have the right to be represented by counsel of its own choice.

(b) Janssen shall have the right, but not the obligation, to initiate and prosecute any such legal action at its own expense and in the name of Protagonist and Janssen (or just Protagonist or just Janssen, if the laws of the jurisdiction so dictate), or to control the defense of any declaratory judgment action relating to Janssen Collaboration Patent Rights, Joint Collaboration Patent Rights or any Janssen Collaboration Know-How. The costs of any legal action commenced or the defense of any declaratory judgment shall be borne by Janssen. Janssen shall promptly inform Protagonist if it elects not to exercise such right with respect to Collaboration Patent Rights and Protagonist shall thereafter have the right at its sole cost to either initiate and prosecute such action or to control the defense of such declaratory judgment action in the name of Protagonist and, if necessary, Janssen. Each Party shall have the right to be represented by counsel of its own choice.

8.5.3. Following the Opt-In Effective Date:

(a) Janssen shall have the right, but not the obligation, to initiate and prosecute any such legal action, or to control the defense of any declaratory judgment action relating to, the Protagonist Patent Rights (other than the Protagonist-Controlled Patent Rights, but including any Protagonist Collaboration Patent Rights and any Joint Collaboration Patent Rights) or Joint Collaboration Patent Rights, or any Protagonist Know-How or Collaboration Know-How, at its own expense and in the name of Protagonist and Janssen (or just Protagonist or just Janssen, if the laws of the jurisdiction so dictate). The costs of any legal action commenced or the defense of any declaratory judgment shall be borne by Janssen. Janssen shall promptly inform Protagonist if it elects not to exercise such right with respect to such Protagonist Patent Rights or Protagonist Know-How and Protagonist shall thereafter have the right at its sole cost to either initiate and prosecute such action or to control the defense of such declaratory judgment action in the name of Protagonist and, if necessary, Janssen; *provided, however,*

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that Protagonist shall not have the right to initiate or prosecute such action, or to control the defense of such declaratory judgment action, to the extent it relates to any Protagonist IL23 Receptor Inhibitor Patent Right without Janssen's prior written consent, which Janssen may grant in its sole discretion. Each Party shall have the right to be represented by counsel of its own choice.

(b) Janssen shall be solely responsible for the enforcement or defense of any Janssen Collaboration Patent Rights and shall have no obligation to Protagonist with respect to such enforcement or defense, except as set forth in Section 8.5.5 (provided that Protagonist shall have no right of consultation or approval with respect to any proposed settlement).

(c) Protagonist shall be solely responsible for the enforcement or defense of any Protagonist-Controlled Patent Rights. Janssen shall have the right to consult with Protagonist regarding such enforcement or defense of any Retained Patent Rights, and to comment thereon to Protagonist, or at Protagonist's request, to Protagonist's designated outside counsel. Protagonist shall reasonably consider in good faith all such comments offered by Janssen; *provided, however*, that all final decisions respecting conduct of such enforcement or defense shall rest solely in the discretion of Protagonist, so long as such decisions do not adversely impact the Protagonist IL23 Receptor Inhibitor Patent Rights.

8.5.4. For any action to terminate any infringement of Protagonist Patent Rights (other than the Protagonist-Controlled Patent Rights) or Joint Collaboration Patent Rights, or any misappropriation or misuse of Protagonist Know-How, if Janssen is unable to initiate or prosecute such action solely in its own name (where it is permitted to do so under Sections 8.5.2 and 8.5.3), Protagonist shall join such action voluntarily, and shall execute and cause its Affiliates to execute all documents necessary for Janssen to initiate litigation to prosecute and maintain such action. Janssen shall reimburse Protagonist for its reasonable costs and expenses of participating in such action.

8.5.5. In connection with any action to terminate any infringement of Protagonist Patent Rights (including the Protagonist-Controlled Patent Rights) or Joint Collaboration Patent Rights, or any Janssen Collaboration Patent Rights, the Parties shall cooperate fully and shall provide each other with any information or assistance that either may reasonably request. Each Party shall keep the other informed of developments in any action or proceeding, including, to the extent permissible by law, the consultation and (except with respect to Janssen Collaboration Patent Rights) approval of any settlement negotiations and the terms of any offer related thereto, except as otherwise expressly noted above in Section 8.4.

8.5.6. Any recovery obtained by either or both Janssen and Protagonist in connection with or as a result of any action contemplated by this Section 8.5, whether by settlement or otherwise, shall be shared in order as follows:

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- (a) the Party that initiated and prosecuted the action will [*] in connection with the action;
- (b) the other Party will [*] in connection with the action; and
- (c) the amount of any recovery remaining following such reimbursement will be [*]; *provided, however*, that that any portion of such remaining recovery that [*].

8.5.7. Janssen agrees that neither it nor any Affiliate of Janssen, acting alone or through a Third Party will assert, enforce or seek to assert or enforce any Protagonist IL23 Receptor Inhibitor Patent Rights against Protagonist or any of its Affiliates or licensees with respect to the manufacture, import, use, sale, export or offer for sale of any Retained Compound in the Territory.

8.5.8. Except as expressly provided for herein, neither Protagonist, nor any Affiliate of Protagonist, acting alone or through a Third Party, shall assert, enforce or seek to assert or enforce any Protagonist IL23 Receptor Inhibitor Patent Rights against any Third Party.

8.6. **Patent Term Restoration.** The Parties shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents (“**Patent Term Restoration**”) in any country in the Territory where applicable to Protagonist Patent Rights and Joint Collaboration Patent Rights. Janssen shall be solely responsible for any Patent Term Restoration relating to Janssen Collaboration Patent Rights and, after the Opt-In Effective Date, the Protagonist Patent Rights (other than the Protagonist-Controlled Patent Rights), and shall report to Protagonist on the status thereof through the Patent Representatives, but shall otherwise have no obligation to Protagonist with respect thereto.

8.7. **Third Party Claims.**

8.7.1. Without prejudice to Section 8.5, if any action, suit or proceeding is brought against either Party, or any Affiliate or sublicensee of either Party, alleging the infringement of the intellectual property rights of a Third Party by reason of the Development, making, having made, use, having used, sale, having sold, offering for sale, having offered for sale, import, having imported, or other exploitation or Commercialization of a Licensed Compound or Licensed Product in the Territory, each of the Parties shall have the right, but not the obligation, to defend itself in such action, suit or proceeding at its sole expense, subject to the indemnification obligations set forth in Article 11. The Parties shall cooperate with each other in any defense of any such suit, action or proceeding. The Parties shall give each other prompt written notice of the commencement of any such suit, action or proceeding, or receipt of any claim of infringement, and shall furnish each other a copy of each communication relating to the alleged infringement.

8.7.2. Neither Party shall compromise, litigate, settle or otherwise dispose of any such suit, action or proceeding without the other Party’s advice and prior consent, *provided*

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that the Party not having the right to defend the suit shall not unreasonably withhold or delay its consent to any settlement which does not have a material adverse effect on its rights, obligations or benefits, either under this Agreement or otherwise. Notwithstanding the foregoing, Janssen may seek to obtain a license from the applicable Third Party at its sole cost and expense (subject to the provisions of Section 8.10), *provided* that the terms and conditions of such license do not include an admission of invalidity of any Protagonist Patent Rights or Joint Collaboration Patent Rights, or restrict the other Party's ability to challenge or litigate the validity or applicability of any intellectual property to which the license relates.

8.7.3. The Party first having actual notice of any claim, action or proceeding referenced in Section 8.7.1 shall promptly notify the other Party in writing, setting forth in reasonable detail, to its knowledge, the facts related to any such claim, action or proceeding. The Parties shall promptly discuss proposed responses to any such matters.

8.8. **Product Trademarks.** During the License Term, Janssen shall have (directly and through its Affiliates and Third Party sublicensees Commercializing Licensed Products) 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 such Licensed Products in its own name.

8.9. **Protagonist IL23 Receptor Inhibitor Patent Rights.** During the Term, if Protagonist assigns, sells, transfers or otherwise disposes of any Protagonist IL23 Receptor Inhibitor Patent Right to any Affiliate or Third Party, Protagonist shall, at or prior to consummation of such transaction and as a condition thereto, cause such Affiliate or Third Party to execute and deliver to Janssen an agreement pursuant to which such Affiliate or Third Party agrees to be bound by this Agreement to the same extent as Protagonist with respect to such Protagonist IL23 Receptor Inhibitor Patent Right.

8.10. **Third Party In-Licenses.**

8.10.1. During the Term, Protagonist shall be responsible for the payment of any amounts that become due to any Third Party under any agreement to which Protagonist is a party that is in effect on the Effective Date (including any Existing Protagonist License Agreements) as a result of either Party's activities with respect to the Licensed Compounds or Licensed Products under this Agreement. In the event Janssen makes any such payment to a Third Party, Protagonist shall reimburse Janssen for such amount.

8.10.2. Prior to the Opt-In Effective Date, neither Party shall obtain a license from a Third Party under any Third Party Blocking Intellectual Property Rights without first (i) discussing the proposed license with the other Party, (ii) obtaining the consent of the other Party, (such consent not to be unreasonably withheld, conditioned, or delayed), and (iii) if applicable, agreeing upon the allocation of any royalties or other consideration payable to such Third Party between those related to the use of such Third Party Blocking Intellectual Property Rights for Licensed Compounds or Licensed Products under this Agreement and those related to the use of such Third Party Blocking Intellectual Property

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Rights for any other products covered by such license. Such royalties and other consideration allocable to Licensed Compounds and Licensed Products will, unless otherwise agreed by the Parties, be shared in accordance with the principles set forth in Section 7.2 during the Development Term and be subject to the royalty reduction provisions set forth in Section 7.5.2(a) during the License Term. For the avoidance of doubt, any rights or licenses which a Party obtains under Third Party Blocking Intellectual Property Rights as a result of a merger with or acquisition of a Third Party who had prior to such transaction obtained such Third Party Blocking Intellectual Property Rights shall not be deemed a violation of this Section 8.10.2.

8.10.3. On and after the Opt-In Effective Date, if Janssen or its Affiliate or sublicensee is required, or [*] it necessary for Janssen or one of its Affiliates or sublicensees, to obtain a license from a Third Party under any Third Party Blocking Intellectual Property Rights in a country, Janssen (or its Affiliate or sublicensee) shall have the sole right to obtain such license. Such royalties and other consideration allocable to Licensed Compounds and Licensed Products will, unless otherwise agreed by the Parties, be subject to the royalty reduction provisions set forth in Section 7.5.2(a) during the License Term. On and after the Opt-In Effective Date, Protagonist shall not obtain a license from a Third Party under any Third Party Blocking Intellectual Property Rights without Janssen's prior written consent. For the avoidance of doubt, any rights or licenses which Protagonist obtains under Third Party Blocking Intellectual Property Rights as a result of a merger with or acquisition of a Third Party who had prior to such transaction obtained such Third Party Blocking Intellectual Property Rights shall not be deemed a violation of this Section 8.10.3.

8.10.4. To the extent (a) Protagonist obtains a license from a Third Party after the Execution Date under any Know-How or Patent Rights that (i) fall within the definition of Protagonist Know-How or Protagonist Patent Rights and (ii) are not Third Party Blocking Intellectual Property Rights and (b) the sublicensing of such Know-How or Patent Rights hereunder to Janssen triggers payments to such Third Party under such license agreement, they shall not be automatically sublicensed to Janssen hereunder as Protagonist Know-How or Protagonist Patent Patents unless and until Janssen and Protagonist agree on the appropriate allocation of any royalties or other consideration payable to such Third Party between those related to the use of such Know-How or Patent Rights for Licensed Compounds or Licensed Products under this Agreement and those related to the use of such Know-How or Patent Rights for any other products covered by such license. Such royalties and other consideration allocable to Licensed Compounds and Licensed Products will, unless otherwise agreed by the Parties, be shared in accordance with the principles set forth in Section 7.2 during the Development Term.

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Article 9
CONFIDENTIALITY; PUBLICITY

9.1. **Nondisclosure.**

9.1.1. Each Party agrees that, during the Term and for a period of [*] thereafter, the Party (the “**Receiving Party**”) receiving or holding 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 9.3 and 9.4; and (c) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this Article 9 shall not create or imply any rights or licenses not expressly granted under this Agreement).

9.1.2. Notwithstanding the foregoing, prior to the Opt-In Effective Date (or if this Agreement is terminated prior to the Opt-In Effective Date, the effective date of termination of this Agreement), all Collaboration Information shall be deemed to be Confidential Information of each Party and each Party shall: (a) maintain in confidence all Collaboration Information 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 Collaboration Information to any Third Party without the prior written consent of the other Party, except for disclosures expressly permitted in Sections 9.3 and 9.4; and (c) not use any Collaboration Information for any purpose except those permitted by this Agreement (it being understood that this Article 9 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 Collaboration Information. In addition, prior to the Opt-In Effective Date (or if this Agreement is terminated prior to the Opt-In Effective Date, the effective date of termination of this Agreement), neither Party shall grant any right to any Third Party with respect to any Collaboration Know-How except a Third Party Subcontractor solely for use in conducting Collaboration Activities in accordance with this Agreement.

9.1.3. During the License Term, the Collaboration Information as defined in subsections (a)-(d) of Section 1.20 shall be deemed to be Confidential Information of Janssen for the purposes of this Article 9 and Janssen shall be deemed the Disclosing Party and Protagonist shall be deemed the Receiving Party with respect to such information.

9.2. **Exceptions.** The obligations in Section 9.1 shall not apply to the extent of any portion of the Confidential Information that the Receiving Party can show by competent written evidence:

- (a) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party under this Agreement;

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- (b) is known to the Receiving Party or any of its Affiliates, without any obligation to the Disclosing Party to keep it confidential or any restriction on its use, 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 Collaboration Information prior to the Opt-In Effective Date);
- (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 after due inquiry, is not bound by a duty of confidentiality to the Disclosing Party or restriction on its use;
- (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.

9.3. **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 filing for 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 9.4, complying with Applicable Law (including regulations promulgated by securities exchanges) or court or administrative orders;
- (e) complying with any obligation under this Agreement;
- (f) in communications with existing or bona fide prospective investors, consultants and advisors of the Receiving Party in connection with financing transactions or bona fide prospective financing transactions, 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* that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Third Party who receives Confidential

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Information pursuant to this Section 9.3(f); *provided further, however*, that this Section 9.3(f) does not apply to the disclosure by Protagonist of Collaboration Information (other than the terms of this Agreement) during the Term (or, if the Opt-In Effective Date occurs, after the Term) to any bona fide prospective investor that is, or is an Affiliate of, a pharmaceutical or biotechnology company, except to the extent required and when required, in the reasonable opinion of Protagonist'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 or other Applicable Law;

(g) to its Affiliates and existing or prospective (sub)licensees, 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* 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 9.3(g); and *provided, further, however*, that this Section 9.3(g) does not apply to the disclosure by Protagonist of any Confidential Information of Janssen (other than the terms of this Agreement) during the Term (or, if the Opt-In Effective Date occurs, after the Term) to any prospective (sub)licensee that is, or is an Affiliate of, a pharmaceutical or biotechnology company; 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* 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 9.3(h); *provided, further, however* that this Section 9.3(h) does not apply to the disclosure by Protagonist of Collaboration Information (other than the terms of this Agreement) during the Term (or, if the Opt-In Effective Date occurs, after the Term) to a Third Party that is, or is an Affiliate of, a pharmaceutical or biotechnology company unless and until such Third Party has provided Protagonist with a non-binding written proposal (including financial consideration) for such a transaction and Protagonist's board of directors has determined to engage in negotiations with such Third Party with respect to such proposal.

If and whenever any Confidential Information is disclosed in accordance with this Section 9.3, 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

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foregoing, (x) in the event a Party intends to make a disclosure of the other Party's Confidential Information pursuant to Section 9.3(c) or Section 9.3(d), it will, except where impracticable or not legally permitted, give [*] advance notice (or, if [*] notice is not possible under the circumstances, 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 (but no less than reasonable efforts); and (y) in the event Protagonist intends to make a disclosure of Collaboration Information or Janssen's Confidential Information pursuant to Section 9.3(f), 9.3(g) or 9.3(h), it will give [*] notice of such disclosure to Janssen (which need not include the name of the party accessing Collaboration Information or Janssen's Confidential Information or the nature of the transaction being contemplated).

9.4. **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 9.3, 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 9.4, 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 in a timely manner.

9.5. **Public Announcements.**

9.5.1. Each Party may, but is not obligated to, make a public announcement of the execution of this Agreement in the forms attached as Exhibits F and G to this Agreement, which shall be issued at a time to be mutually agreed by the Parties no later than two (2) Business Days after the Execution Date.

9.5.2. Except as required to comply with Applicable Law or as permitted by Section 9.3, 9.4 or 9.5.1, each Party agrees not to issue any press release or other public statement disclosing any information relating to this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. If 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. Notwithstanding the foregoing, once information relating to this Agreement has been publicly disclosed as permitted under this Agreement, neither Party shall be required to obtain the other Party's consent or provide notice of its further public disclosure, provided that such information remains accurate and not misleading in all material respects at the time of such further public disclosure.

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9.6. **Requirement to Cooperate to Enable Accurate Public Disclosure.** To the extent either Party discloses to the other Party any Confidential Information which is a fact, result or event relating to the Development or Commercialization of any Licensed Compound or Licensed Product or the Collaboration Activities that the receiving Party in good faith reasonably believes is insufficient to allow the receiving Party to fully understand the materiality of such Confidential Information for purposes of determining whether the receiving Party is required to disclose, to any Governmental Authority or publicly, any such Confidential Information in order to comply with Applicable Law (including securities laws or regulations and the applicable rules of any public stock exchange), the Disclosing Party agrees to discuss such Confidential Information with the Receiving Party to enable the Receiving Party to assess the materiality of such information for such public disclosure purposes.

9.7. **Prior Non-Disclosure Agreement.** As of the Execution Date, the terms of this Article 9 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 under this Agreement.

9.8. **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 9. 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 9.

9.9. **Scientific Publications.** Either Party 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 Licensed Compound or Licensed Product, *provided* that (a) Janssen shall not have such right until after the Opt-In Effective Date, except with Protagonist's prior written consent, which consent will not be unreasonably withheld, (b) the other Party shall first have the right to review and comment on a draft of any such material proposed for publication by such Party, including for purposes of ensuring that none of its Confidential Information is disclosed without its consent, and (c) such Party may not include any Confidential Information of the other Party in such publication without the other Party's prior written consent, which consent will not be unreasonably withheld. The publishing Party shall deliver a complete draft to the other Party at least [*] ([*] in the case of abstracts) prior to submitting the material to a publisher or initiating any other release. The non-publishing Party shall review any such material and give its comments to the publishing Party within [*] ([*] in the case of abstracts) after the delivery of such draft to the non-publishing Party, and the publishing Party shall consider such comments in good faith. The publishing Party shall comply with the non-publishing Party's request to: delete from any such proposed publication material prior to its submission or release any references to the non-publishing Party or any of its Confidential Information; or delay any submission or release for a period of up to an additional [*] to permit the non-publishing Party to prepare and file, or have prepared and filed, any patent applications for any Collaboration Inventions as contemplated hereunder. For the avoidance of doubt, this Section 9.9 shall not apply to public

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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 markets in other countries, as applicable, which are governed by Sections 9.4 and 9.5.

9.10. **Attorney-Client Privilege.** Neither Party is waiving, nor shall be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges as a result of disclosing information pursuant to this Agreement (including Confidential Information related to pending or threatened litigation) to the Receiving Party, regardless of whether the Disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties: (a) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections; (b) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (c) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the Disclosing Party's Confidential Information covered by such protections and privileges relates; and (d) intend that after the Execution Date both the Receiving Party and the Disclosing Party shall have the right to assert such protections and privileges.

Article 10 REPRESENTATIONS AND WARRANTIES

10.1. **Mutual Representations and Warranties.** Each Party represents and warrants to the other Party that, as of the Execution Date:

10.1.1. 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;

10.1.2. this Agreement has been duly executed by it and constitutes a legal, valid and binding obligation of it, enforceable in accordance with its terms;

10.1.3. 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 Governmental Authority having jurisdiction over it, subject to obtaining any required clearance of this Agreement under the HSR Act; and

10.1.4. it has not granted any right to any Third Party that would conflict with the rights granted to the other Party under this Agreement, except as set forth in Schedule 10.1.4.

10.2. **Mutual Covenants.** Each Party covenants that it 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 Execution Date to a Third Party under any intellectual property that is Controlled by the granting Party on the Execution Date that would

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conflict with the rights to such intellectual property granted to the other Party under this Agreement).

10.3. **Additional Representations and Warranties of Protagonist.** Protagonist represents and warrants to Janssen that, as of the Execution Date:

10.3.1. Schedule 10.3.1 lists all Patent Rights existing as of the Execution Date that are owned or licensed by Protagonist or any of its Affiliates and that include any claim Covering any Licensed Compound or Licensed Product (as it exists on the Execution Date), or its formulation, Manufacture or use, as each is contemplated as of the Execution Date (the “**Existing Protagonist Patents**”);

10.3.2. Schedule 10.3.2 identifies any agreement existing as of the Execution Date between Protagonist or any of its Affiliates and a Third Party pursuant to which any Existing Protagonist Patents or Existing Protagonist Know-How are licensed to Protagonist or any of its Affiliates (each, an “**Existing Protagonist License Agreement**”); each Existing Protagonist License Agreement is in effect and is valid and binding on Protagonist or its Affiliate, enforceable in accordance with its terms, and neither Protagonist nor any of its Affiliates, nor to the knowledge of Protagonist, any other party thereto, is in material breach of, or material default under, any Existing Protagonist License Agreement, 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 Protagonist or any of its Affiliates thereunder;

10.3.3. Protagonist or its Affiliate is the sole and exclusive owner or exclusive licensee of the Existing Protagonist Patents (as specified in Schedule 10.3.1) 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 Protagonist is entitled to grant the licenses under such Patent Rights specified herein;

10.3.4. to the knowledge of Protagonist, Protagonist has the right to use and disclose and to enable Janssen to use and disclose (in each case under appropriate conditions of confidentiality) the Protagonist Know-How existing as of the Execution Date (the “**Existing Protagonist Know-How**”) to the extent that Janssen is granted the right to use and disclose such Existing Protagonist Know-How pursuant to this Agreement;

10.3.5. neither Protagonist 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 Protagonist Know-How and Existing Protagonist Patents with respect to the Licensed Compounds or Licensed Products under this Agreement;

10.3.6. neither Protagonist nor any of its Affiliates has received written notice of any claim or threatened claim by any Third Party, and Protagonist is not otherwise aware, that (i) any Third Party has any rights to any of the Existing Protagonist Know-How or

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Existing Protagonist Patents, (ii) any of the Existing Protagonist 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 Protagonist or its Affiliate prior to the Execution Date infringed or misappropriated the intellectual property rights of such Third Party;

10.3.7. (i) to Protagonist's knowledge, there are no pending actions, claims, investigations, suits or proceedings against Protagonist or any of its Affiliates, at law or in equity, or before or by any Regulatory Authority, and (ii) neither Protagonist nor any of its Affiliates has received any written notice regarding any pending or threatened actions, claims, investigations, suits or proceedings against Protagonist 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 Protagonist Know-How or Existing Protagonist Patents, and (iii) to Protagonist's knowledge, no Existing Protagonist Patent is the subject of any interference, opposition, cancellation or other protest proceeding;

10.3.8. all current and former officers, employees, agents, advisors, consultants, contractors or other representatives of Protagonist or any of its Affiliates who are inventors of or have otherwise contributed in a material manner to the creation or development of any Protagonist Intellectual Property have executed and delivered to Protagonist or any such Affiliate a valid and enforceable assignment or other agreement regarding the protection of proprietary information and the assignment (or exclusive license) to Protagonist or any such Affiliate of such Person's entire right, title and interest in and to any Protagonist Intellectual Property and, to Protagonist's knowledge, there are no current, potential or outstanding disputes between Protagonist and any party or individual with respect to the foregoing;

10.3.9. to Protagonist's knowledge, no current officer, employee, agent, advisor, consultant or other representative of Protagonist or any of its Affiliates is in violation of any term of any assignment, license, consulting, employment or other agreement regarding the protection of Protagonist Intellectual Property with Protagonist or any such Affiliate;

10.3.10. to the knowledge of Protagonist, there is no actual infringement of any Existing Protagonist Patents by any Third Party;

10.3.11. neither Protagonist 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;

10.3.12. Protagonist and its Affiliates have conducted Development activities with respect to the Licensed Compounds and Licensed Products 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; and

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10.3.13. the peptide with the chemical structure set forth on Schedule 1.62 is the peptide that Protagonist refers to internally as “PTG-200” and that has been the subject of preclinical testing (including IND-enabling studies) conducted by Protagonist and its Affiliates prior to the Effective Date.

10.4. **Additional Representations and Warranties of Janssen.** Janssen represents and warrants to Protagonist that, as of the Execution Date, 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.

10.5. **Additional Representations, Warranties and Covenants.**

10.5.1. **Assignments.** Each Party shall ensure that each individual employee or agent performing activities set forth in the Clinical Development Plan on behalf of such Party or its Affiliate during the Development Term 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.

10.5.2. **Healthcare Compliance.**

(a) *Anti-Kickback and Stark Compliance.*

(1) Each Party represents and warrants to the other Party as of the Execution Date that the Party making such representation and warranty and its Affiliates that are or have been involved in the Development, Manufacturing and Commercialization of Licensed Compounds and Licensed Products are in compliance 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)(collectively, “**Anti-Kickback Laws**”) in connection with its activities under this Agreement. Protagonist represents and warrants to Janssen as of the Execution Date that it has complied with the foregoing in connection with its activities with respect to Licensed Compounds and Licensed Products prior to the Execution Date.

(2) Each Party covenants to the other Party that the Party making such covenant and its Affiliates involved in the Development, Manufacturing and Commercialization of Licensed Compounds and Licensed Products will comply with all Anti-Kickback Laws in connection with its activities under this Agreement.

(3) No part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or

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the ordering of items or services, nor are the payments intended to induce illegal referrals of business.

(b) *Exclusion from Federal Health Care Programs.*

(1) Protagonist represents and warrants to Janssen that it and its Affiliates have conducted their respective activities with respect to the Licensed Compounds and Licensed Products prior to the Execution Date, in accordance with applicable state and federal laws and any applicable regulations regarding Medicare, Medicaid, and other third party-payer programs, if any.

(2) Each Party shall conduct its 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.

(3) Each Party represents and warrants to the other Party, as of the Execution Date, that (A) 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; and (B) 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 Protagonist, did not contract with any employee, contractor, agent, or vendor to perform work relating to the Licensed Compounds and Licensed Products prior to the Execution Date who was excluded from participation in any state or federal healthcare program. Protagonist represents and warrants to Janssen, as of the Execution Date, that it did not contract with any employee, contractor, agent, or vendor to perform work relating to the Licensed Compounds and Licensed Products prior to the Execution Date who was excluded from participation in any state or federal healthcare program.

(4) Each Party represents and warrants to the other Party, as of the Execution Date, that 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.

(5) Each Party shall notify the other Party of any final adverse action, discovery of contract with an excluded entity or individual, or exclusion within [*] of such action.

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10.5.3. **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. 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 [*], provide written confirmation that it has complied with the foregoing obligation.

10.5.4. **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 Protagonist, Protagonist represents and warrants to Janssen that neither Protagonist nor any of its Affiliates has performed any actions in connection with the Licensed Compounds and Licensed Products prior to the Execution Date that are prohibited by Anti-Corruption Laws that were applicable to Protagonist 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.

10.5.5. **Existing Protagonist License Agreements.** Protagonist shall not amend any Existing Protagonist License Agreement in any manner that would adversely affect any rights granted to Janssen hereunder, except with Janssen's prior written consent.

10.6. **Disclaimer of Warranties.** 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 LICENSED COMPOUNDS, LICENSED PRODUCTS OR PATENT RIGHTS THAT ARE LICENSED OR TRANSFERRED TO THE OTHER PARTY 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.

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Article 11
INDEMNIFICATION AND INSURANCE

11.1. Indemnification.

11.1.1. **Indemnification by Janssen.** Subject to Section 11.2, Janssen shall defend, indemnify and hold harmless Protagonist and each of its Affiliates, and each of its and their directors, officers, employees and agents (each, a “**Protagonist 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 Protagonist Indemnified Party resulting from any claim, action or proceeding brought or initiated by a Third Party (“**Third Party Claim**”) against a Protagonist Indemnified Party, to the extent that such Losses arise out of or relate to, directly or indirectly:

- (a) the breach by Janssen of any of its representations, warranties, covenants, or obligations set forth herein;
- (b) the negligence, recklessness or wrongful intentional acts or omissions of any Janssen Indemnified Party; or
- (c) 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 and during the Term (or any post-termination or post-expiration period pursuant to Section 12.6);

except, in each case ((a) through (c)), to the extent such Losses arise directly or indirectly from (i) the breach by Protagonist of any of its representations, warranties, covenants, or obligations set forth herein, (ii) the negligence, recklessness or wrongful intentional acts or omissions of any Protagonist Indemnified Party, or (iii) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Protagonist or any of its Affiliates prior to the Effective Date or during any post-termination or post-expiration period pursuant to Section 12.6.

11.1.2. **Indemnification by Protagonist.** Subject to Section 11.2, Protagonist shall defend, indemnify and hold harmless Janssen and each 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 Losses incurred by any Janssen 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) the breach by Protagonist of any of its representations, warranties, or covenants or obligations set forth herein; and
- (b) the negligence, recklessness or wrongful intentional acts or omissions of any Protagonist Indemnified Party;

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(c) the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product by or on behalf of Protagonist or any of its Affiliates prior to the Effective Date or during any post-termination or post-expiration period pursuant to Section 12.6, or the Development or Manufacture of any Licensed Compound or Licensed Product by or on behalf of Protagonist or any of its Affiliates during the Development Term; or

(d) the research, development, manufacture or commercialization of any Retained Compound by or on behalf of Protagonist or any of its Affiliates.

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, covenants, or obligations 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 and during the Term (or any post-termination or post-expiration period pursuant to Section 12.6).

11.2. **Conditions to Indemnification.** If either a Janssen Indemnified Party or a Protagonist Indemnified Party (each, an “**Indemnified Party**”) intends to seek indemnification under Section 11.1, the Indemnified Party must: (a) give the other Party (the “**Indemnifying Party**”) reasonably prompt written notice upon becoming aware of any Third Party Claim 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 11.2 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. So long as the Indemnifying Party is actively defending such Third Party Claim in good faith, the Indemnified Party shall not settle any such claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the claim as provided above, (i) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (ii) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this Article 11.

11.3. **LIMITATIONS OF LIABILITY.** 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

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SUCH OTHER PARTY) PURSUANT TO THIS Article 11 OR ANY BREACH OF Article 9 (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 ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY (INCLUDING FOR LOST PROFITS, LOST REVENUE, LOST SAVINGS, LOSS OF USE OR DAMAGE TO GOODWILL TO THE EXTENT THEY CONSTITUTE CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES DAMAGES), INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

11.4. **Insurance.** Each Party shall, at its own expense, procure and maintain during the Term and for a period of five (5) years thereafter, insurance policies, including product liability insurance, adequate to cover the activities to be conducted by it and its obligations under this Agreement and which are consistent with normal business practices of prudent companies similarly situated; provided, however, that in no event shall such product liability insurance be written in amounts less than USD \$[*] per claim or per occurrence and annual aggregate. All such insurance shall include worldwide coverage. Prior to the initiation of any clinical trial of a Licensed Compound or Licensed Product, the Party responsible for such clinical trial shall secure, and maintain in full force and effect, clinical trial insurance as required by applicable Law in those territories where such clinical trial shall be conducted. Upon request, each Party shall provide the other Party with a certificate of insurance evidencing the coverage required under this Section 11.4. Such insurance shall not be construed to create a limit of a Party's liability with respect to its obligations under this Agreement. Each Party shall provide the other Party with prompt written notice of cancellation, non-renewal or material change in such insurance that could materially adversely affect the rights of such other Party hereunder, and shall provide such notice within [*] after any such cancellation, non-renewal or material change. Notwithstanding the foregoing, either Party's failure to maintain adequate insurance shall not relieve that Party of its obligations set forth in this Agreement. The Parties acknowledge and agree that Janssen may meet its obligations under this Section 11.4 through self-insurance consistent with the levels set forth herein with prior written notice to Protagonist. In such event, Janssen shall provide a written certification of such self-insurance to Protagonist from upon request.

Article 12 TERM AND TERMINATION

12.1. **Term.** The term of this Agreement (the "**Term**") will commence on the Execution Date and, unless this Agreement is terminated earlier in accordance with Section 4.1.4, Section 4.2.4 or this Article 12, will expire upon expiration of all of the payment obligations under Article 7 with respect to Licensed Products Developed and/or Commercialized by Janssen pursuant to this Agreement. The provisions of Article 1 (Definitions), Article 9 (Confidentiality; Publicity), Article 10 (Representations and Warranties), Article 13 (Dispute Resolution), and Article 14 (Miscellaneous), and Section 12.3 (Termination for Material Breach) and Section 12.5 (HSR

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Filing; Termination Upon HSR Denial), shall become effective on the Execution Date; the other provisions of this Agreement shall not become effective until the Effective Date.

12.2. **Termination by Janssen Without Cause.** Janssen may terminate this Agreement in its entirety at any time without cause by providing [*] prior written notice to Protagonist.

12.3. **Termination for Material Breach.**

12.3.1. A Party (the “**Terminating Party**”) may terminate this Agreement in its entirety if the other Party (the “**Breaching Party**”) has materially breached this Agreement and such material breach has not been cured within [*] (or, if the basis of such material breach is failure to make payment, [*], other than payment of the Opt-In Maintenance Fee, which shall be addressed as set forth in Section 4.1.4(b), and other than payment of the Opt-In Exercise Fee, which shall be addressed as set forth in Section 4.2.4(b)) 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 pursuant to this Section 12.3.1 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. Notwithstanding the foregoing, if such breach (other than a breach of payment obligations) is capable of being cured but 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 [*] after notice of termination is given pursuant to this Section 12.3.1, *provided* that (a) the Breaching Party notifies the other Party of its plan for curing such breach during the Cure Period, (b) the Breaching Party commences such plan during the Cure Period and (c) 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 as provided in this Section 12.3.1 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.

12.3.2. 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 13. Notwithstanding anything to the contrary contained in Section 12.3.1, 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 13 and for [*] thereafter, and no termination pursuant to Section 12.3.1 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 13 and for 10 days thereafter.

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12.4. **Termination for Bankruptcy.**

12.4.1. **Right to Terminate.** 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 [*]), 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**”).

12.4.2. **Provisions for Insolvency.**

(a) All rights and licenses now or hereafter granted by either Party to the other Party under or pursuant to this Agreement, including, for the avoidance of doubt, the licenses granted to Janssen pursuant to Section 6.1 are, for all purposes of Section 365(n) of Title 11 of the United States Code, as amended (such Title 11, the “**Bankruptcy Code**”), licenses of rights to “intellectual property” as defined in the Bankruptcy Code. Upon the occurrence of any Insolvency Event with respect to a Party, such Party agrees that the other Party, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.

(b) Without limiting the generality of the foregoing, Protagonist and Janssen intend and agree that any sale of the Protagonist Intellectual Property licensed hereunder under Section 363 of the Bankruptcy Code shall be subject to Janssen’s rights under Section 365(n), that Janssen cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser “free and clear” of Janssen’s rights under this Agreement and Section 365(n) without the express, contemporaneous consent of Janssen. Further, each Party agrees and acknowledges that all payments by Janssen to Protagonist hereunder, other than the Opt-In Maintenance Fee, Opt-In Exercise Fee, the royalty payments pursuant to Section 7.5, the Milestone Payments pursuant to Section 7.3 and the Sales Milestone Payments pursuant to Section 7.4, the allocation of recoveries under Section 8.5.6 and reimbursements for amounts paid under Third Party Blocking Intellectual Property Rights licenses pursuant to Section 8.10, do not constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code or relate to licenses of intellectual property hereunder.

(c) Protagonist shall, during the Term, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate

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embodiments, to the extent feasible, of all Protagonist Intellectual Property licensed hereunder, in accordance with Section 3.6.3. Protagonist and Janssen acknowledge and agree that “embodiments” of intellectual property within the meaning of Section 365(n) include [*]. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Protagonist under the Bankruptcy Code and any similar laws in any other country in the Territory, Janssen will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same, if not already in Janssen’s or its Affiliates’ possession, will be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon its written request therefor, unless Protagonist elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i) above, following the rejection of this Agreement by or on behalf of Protagonist upon written request therefor by Janssen. Whenever Protagonist or any of its successors or assigns provides to Janssen any of the intellectual property licensed hereunder (or any embodiment thereof) pursuant to this Section 12.4.2, Janssen shall have the right to perform Protagonist’s obligations hereunder with respect to such intellectual property, but neither such provision nor such performance by Janssen shall release Protagonist from liability resulting from rejection of the license or the failure to perform such obligations. Protagonist (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall not interfere with Janssen’s rights under this Agreement, or any agreement supplemental hereto, to such intellectual property (including such embodiments), including any right to obtain such intellectual property (or such embodiments) from another entity, to the extent provided in Section 365(n) of the Bankruptcy Code.

(d) All rights, powers and remedies of Janssen provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code with respect to Protagonist. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, and to be enforceable under Bankruptcy Code Section 365(n):

- (1) the right of access to any intellectual property (including all embodiments thereof) of Protagonist licensed to Janssen pursuant to Section 6.1, or any Third Party with whom Protagonist contracts to perform an obligation of Protagonist under this Agreement, and, in the case of the Third Party, which is necessary for the manufacture, use, sale, import or export of Licensed Compounds and Licensed Products; and
- (2) the right to contract directly with any Third Party to complete the contracted work.

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12.5. **HSR Filing: Termination upon HSR Denial.** If Janssen and Protagonist determine that an HSR Filing is necessary, each Party shall, within ten (10) Business Days of the Execution Date (or such later time as may be agreed to in writing by the Parties), file with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice, and/or with equivalent foreign authorities, any HSR Filing required of it under the HSR Act or applicable antitrust or competition Laws of other jurisdictions in the reasonable opinion of either Party with respect to the transactions contemplated hereby. Neither Party shall seek expedited treatment of any HSR Filing without the other Party's prior written consent. Each Party will use reasonable efforts to do, or cause to be done, all things necessary, proper and advisable to, as promptly as practicable, take all actions necessary to make the filings required of such Party or its Affiliates under the HSR Act. The Parties shall cooperate with one another to the extent necessary in the preparation of any such HSR Filing. Each Party shall be responsible for its own costs, expenses, and filing fees associated with any HSR Filing; *provided, however*, that Janssen shall be solely responsible for any fees (other than penalties that may be incurred as a result of actions or omissions on the part of Protagonist) required to be paid to any governmental agency in connection with making any such HSR Filing. If the Parties make an HSR Filing hereunder, then this Agreement shall terminate (a) at the election of either Party, immediately upon written notice to the other Party, if the U.S. Federal Trade Commission or the U.S. Department of Justice, or an equivalent authority in the European Union, seeks a preliminary injunction under the applicable Antitrust Laws against Janssen and Protagonist to enjoin the transactions contemplated by this Agreement; or (b) at the election of either Party, immediately upon written notice to the other Party, in the event that the HSR Clearance Date shall not have occurred on or prior to [*] after the effective date of the HSR Filing. In the event of such termination, this Agreement shall be of no further force and effect.

12.6. **Effects of Termination or Expiration.**

12.6.1. **Effects of Termination.** If this Agreement is terminated for any reason, then the provisions of this Section 12.6.1 shall apply.

(a) The licenses and other rights granted to Janssen under this Agreement, other than those that expressly survive termination of this Agreement (including the license granted pursuant to Section 6.1.3), shall terminate on the effective date of termination, except as expressly provided in Section 7.5.3 or to the extent necessary to enable Janssen to perform any of its obligations that survive termination.

(b) Janssen shall have no further obligation to commence new Development activities with respect to a Licensed Compound or Licensed Product after the date of notice of termination.

(c) If this Agreement is terminated by Janssen during the conduct of any Phase 2 Activities or Collaboration CMC Activities for the Phase 2 Activities, Protagonist shall have [*] after the date that Janssen notifies Protagonist of termination (or, in the event of termination pursuant to Section 4.1.4 or Section 4.2.4, the date of termination under Section 4.1.4 or Section 4.2.4, as applicable)

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to notify Janssen (i) whether Protagonist elects to have Janssen complete or wind down any such on-going Phase 2 Activities and (ii) whether Protagonist elects to have Janssen wind down or transfer to Protagonist any such ongoing Collaboration CMC Activities. Notwithstanding the foregoing, if Janssen terminates this Agreement pursuant to Section 12.3 or 12.4, then Protagonist shall not have the right to make the election described in this paragraph and Janssen shall wind down any ongoing activities as soon as practicable after the date of notice of termination. The following provisions of this Section 12.6.1(c) shall apply after Protagonist makes such elections.

(1) If Protagonist elects to have Janssen wind down on-going Phase 2 Activities or Collaboration CMC Activities, then Janssen shall wind-down such Phase 2 Activities or Collaboration CMC Activities as soon as practicable, subject to compliance with ethical and legal requirements, and the Parties shall continue to share the costs of such activities in accordance with Section 7.2 until such wind-down is complete.

(2) If Protagonist elects to have Janssen complete on-going Phase 2 Activities, then (x) Janssen shall continue to conduct such Phase 2 Activities in accordance with Article 3, (y) the Parties shall continue to share the Phase 2 Development Costs for such activities in accordance with Section 7.2, except that [*] with respect to any Phase 2 Development Costs incurred after the effective date of termination and (z) Article 2, Article 3 (other than Sections 3.4.5 and 3.4.6), Section 4.2.1, Article 6 and Section 10.5 shall survive to the extent applicable to, or necessary to conduct, such Phase 2 Activities, until the Phase 2 Data Package is delivered by Janssen to Protagonist in accordance with Section 4.2.1.

(3) If Protagonist elects to have Janssen transfer to Protagonist on-going Collaboration CMC Activities, then Janssen shall use Commercially Reasonable Efforts to transfer, and Protagonist shall use Commercially Reasonable Efforts to assume, such activities as promptly as practicable (and, in any event, within [*] after the effective date of termination). The Parties shall continue to share the costs of such activities in accordance with Section 7.2 until the effective date of termination and, thereafter, the costs of such activities shall be borne solely by Protagonist; *provided, however*, that each Party shall bear its own costs associated with the transfer of such Collaboration CMC Activities from Janssen to Protagonist. Protagonist shall reimburse Janssen for any such costs for which Protagonist is solely responsible incurred by Janssen and its Affiliates after the effective date of termination.

(d) If this Agreement is terminated for any reason (other than by Janssen during the conduct of any Phase 2 Activities or Collaboration CMC Activities for

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the Phase 2 Activities, in which case Section 12.6.1(c) shall apply) and Janssen is conducting any Development activity with respect to a Licensed Compound or Licensed Product on the date of notice of termination, then Protagonist shall notify Janssen within [*] after the notice of termination: (i) with regard to any Clinical Trial, whether Protagonist elects to have Janssen (A) complete such Clinical Trial on behalf of Protagonist (unless Janssen has material safety concerns regarding continuation of such Clinical Trial of which it has notified Protagonist in writing), (B) wind down such Clinical Trial as soon as practicable, subject to compliance with ethical and legal requirements or (C) transfer such Clinical Trial to Protagonist as soon as practicable; and (ii) with regard to any other Development activity, whether Protagonist elects to have Janssen wind down or transfer such activity to Protagonist. Notwithstanding the foregoing, if Janssen terminates this Agreement pursuant to Section 12.3 or 12.4, then Protagonist shall not have the right to make the election described in this paragraph and Janssen shall wind down any ongoing Development activities as soon as practicable after the date of notice of termination.

- (1) If Protagonist notifies Janssen of its election to have Janssen complete a Clinical Trial on behalf of Protagonist, Janssen and Protagonist will negotiate in good faith a separate agreement pursuant to which Janssen would complete such Clinical Trial. If the Parties fail to reach agreement within [*] after Protagonist makes such election, Janssen may wind down such Clinical Trial.
- (2) If Protagonist notifies Janssen of its election to have Janssen wind down such Clinical Trial or other Development activity (or fails to provide notice within such [*] period), then Janssen shall wind-down such Clinical Trial or Development activity as soon as practicable, subject to compliance with ethical and legal requirements.
- (3) If Protagonist notifies Janssen of its election to have Janssen transfer such Clinical Trial or other Development activity to Protagonist, then Janssen shall use Commercially Reasonable Efforts to transfer, and Protagonist shall use Commercially Reasonable Efforts to assume, such Clinical Trial or other Development activity as promptly as practicable (and, in any event, within [*]) after the effective date of termination.
- (4) The costs of any such Development activity (other than a Clinical Trial with respect to which the Parties enter into a separate agreement pursuant to Section 12.6.1(d)(1)) shall be borne solely by Janssen until the effective date of termination (or, with respect to the wind-down of a Clinical Trial, through the completion of such Clinical Trial), and thereafter shall be borne solely by Protagonist.
- (5) Each Party shall bear its own costs associated with the transfer of any such Development activity from Janssen to Protagonist.

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(e) Janssen shall, within [*] after the effective date of termination and at Janssen's expense, return or destroy, at Protagonist's election, all Protagonist Know-How and other Confidential Information of Protagonist (*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 9.3, Janssen's use of Commercially Reasonable Efforts to return or destroy such Confidential Information shall satisfy its obligation under this Section 12.6.1(e), and (iii) Janssen may retain and continue to use Protagonist Know-How and other Confidential Information of Protagonist solely to practice any licenses and other rights granted to Janssen under this Agreement that expressly survive expiration of this Agreement.

(f) Janssen shall, and hereby does, assign to Protagonist, as of the effective date of termination, all its right, title and interest in, to and under all of Janssen's and its Affiliates' ownership interest in any Regulatory Documentation solely related to the Licensed Compounds and Licensed Products, including any Regulatory Approvals for the Licensed Compounds and Licensed Products, and Janssen shall transfer all such Regulatory Documentation to Protagonist promptly after the effective date of termination.

(g) Janssen shall, and hereby does, grant to Protagonist, as of the effective date of termination, an exclusive, perpetual, royalty-free (except to the extent set forth in Section 12.6.2), freely sublicensable, transferable license under the Janssen Collaboration Know-How, Janssen Collaboration Patent Rights and Janssen's interest in the Joint Collaboration Patent Rights solely to the extent necessary to Develop, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported, and otherwise exploit, Manufacture and Commercialize Licensed Compounds and Licensed Products in the Field in the Territory.

(h) At Protagonist's request, Janssen shall assign and transfer to Protagonist any inventory of Licensed Compounds or Licensed Products then in Janssen's or any of its Affiliate's possession or control subject to Protagonist's reimbursement of Janssen's reasonable, documented costs incurred in acquiring such inventory and with respect to shipping thereof.

(i) Subject to Section 6.1.3, all Collaboration Information as defined in subsections (a)-(d) of Section 1.20 that is licensed, assigned or transferred to Protagonist pursuant to this Section 12.6.1 shall be deemed to be Confidential Information of Protagonist for the purposes of Article 9 and Protagonist shall be deemed the Disclosing Party and Janssen shall be deemed the Receiving Party with respect to such information.

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(j) Janssen shall take such other actions, and execute any instruments, assignments and documents, as reasonably requested by Protagonist as may be necessary to effect the foregoing provisions of this Section 12.6.1.

12.6.2. **Post-Termination Royalties to Janssen.** If Janssen delivers the Phase 2 Data Package in accordance with Section 4.2.1, and either (i) Janssen does not make the Second Opt-In Election or (ii) at any time after the Second Opt-In Election, Janssen terminates this Agreement pursuant to Section 12.2, Section 12.3 or Section 12.4, then, in exchange for the license granted by Janssen to Protagonist pursuant to Section 12.6.1(g), Protagonist shall be obligated to pay Janssen royalties in accordance with the rates set forth in the table below on Net Sales of Licensed Products containing the Initial Compound sold on or after the effective date of termination by Protagonist or any of its Affiliates or (sub)licensees.

Timing of Date of Notice of Termination	Royalty Rate and Cap
[*]	[*]%
[*]	[*]% up to a maximum of \$[*]
[*]	[*]% up to a maximum of \$[*]
[*]	[*]%, uncapped

The royalty reporting, payment, record-keeping, audit and withholding tax provisions set forth in Sections 7.5.4, 7.6, 7.7 and 7.8, and “Royalty Term” definition set forth in Section 1.109, shall apply *mutatis mutandis* to royalties payable pursuant to this Section 12.6.2. For purposes of this Section 12.6.2, “Net Sales” shall have the meaning given to it in Section 1.69, as if the references to Janssen in such definition were to Protagonist.

12.6.3. **Janssen Confidential Information.** Protagonist shall, within [*] after the effective date of expiration or termination of this Agreement, and at Protagonist’s expense, return or destroy, at Janssen’s election, all Confidential Information of Janssen (*provided* that (i) Protagonist 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 9.3, Protagonist’s use of Commercially Reasonable Efforts to return or destroy such Confidential Information shall satisfy its obligation under this Section 12.6.3, and

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(iii) Protagonist may retain and continue to use Confidential Information of Janssen to practice any licenses and other rights granted to Protagonist under this Agreement that expressly survive expiration or termination of this Agreement).

12.6.4. **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 Sections 3.6.3(a), 6.1.3, 6.3.2 (3rd sentence only), 6.6, 7.2 (solely with respect to Phase 2 Development Costs and Phase 2 CMC Development Costs incurred prior to the effective date of expiration or termination), 7.5 (solely with respect to Net Sales occurring prior to the effective date of such expiration or termination), 7.6, 7.7, 7.8, 8.1, 8.2, 12.4.2(a) (solely with respect to the license granted pursuant to Section 6.1.3) and 12.6, and Articles 9, 11, 13, and 14 shall survive expiration or termination of this Agreement for any reason.

Article 13 DISPUTE RESOLUTION

13.1. **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 13.2.

13.2. **Mediation.**

13.2.1. If the Parties fail to resolve the Dispute pursuant to Section 13.1, 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 [*].

13.2.2. 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

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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.

13.2.3. 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.

13.3. **Arbitration**

13.3.1. If the Parties fail to resolve the Dispute pursuant to Section 13.1 or Section 13.2, and a Party desires to pursue resolution of the Dispute, subject to Section 13.3.10, the Dispute shall be finally resolved by arbitration in accordance with the then current *CPR Rules for Non-Administered Arbitration Rules* (“**CPR Rules**”) (www.cpradr.org), except where they conflict with these provisions, in which case these provisions control. The place of arbitration shall be [*]. All aspects of the arbitration shall be treated as confidential.

13.3.2. 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 [*] experience with a law firm or corporate law department of over [*] or who was a judge of a court of general jurisdiction.

13.3.3. 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 [*] U.S. Dollars (\$[*]) and equitable relief is not sought, a single arbitrator shall be appointed 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.

13.3.4. The hearing on the merits shall be concluded within [*] after the initial prehearing conference and the award shall be rendered within [*] of the conclusion of the hearing, or of any post-hearing briefing, which briefing shall be completed by both sides within [*] after the conclusion of the hearing, unless the arbitrator(s) determine(s), in a reasoned decision, that the interest of justice or the complexity of the case requires that the time limit for concluding the hearing on the merits and/or rendering the award be extended. 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.

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13.3.5. The hearing on the merits will be concluded in [*] or less, unless the arbitrator(s) determine(s), in a reasoned decision, that the interest of justice or the complexity of the case requires that the time limit for concluding the hearing on the merits and/or rendering the award be extended. 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.

13.3.6. The Parties shall allow and participate in discovery in accordance with the United States Federal Rules of Civil Procedure. Unresolved discovery disputes shall be submitted to the arbitrator(s).

13.3.7. 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*.”

13.3.8. 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.

13.3.9. The arbitrator(s) shall render a written opinion stating the reasons upon which the award is based. The Parties consent to the entry of judgment on any award rendered hereunder. Judgment on the award may be entered in any court of competent jurisdiction.

13.3.10. 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.

13.4. **Waiver of Trial by Jury.** EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY.

Article 14 MISCELLANEOUS

14.1. **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 directly liable hereunder for the prompt payment and performance of all their respective obligations and duties 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.

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14.2. **Entire Agreement.** This Agreement together with 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 9 and each Party shall retain all rights and remedies available at law or equity with respect to any breach of the Non-Disclosure Agreement occurring prior to the Execution Date, whether oral or written, regarding such subject matter.

14.3. **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 to carry out the purposes and intent of this Agreement.

14.4. **Binding Effect.** This Agreement and the rights granted herein will be binding upon, and will inure to the benefit of Janssen, Protagonist and their respective lawful successors and permitted assigns.

14.5. **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 of such Party without the other Party's consent;
- (b) either Party 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 the other Party's consent; and
- (c) 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 Section 14.5(a), Section 14.5(b) or Section 14.5(c). 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 14.5 shall be null, void and of no legal effect.

14.6. **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

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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, or in connection with the attribution of data in accordance with good scientific practices. 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.

14.7. **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.

14.8. **Force Majeure Event.** Any delay in performance by a Party under this Agreement shall not be considered a breach of this Agreement if and to the extent such performance is prevented by occurrences beyond the reasonable control of the Party affected, including acts of God, embargoes, governmental restrictions (other than those imposed as a result of such Party's failure to comply with Applicable Law), strikes or other concerted acts of workers, fire, flood, earthquakes, explosions, riots, wars, civil disorder, rebellion or sabotage (but not including delays incident to the ordinary course of drug development); provided, however, the payment of invoices due and owing hereunder may not be delayed by the payor because of a force majeure affecting the payor. The Party suffering such occurrence shall immediately notify the other Party, and any time for performance hereunder shall be extended by the actual time of delay caused by the occurrence so long as the nonperforming Party has not caused such event(s) to occur and takes reasonable efforts to remove the condition. In the event that the suspension of performance continues for [*] after the date such force majeure commences, the Parties shall meet to discuss in good faith how to proceed in order to accomplish the objectives of this Agreement.

14.9. **Independent Contractors.** Neither Party is, nor will be deemed to be, an employee, agent or legal representative of the other Party for any purpose. Neither Party will be entitled to enter into any contracts in the name of, or on behalf of the other Party, nor will a Party be entitled to pledge the credit of the other Party in any way or hold itself out as having authority to do so. It is expressly agreed that Protagonist, on the one hand, and Janssen, on the other hand, are independent contractors, and that this Agreement is an arm's-length agreement between the Parties and shall not constitute or be construed as a partnership, joint venture or agency. All individuals employed by a Party shall be employees of that Party and not of the other Party and all costs and obligations incurred by reason of such employment shall be for the account and expense of such Party.

14.10. **Notices and Deliveries.** Any notice, delivery or other communication required or permitted to be given to either Party hereto shall be in writing unless otherwise specified and shall be deemed to have been properly given and to be effective on the date delivered, if delivered personally, or on the next business day after being sent by reputable overnight courier

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(with delivery tracking provided, signature required and delivery prepaid), in each case to the other Party at the following address (or such other address as a Party may specify in writing pursuant to this Section 14.10):

If to Protagonist:

Protagonist Therapeutics, Inc.
7707 Gateway Blvd., Suite 410
Newark, CA 94560
Attention: President and CEO

with a copy to:

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304
Attention: Barbara A. Kosacz

If to Janssen:

Janssen Biotech, Inc.
800/850 Ridgeview Dr.
Horsham, PA 19044
Attention: President
Facsimile: [*]

with a copy to:

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Attention: General Counsel, Pharmaceuticals
Facsimile: [*]

14.11. **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.

14.12. **Severability.** If any provision of this Agreement is, for any reason, 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. The Parties will in such an instance use their reasonable efforts to replace the invalid or unenforceable provision with a valid and enforceable provision that accomplishes, as nearly as possible, the original intention of the Parties with respect thereto.

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14.13. **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 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 14.10. Notwithstanding anything to the contrary herein, the interpretation and construction of any Patent Rights shall be governed in accordance with the laws of the jurisdiction in which such Patent Rights were filed or granted, as the case may be.

14.14. **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.

14.15. **Counterparts.** 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™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

14.16. **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,” “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; (e) the word “or” has the inclusive meaning that is typically associated with the phrase “and/or” unless the context clearly dictates otherwise because the subjects of the conjunction are mutually exclusive; (f) the word “will” means “shall”; (g) 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; (h) references to a particular entity include such entity’s successors and assigns to the extent not prohibited by this Agreement; (i) 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 (j) 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).

{Signature Page Follows}

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SCHEDULE 1.59

JOHNSON & JOHNSON UNIVERSAL CALENDAR

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2017 UNIVERSAL CALENDAR

	M	T	W	T	F	S	S		M	T	W	T	F	S	S				
JAN (4 Weeks)		2	3	4	5	6	7	8	JUL (4 Weeks)		3	4	5	6	7	8	9		
		9	10	11	12	13	14	15			10	11	12	13	14	15	16		
		16	17	18	19	20	21	22			17	18	19	20	21	22	23		
		23	24	25	26	27	28	29			24	25	26	27	28	29	30		
FEB (4 Weeks)		30	31						AUG (4 Weeks)		31								
				1	2	3	4	5				1	2	3	4	5	6		
		6	7	8	9	10	11	12				7	8	9	10	11	12	13	
		13	14	15	16	17	18	19				14	15	16	17	18	19	20	
		20	21	22	23	24	25	26				21	22	23	24	25	26	27	
MAR (5 Weeks)			27	28					SEP (5 Weeks)			28	29	30	31				
					1	2	3	4								1	2	3	
		6	7	8	9	10	11	12				4	5	6	7	8	9	10	
		13	14	15	16	17	18	19				11	12	13	14	15	16	17	
		20	21	22	23	24	25	26				18	19	20	21	22	23	24	
		27	28	29	30	31						25	26	27	28	29	30		
							1	2										1	
APR (4 Weeks)		3	4	5	6	7	8	9	OCT (4 Weeks)		2	3	4	5	6	7	8		
		10	11	12	13	14	15	16			9	10	11	12	13	14	15		
		17	18	19	20	21	22	23			16	17	18	19	20	21	22		
		24	25	26	27	28	29	30			23	24	25	26	27	28	29		
MAY (4 Weeks)		1	2	3	4	5	6	7	NOV (4 Weeks)		30	31							
		8	9	10	11	12	13	14					1	2	3	4	5		
		15	16	17	18	19	20	21					6	7	8	9	10	11	12
		22	23	24	25	26	27	28					13	14	15	16	17	18	19
												20	21	22	23	24	25	26	
JUN (5 Weeks)			29	30	31				DEC (5 Weeks)			27	28	29	30				
						1	2	3								1	2	3	
		5	6	7	8	9	10	11				4	5	6	7	8	9	10	
		12	13	14	15	16	17	18				11	12	13	14	15	16	17	
		19	20	21	22	23	24	25				18	19	20	21	22	23	24	
		26	27	28	29	30						25	26	27	28	29	30	31	
							1	2											

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SCHEDULE 1.62

PTG-200

[*]

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SCHEDULE 1.97

PROTAGONIST IL23R INHIBITOR PATENT RIGHTS

{Redacted content comprises approximately two and one-half pages.}

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SCHEDULE 3.3.2

PHASE I DATA PACKAGE ADDITIONAL INFORMATION

[*]

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SCHEDULE 3.6.2

THIRD PARTY SUBCONTRACTORS

[*]

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SCHEDULE 10.1.4

EXCEPTIONS TO REPRESENTATIONS AND WARRANTIES

[*]

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SCHEDULE 10.3.1

EXISTING PROTAGONIST PATENTS

Schedule 1.97 is incorporated by reference into this Schedule 10.3.1.

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SCHEDULE 10.3.2

EXISTING PROTAGONIST LICENSE AGREEMENTS

[*]

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EXHIBIT A

CLINICAL DEVELOPMENT PLAN

(See attached)

{Redacted content comprises approximately 11 pages}

[*]

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EXHIBIT B

INITIAL CMC DEVELOPMENT PLAN

[*]

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EXHIBIT C

ASSAY DESCRIPTIONS

[*]

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EXHIBIT D

Summary of Phase 2 Clinical and CMC Development Budget

[*]

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EXHIBIT E

JANSSEN DATA GENERATION, PROCESSING AND STORAGE POLICIES

[*]

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EXHIBIT F

JANSSEN PRESS RELEASE

CONFIDENTIAL — FINAL



News Release

Media Contact:

Brian Kenney
Office: 215-628-7010
Mobile: 215-620-0111

Investor Contacts:

Joseph J. Wolk
Johnson & Johnson
Office: 732-524-1142

Lesley Fishman
Johnson & Johnson
Office: 732-524-3922

**JANSSEN ENTERS INTO WORLDWIDE EXCLUSIVE LICENSE AND COLLABORATION AGREEMENT
WITH PROTAGONIST THERAPEUTICS INC. FOR ORAL INTERLEUKIN-23 RECEPTOR ANTAGONIST DRUG CANDIDATE FOR THE
TREATMENT OF INFLAMMATORY BOWEL DISEASE**

Long-standing relationship between Johnson & Johnson Innovation, Janssen and Protagonist Therapeutics leads to advancement of promising oral drug candidate for Crohn's disease and ulcerative colitis

Horsham, Pa., May 30, 2017 — Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, announced today it has entered into a worldwide exclusive license and collaboration agreement with Protagonist Therapeutics, Inc. (Protagonist) to develop, manufacture and commercialize PTG-200, a first-in-class, oral interleukin (IL)-23 receptor antagonist drug candidate in development for the treatment of Crohn's disease and ulcerative colitis (UC). Under the terms of the agreement and subject to the termination or expiration of any applicable waiting periods under the Hart-Scott-Rodino Act, Protagonist will receive an upfront payment and is eligible to receive development and commercialization milestone payments. If PTG-200 is commercialized, Protagonist would be eligible to receive royalties on net sales, and will also have the option to co-detail in the US. The agreement stems from a long-standing collaboration fostered through a series of equity investments by Johnson & Johnson Innovation — JJDC, Inc. in Protagonist to study and advance oral peptide-based therapeutics.

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Inflammatory bowel disease (IBD), which includes Crohn's disease and UC, affects five million people globally, and the incidence is growing with almost a three-time increase in the U.S. as recently reported by the Centers for Disease Control and Prevention^{1,2}. In addition, many patients who receive treatment today do not achieve remission and approximately 80 percent of patients with Crohn's disease and 30 percent of patients with UC will progress to surgery.³

"The addition of PTG-200 to the Janssen Immunology portfolio builds upon our expertise and leadership in the IL-23 pathway, and we look forward to advancing this novel oral IL-23 receptor antagonist into clinical development," said Susan B. Dillon, PhD, Global Therapeutic Area Head, Immunology, Janssen. "Together with Johnson & Johnson Innovation, we have forged a strong relationship with the Protagonist Therapeutics team over the course of several years. We look forward to continuing a strong and productive collaboration in progressing this novel oral candidate for the treatment of inflammatory bowel disease."

PTG-200, a potential first-in-class oral IL-23R antagonist, is currently in Investigational New Drug (IND) enabling studies and the initiation of a Phase 1 clinical trial is planned in 2017.

"We look to continue to pioneer the science of inflammatory bowel disease and advance novel therapeutics like PTG-200, an oral therapy that targets a validated pathway and acts locally in the gut at the site of disease," said Scott E. Plevy, MD, Disease Area Leader, Inflammatory Bowel Disease, Immunology Therapeutic Area, Janssen. "We're particularly excited to add an oral, peptide-based therapy to our robust portfolio as we aim to address the increasing incidence of inflammatory bowel disease and the growing needs of people living with Crohn's disease and ulcerative colitis around the world."

The transaction is expected to close in the third quarter of 2017.

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at [Twitter.com/JanssenGlobal](https://twitter.com/JanssenGlobal).

¹ World IBD Associations. World IBD Day. Available at <http://worldibdday.org/>. Accessed September 6, 2016.

² CDC 2016. IBD (<https://www.cdc.gov/mmwr/volumes/65/wr/mm6542a3.htm>) 4. Crohn's & Colitis Foundation. *What are Crohn's & Colitis*. <http://www.crohnscolitisfoundation.org>

³ Loftus EV. Progress in the Diagnosis and Treatment of Inflammatory Bowel Disease. *Gastroenterology & Hepatology*. 2011;7(2 Suppl 3):3-16.

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About Johnson & Johnson Innovation

Johnson & Johnson Innovation is working to accelerate scientific innovation at all stages of development worldwide to deliver cutting-edge solutions that solve unmet needs for patients. Johnson & Johnson Innovation provides scientists, entrepreneurs and emerging companies with one-stop access to the broad resources of the Johnson & Johnson Family of Companies across the Pharmaceutical, Medical Devices and Consumer healthcare segments. This includes access to dealmakers, through the innovation centers located in global life science hot spots and Johnson & Johnson Innovation, Janssen Business Development; venture investment, through Johnson & Johnson Innovation-JJDC, Inc.; company incubation, through Johnson & Johnson Innovation, JLABS; as well as R&D, manufacturing and commercialization expertise across all three segments. For more information, visit www.jnjinnovation.com or follow @JNJInnovation.

Cautions Concerning Forward-Looking Statements

This press release contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995, regarding a new license and collaboration agreement and the development, manufacture and commercialization of a new drug candidate. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Biotech, Inc., Janssen Research & Development, LLC, Johnson & Johnson Innovation — JJDC, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: the potential that the expected benefits and opportunities related to the collaboration may not be realized or may take longer to realize than expected; challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success for new products; competition, including technological advances, new products and patents attained by competitors; challenges to patents; manufacturing difficulties or delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson’s Annual Report on Form 10-K for the fiscal year ended January 1, 2017, including under “Item 1A. Risk Factors,” its most recently filed Quarterly Report on Form 10-Q, including under the caption “Cautionary Note Regarding Forward-Looking Statements,” and the company’s subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. The Janssen Pharmaceutical Companies, Johnson & Johnson Innovation — JJDC, Inc. and Johnson & Johnson do not undertake to update any forward-looking statement as a result of new information or future events or developments.

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EXHIBIT G

PROTAGONIST PRESS RELEASE

Protagonist Therapeutics Enters into Worldwide Agreement with Janssen to Co-Develop and Commercialize PTG-200 for Inflammatory Bowel Disease

- Protagonist grants Janssen exclusive, worldwide rights to PTG-200, a first-in-class oral peptide IL-23 receptor antagonist currently in pre-clinical development
- Protagonist to receive a \$50 million upfront payment and potentially up to an additional \$940 million in development and sales milestones; double-digit tiered royalties on net sales
- Protagonist and Janssen to co-fund development through Phase 2; Protagonist retains option to co-detail U.S. prescribers
- Protagonist to host conference call and webcast today, May 30, at 8:00 a.m. Eastern Daylight Time

Newark, California (May 30, 2017): Protagonist Therapeutics, Inc. (Nasdaq: PTGX) today announced that the company has entered into a worldwide license and collaboration agreement with Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, for the co-development and commercialization of PTG-200, Protagonist's first-in-class, oral peptide IL-23 receptor antagonist for all indications including inflammatory bowel disease (IBD). PTG-200 is expected to enter Phase 1 clinical testing in normal healthy volunteers in the second half of 2017. The agreement builds upon a Johnson & Johnson Innovation — JJDC, Inc. Series B venture financing from 2013 in support of the discovery and development of Protagonist's pipeline of oral peptide therapeutics.

"We are very pleased to partner with Janssen, a world-leader in the development of innovative therapies for patients suffering with chronic inflammatory and immunomodulatory diseases. As an oral IL-23 receptor antagonist, PTG-200 nicely complements Janssen's current IBD portfolio," said Dinesh V. Patel, Ph.D., Protagonist's President and Chief Executive Officer. "The funding provided by this transaction enables us to advance our platform and clinical pipeline of innovative peptide drugs, including our lead oral peptide alpha-4-beta-7 integrin antagonist, PTG-100, which is currently in a Phase 2b clinical trial as a potential treatment for ulcerative colitis."

"Our oral peptide PTG-200 works by blocking the IL-23 pathway, a mechanism which has been proven by injectable antibodies, including an approved drug and others in different stages of clinical development," said David Y. Liu, Ph.D., Protagonist's Chief Scientific Officer and Head of R&D. "As evidenced by PTG-200, we believe our technology platform is validated in its ability to generate potential first-in-class oral peptides as the next generation of targeted therapy drugs for IBD."

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Terms of the Collaboration

Under the terms of the license and collaboration agreement, Protagonist will receive an upfront payment of \$50 million from Janssen, and will also be eligible to receive up to an additional \$940 million in development, regulatory, and sales milestones. The development milestones represent significant payments that Protagonist would receive upon completion of each component of the Phase 2a/2b clinical trial in Crohn's disease if Janssen elects to retain its license following each of those events. Janssen will receive exclusive, worldwide rights to develop and commercialize PTG-200, and Protagonist will receive double-digit tiered royalties on net product sales.

Protagonist Therapeutics and Janssen will jointly conduct the development of PTG-200 through Phase 2 clinical proof-of-concept in Crohn's disease, after which time Janssen will be responsible for development and commercialization. Per the terms of the agreement, Protagonist will have the right to co-detail PTG-200 in the United States.

The transaction is expected to close in the third quarter of 2017, subject to customary closing conditions.

Additional details regarding the collaboration can be found in Protagonist's Form 8-K filed today with the Securities and Exchange Commission.

Conference Call and Webcast Information

Protagonist Therapeutics will host a conference call to discuss this transaction at 8:00 a.m. EDT today, May 30, 2017. The live webcast can be accessed under "Calendar of Events" in the Investors section of the company's website at www.protagonist-inc.com. The webcast will be available for replay for 30 days on the company website. Alternatively, investors may listen to the call by dialing toll-free 855-859-2056 from locations in the United States or via toll call +1-404-537-3406 from outside the United States. Please refer to conference ID number 30341699.

About PTG-200

PTG-200 is a first-in-class oral Interleukin-23 receptor (IL-23R) antagonist being co-developed with Janssen initially for the treatment of Crohn's disease. PTG-200 is currently in pre-clinical development studies, and is expected to enter Phase 1 clinical testing in the second half of 2017.

PTG-200 may have the potential to transform the existing IBD treatment paradigm because it is designed to offer significant advantages over injectable antibody drugs, including improved convenience, patient compliance, and the potential for improved safety and tolerability compared to currently approved injectable antibody drugs.

About Protagonist Therapeutics

Protagonist Therapeutics is a clinical-stage biopharmaceutical company with a proprietary technology platform which is utilized to discover and develop novel peptide-based drugs to address significant

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unmet medical needs. Its primary focus is on developing potential first-in-class oral targeted therapy-based peptide drugs that work by blocking biological pathways that are currently targeted by marketed injectable antibody drugs. Protagonist's initial lead peptide product candidates, PTG-100 and PTG-200, are based on this approach, and the company believes these candidates have the potential to transform the existing treatment paradigm for inflammatory bowel disease (IBD), chronic gastrointestinal diseases consisting primarily of ulcerative colitis and Crohn's disease.

PTG-100, a potential first-in-class oral peptide alpha-4-beta-7 integrin antagonist, is currently in a global Phase 2b clinical trial for treatment of moderate-to-severe ulcerative colitis. PTG-200, a first-in-class oral Interleukin-23 receptor antagonist for potential treatment of IBD, initially Crohn's disease, is currently in pre-clinical development and is expected to enter a Phase 1 clinical study in the second half of 2017.

In addition to PTG-100 and PTG-200, the company is developing an injectable hepcidin mimetic PTG-300 as a potential orphan drug for the treatment of rare diseases such as beta-thalassemia. PTG-300 is currently being studied in a Phase 1 clinical trial.

Protagonist is headquartered in Newark, California with its pre-clinical and clinical staff in California, and discovery operations both in California and in Brisbane, Queensland, Australia. For further information, please visit <http://www.protagonist-inc.com>.

Forward Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our intentions or current expectations concerning, among other things, the potential for our programs, the timing of our clinical trials, the potential for eventual regulatory approval and commercialization of our product candidates and our potential receipt of milestone payments and royalties under our collaboration agreement with Janssen. In some cases you can identify these statements by forward-looking words such as "may," "will," "continue," "expect," "potential," or the negative or plural of these words or similar expressions. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, our history of net operating losses, our reliance on third parties and uncertainty regarding our ability to achieve profitability, our ability to develop and commercialize our product candidates, our ability to use and expand our programs to build a pipeline of product candidates, our ability to obtain and maintain regulatory approval of our product candidates, our ability to operate in a competitive industry and compete successfully against competitors that have greater resources than we do, and our ability to obtain and adequately protect intellectual property rights for our product candidates. We discuss many of these risks in greater detail under the heading "Risk Factors" contained in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed with the Securities and Exchange Commission on May 10, 2017. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we

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operate, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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