UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q/A

	Amendment I	No. 1			
(Marl ⊠	QUARTERLY REPORT PURSUANT TO SECTION 13 OR OF 1934.	15(d) OF THE SEC	CURITIES EXCH	ANGE ACT	
	For the quarterly period en	ded June 30, 2016			
	OR				
	TRANSITION REPORT PURSUANT TO SECTION 13 OR OF 1934.	15(d) OF THE SEC	CURITIES EXCH	ANGE ACT	
	For the transition period from	to	_•		
	Commission File No	. 001-36276			
	ULTRAGENYX PHARN (Exact name of registrant as sp		ICAL IN	C.	
	Delaware (State or other jurisdiction of incorporation or organization)		27-2546083 (I.R.S. Employer Identification No.)		
	60 Leveroni Court Novato, California (Address of principal executive offices)		94949 (Zip Code)		
	(415) 483-88 (Registrant's telephone number,				
during	te by check mark whether the registrant (1) has filed all reports required to be the preceding 12 months (or for such shorter period that the registrant was requented for the past 90 days. YES \square NO \square	filed by Section 13 or 15 uired to file such reports	(d) of the Securities an), and (2) has been sub	d Exchange Act of 1934 ject to such filing	
submi	te by check mark whether the registrant has submitted electronically and postected and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chap ant was required to submit and post such files). YES \square NO \square				be
	te by check mark whether the registrant is a large accelerated filer, an accelerations of "large accelerated filer," "accelerated filer" and "smaller reporting com				
	Large accelerated filer \square	Accele	rated filer		
	Non-accelerated filer \qed (Do not check if a smaller reporting comparing \qed	any) Smalle	r reporting company		
Indica	te by check mark whether the registrant is a shell company (as defined in Rule	12b-2 of the Exchange A	Act). YES 🗆 NO 🗹		
As of	August 3, 2016, the registrant had 39,435,593 shares of common stock issued a	nd outstanding.			
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EXPLANATORY NOTE

Ultragenyx Pharmaceutical Inc. (the Company) is filing this Amendment No. 1 (the Amendment) to its Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016 (the Form 10-Q) filed with the Securities and Exchange Commission (the SEC) on August 9, 2016, solely to refile Exhibits 10.1 and 10.2 to the Form 10-Q in response to communications with the SEC's staff regarding a request for confidential treatment made by the Company with respect to portions of these exhibits. Certain information that previously was redacted within Exhibits 10.1 and 10.2 as filed with the Form 10-Q has been disclosed in such exhibits as refiled with this Amendment.

This Amendment is an exhibits-only filing solely for the purpose of filing revised versions of Exhibits 10.1 and 10.2. This Amendment does not affect any other parts of, or exhibits to, the Form 10-Q, and those unaffected parts or exhibits are not included in this Amendment. Except as expressly stated in this Amendment, the Form 10-Q continues to speak as of the date of the original filing of the Form 10-Q, and the Company has not updated the disclosure contained in this Amendment to reflect events that have occurred since the filing of the Form 10-Q. Accordingly, this Amendment must be read in conjunction with the Company's other filings made with the SEC subsequent to the filing of the Form 10-Q, including amendments to those filings, if any.

PART II – OTHER INFORMATION

Item 6. EXHIBITS

		In			
Exhibit Number	Exhibit Description	Form	Date	Number	Furnished or
3.1	Amended and Restated Certificate of Incorporation of Ultragenyx Pharmaceutical Inc.	8-K	2/5/2014	3.1	Filed Herewith
3.2	Ultragenyx Pharmaceutical Inc. Amended and Restated Bylaws	8-K	2/5/2014	3.2	
10.1†	License and Collaboration Agreement by and between Takeda Pharmaceutical Company Limited and Ultragenyx Pharmaceutical Inc., dated June 6, 2016				X
10.2†	Common Stock Purchase Agreement between Ultragenyx Pharmaceutical Inc. and Takeda Pharmaceutical Company Limited, dated as of June 6, 2016				X
10.3#	Offer letter, dated as of April 26, 2016, between the Registrant and Karah Parschauer	10-Q	8/9/2016	10.3	
10.4	Sales Agreement, dated as of July 1, 2016, between Ultragenyx Pharmaceutical Inc. and Cowen and Company, LLC	8-K	7/5/2016	1.1	
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. 1350	10-Q	8/9/2016	32.1	
101.INS	XBRL Instance Document	10-Q	8/9/2016	101.INS	
101.SCH	XBRL Taxonomy Extension Schema Document	10-Q	8/9/2016	101.SCH	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	10-Q	8/9/2016	101.CAL	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	10-Q	8/9/2016	101.DEF	
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document	10-Q	8/9/2016	101.LAB	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	10-Q	8/9/2016	101.PRE	

[†] Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment, and this exhibit has been filed separately with the SEC.

[#] Indicates management contract or compensatory plan

SIGNATURES

Pursuant to the requirements of the Securities	Exchange Act of 1934,	, the registrant has duly	caused this report to	be signed on its beh	alf by the un	ıdersigned
hereunto duly authorized.						

Date: December 9, 2016	By:	/s/ Shalini Sharp
		Shalini Sharp
		Executive Vice President and Chief Financial Officer
		(Principal Financial Officer)

ULTRAGENYX PHARMACEUTICAL INC.

LICENSE AND COLLABORATION AGREEMENT

BY AND BETWEEN

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND **ULTRAGENYX PHARMACEUTICAL INC. JUNE 6, 2016**

1

LICENSE AND COLLABORATIONAGREEMENT

This License and Collaboration Agreement (this "Agreement") is made as of the 6th day of June, 2016 (the "Execution Date") by and between Takeda Pharmaceutical Company Limited, a company incorporated under the laws of Japan having its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan ("Takeda"), and Ultragenyx Pharmaceutical Inc., a company incorporated under the laws of California, having its principal place of business at 60 Leveroni Court, Novato, CA 94949, United States ("Ultragenyx"). Ultragenyx and Takeda are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, Takeda has developed certain compounds and products potentially applicable to rare genetic disease indications;

WHEREAS, Ultragenyx is a pharmaceutical company with significant experience with the development of products for rare genetic disease indications; and

WHEREAS, Ultragenyx and Takeda desire to establish a collaboration for the further development and commercialization of certain products potentially applicable to rare genetic disease and other indications.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1 - DEFINITIONS

1.1	"[***] <u>Development Plans</u> " has the meaning set forth in Section 4.3(b).
1.2	"[***] <u>License Negotiation Period</u> " has the meaning set forth in Section 5.1(a).
1.3	"[***] Option" has the meaning set forth in Section 5.1(a).
1.4	"[***] Option Term" has the meaning set forth in Section 5.1(a).
1.5	"[***] Patent Prosecution" has the meaning set forth in Section 12.3(a).
1.6	"[***] <u>Compound</u> " means [***].

2

CONFIDENTIAL TREATMENT REQUESTED

- 1.7 "[***] Product" means any pharmaceutical product that contains a [***] Compound, including all forms, presentations, strengths, doses and formulations (including any method of delivery).
- 1.8 "[***] Research Plan" has the meaning set forth in Section 6.3(a).
- 1.9 "Accounting Standards" mean GAAP in the case of Ultragenyx and IFRS in the case of Takeda.
- 1.10 "Affiliate" means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise.
- 1.11 "Agreement" has the meaning set forth in the preamble.
- 1.12 "Alliance Manager" means the person appointed by each Party from within their respective organization to coordinate and facilitate the communication, interaction and cooperation of the Parties pursuant to this Agreement.
- 1.13 "Applicable Laws" means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any Governmental Authority, including the U.S. Food, Drug and Cosmetic Act, (21 U.S.C. §301 et seq.) (the "FFDCA"), Prescription Drug Marketing Act, the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335a et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal Civil 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.
- 1.14 "Bankruptcy Laws" has the meaning set forth in Section 15.6(b).
- 1.15 "Bayh-Doyle Act" means the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as well as any regulations promulgated pursuant thereto, including 37 C.F.R. Part 401, and any successor statutes or regulations.
- 1.16 "[***] <u>License Agreement</u>" means the License Agreement by and between Ultragenyx and [***].
- 1.17 "Breaching Party" has the meaning set forth in Section 15.2(a).
- 1.18 "Bulk Drug Product" means a Product that has been Manufactured into a final pharmaceutical product, including drug substance (e.g., tablets or granules) for administration to humans in accordance with Applicable Laws, but has not been Packaged for use in Clinical Trials or for Commercialization.

CONFIDENTIAL TREATMENT REQUESTED

- 1.19 "Business Day" means a day other than Saturday, Sunday or any other day on which commercial banks located in the State of New York, U.S., or Japan, are authorized or obligated by Applicable Laws to close.
- 1.20 "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that
- (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.
- 1.21 "<u>Calendar Year</u>" means the twelve-month period ending on December 31; provided however, that (a) the first Calendar Year of the Term, shall begin on the Effective Date and end on December 31, 2016; and (b) the last Calendar Year of the Term shall end on the date of expiration or termination of this Agreement.
- 1.22 "Candidate Product" has the meaning set forth in Section 6.2(a).
- 1.23 "Change of Control" of Ultragenyx means if: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of Ultragenyx, or if the percentage ownership of such person or entity in the voting securities of Ultragenyx 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 voting securities representing more than fifty percent (50%) of the total voting power of all of the thenoutstanding voting securities of Ultragenyx; (b) the consummation of a merger, consolidation, recapitalization, or reorganization of Ultragenyx, other than any such transaction, which would result in stockholders or equity holders of Ultragenyx, or an Affiliate of Ultragenyx, immediately prior to such transaction owning at least fifty percent (50%) of the outstanding securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the stockholders or equity holders of Ultragenyx approve a plan of complete liquidation of Ultragenyx, or an agreement for the sale or disposition by Ultragenyx of all or a substantial portion of Ultragenyx's assets, other than pursuant to the transaction as described above or to an Affiliate; or (d) the sale or other transfer to a Third Party of all or substantially all of Ultragenyx's assets which relate to this Agreement.
- "Claim" has the meaning set forth in Section 17.1.
- 1.25 "Clinical Trial" means any human clinical study or trial of a pharmaceutical product in the Licensed Field in the Territory, including Phase I Trials, Phase II Trials, Phase III Trials and Phase IV Trials.
- 1.26 "Collaboration Activities" has the meaning set forth in Section 2.2(a).
- 1.27 <u>"Collaboration Term"</u> means (a) with respect to [***] Products, twenty-four (24) months from the Effective Date and (b) other than with respect to [***] Products, five (5) years from the Effective Date, unless, in case of each of the foregoing clauses (a) or (b), (i) extended by mutual agreement of the Parties, or (ii) terminated earlier in accordance with the terms of this

CONFIDENTIAL TREATMENT REQUESTED

Agreement; provided that if at the expiration of the foregoing period, an Option Negotiation Period is then ongoing, the Collaboration Term with respect to such Option Product will automatically extend until the earlier of (A) expiration of such Option Negotiation Period or (B) execution of the applicable Option Product License Agreement.

- 1.28 "<u>Combination Product</u>" means a Product that is comprised of or contains a Compound as an active ingredient together with one (1) or more other active ingredients and is sold by a Party, or any of its Affiliates or sublicensees, either as a fixed dose or as separate doses as one (1) product.
- 1.29 "Commercialization" means all activities undertaken in support of the promotion, marketing, sale and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering the applicable Product to customers) of the applicable Product, including Manufacturing Product for commercial sale, sales force efforts, detailing, advertising, marketing, the creation and approval of Promotional Materials, sales and distribution, pricing, customer and government contracting, and medical affairs, including medical education, medical information, clinical science liaison activities, health economics and outcomes research, publications and investigator initiated research studies. "Commercialize" means to engage in Commercialization activities.
- 1.30 "Commercialization Plan" means, as applicable, (a) a plan prepared by Ultragenyx pursuant to Section 5.3 containing an overview of the general strategy and a high-level budget for the promoting and marketing of the Licensed Products in the Ultragenyx Field in the Territory or (b) a plan prepared by Takeda pursuant to Section 5.3 containing an overview of the general strategy for the promoting and marketing of the Licensed [***] Product in the Takeda Field in the Territory.
- 1.31 "Commercially Reasonable Efforts" means with respect to the efforts to be expended, or considerations to be undertaken, by a Party or its Affiliates with respect to any objective, activity or decision to be undertaken under this Agreement with respect to the Compounds or Products, the commercially reasonable efforts, expertise, and resources commonly used by such Party for a product owned by it or to which it has exclusive rights in the applicable territory, which, as compared with a Product, is of similar market potential, at a similar stage in its development or product life, and involves similar risks, all as measured based upon the facts and circumstances at the time such efforts are due, taking into account issues of: efficacy and safety, the competitiveness of alternative products sold by Third Parties, the product profile (including Labeling), the proprietary protection and regulatory exclusivity, the expected and actual profitability and return on investment, and all other similar relevant factors.
- 1.32 "Committee" has the meaning set forth in Section 2.3(a).
- 1.33 "Common Stock Purchase Agreement" means the common stock purchase agreement entered into on even date hereof by and between Ultragenyx and Takeda (or one of its Affiliates) providing for Takeda's (or one of its Affiliate's) purchase of common stock of Ultragenyx.

5

CONFIDENTIAL TREATMENT REQUESTED

- 1.34 "Competing Product" means [***].
- 1.35 "Compound" means the Licensed [***] Compound, a Licensed Analog Compound, [***] Compound, Candidate Product or Ultragenyx Pipeline Compound, as applicable.
- 1.36 "Confidential Information" means all non-public or proprietary Information disclosed by a Party to the other Party under this Agreement, which may include ideas, inventions, discoveries, concepts, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, inventories, machines, techniques, development and commercialization plans and related information, designs, drawings, computer programs, skill, experience, documents, apparatus, results, clinical and regulatory strategies, regulatory documentation, information and submissions pertaining to, or made in association with, filings with any Regulatory Authority, data, including pharmacological, toxicological and clinical data, analytical and quality control data, manufacturing data and descriptions, Patent and legal data, 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, without regard as to whether any of the foregoing is marked "confidential" or "proprietary," or disclosed in oral, written, graphic, or electronic form. Confidential Information shall include: (a) the terms and conditions of this Agreement; and (b) Confidential Information disclosed by either Party pursuant to the Confidentiality Agreement.
- 1.37 "Confidentiality Agreement" means the Mutual Confidential Disclosure Agreement dated March 13, 2015 by and between Takeda Pharmaceuticals International, Inc. and Ultragenyx Pharmaceutical Inc.
- 1.38 "Control" means, with respect to any Information, Patent, trademark or other intellectual property right, ownership or possession by a Party, including its Affiliates, of the ability (without taking into account any rights granted by one Party to the other Party under the terms of this Agreement) to grant access, a license or a sublicense to such Information, Patent, trademark or other intellectual property right without violating the terms of any agreement or other arrangement with, or necessitating the consent of, any Third Party, at such time that the Party would be first required under this Agreement to grant the other Party such access, license or sublicense.
- 1.39 "<u>Cover</u>", "<u>Covering</u>" or "<u>Covered</u>" means, with respect to a product, technology, process or method, that, in the absence of ownership of or a license granted under a Valid Claim, the practice or Exploitation of such product, technology, process or method would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).
- 1.40 "Cure Period" has the meaning set forth in Section 15.2(a).
- 1.41 "Data Package" means the Final [***] Data Package, Final Phase II Data Package or Final Phase III Data Package, as applicable.

CONFIDENTIAL TREATMENT REQUESTED

- 1.42 "<u>Development</u>" means all non-clinical and clinical drug development activities, including toxicology, pharmacology, and other non-clinical efforts, statistical analysis, the performance of Clinical Trials, including the Manufacturing of the applicable Product for use in the Clinical Trials, or other activities necessary to obtain or maintain, Regulatory Approval of the applicable Products. "Development" shall exclude Commercialization activities. When used as a verb, "<u>Develop</u>" means to engage in Development activities.
- 1.43 "<u>Disclosing Party</u>" has the meaning set forth in Section 14.1.
- 1.44 "<u>Dispute</u>" has the meaning set forth in Section 16.1.
- 1.45 "Effective Date" means the date this Agreement becomes effective, as determined in accordance with Section 18.1.
- 1.46 "EMA" means the European Medicines Agency or any successor agency or authority having substantially the same function.
- 1.47 "EU" means all of the European Union member states as of the applicable time during the Term.
- 1.48 "Execution Date" has the meaning set forth in the preamble.
- 1.49 "Exercised Countries" has the meaning set forth in Section 8.2(c).
- 1.50 "Exercised Product License Agreement" has the meaning set forth in Section 8.2(d).
- 1.51 "Exercised Products" has the meaning set forth in Section 8.2(c).
- 1.52 "Expert" means a disinterested, conflict-of-interest-free individual who is neutral and independent of both Parties and all of their respective Affiliates and sublicensees and who, with respect to a dispute concerning a financial, commercial, scientific or regulatory matter, possesses appropriate expertise to resolve such dispute. Neither the Expert (nor any of the Expert's current or former employers) shall be or have been at any time, to the Knowledge of the Parties, an employee, officer, director or, during the previous five (5) years, a consultant or contractor of either Party or any of its Affiliates.
- 1.53 "Exploit" or "Exploitation" means to research, import, Manufacture, have Manufactured, export distribute, use, have used, sell, have sold, or offer for sale, including to Develop, Commercialize, register, modify, enhance, improve or otherwise dispose of.
- 1.54 "FDA" means the U.S. Food and Drug Administration, or any successor agency thereto.
- 1.55 "<u>Final [***] Data Package</u>" means all information the Parties agree that Ultragenyx shall provide to or give access to Takeda at the conclusion of the activities contemplated under the Initial [***] Development Plan for a given Licensed [***] Product as it relates to the Takeda Field, but which will include at a minimum (a) validated and reproducible tables, listings and graphs, (b) all adverse event listings, safety narratives, CMC data and information, and applicable

CONFIDENTIAL TREATMENT REQUESTED

Regulatory Documentation, (c) preclinical study results and final, if possible, or preliminary toxicology and pharmacology reports, and (d) a preliminary Phase I report and all Phase I clinical data.

- 1.56 "<u>Final Phase II Data Package</u>" means on a Product-by-Product basis, all Information the Parties agree that Ultragenyx shall provide to or give access to Takeda at the conclusion of a Phase II Clinical Trial and after database lock, but which will include at a minimum (a) validated and reproducible tables, listings and graphs, (b) all adverse event listings, safety narratives, CMC data and information, and applicable Regulatory Documentation, (c) final, if possible, or preliminary toxicology and pharmacology reports, (d) the Phase I final report and all Phase I clinical data, and (e) a preliminary Phase II report and all Phase II clinical data.
- 1.57 "<u>Final Phase III Data Package</u>" means, on a Product-by-Product basis, all Information the Parties agree that Ultragenyx shall provide to or give access to Takeda at the conclusion of a Phase III Clinical Trial and after database lock, but which will include at a minimum (a) validated and reproducible tables, listings and graphs, (b) all adverse event listings, material safety narratives, CMC data and information, and applicable Regulatory Documentation, (c) final, if possible, or preliminary toxicology and pharmacology reports, (d) the Phase I final report and all Phase I clinical data to the extent not previously provided to Takeda, and (f) the preliminary Phase III report and all Phase III clinical data.
- 1.58 "Finished Product" means Bulk Drug Product that has been Packaged into a form suitable for use in Clinical Trials or for Commercial purposes (i.e., bottles or blisters), including samples, in accordance with Applicable Laws.
- 1.59 "First Commercial Sale" means, on a country-by-country basis, the first sale of a Product under this Agreement by a Party, its Affiliates or its sublicensees to an end user or prescriber for use, consumption or resale of the Product in a country in the applicable territory in the applicable field where Regulatory Approval of the Product has been obtained and where the sale results in a recordable Net Sale. Sale of a Product under this Agreement by a Party to an Affiliate or a sublicensee of such Party shall not constitute a First Commercial Sale unless such Affiliate or such sublicensee is the end user of such Product. Also, sale of a Product under this Agreement by a Party, its Affiliates or its sublicensees in a jurisdiction where Regulatory Approval for that Product has not yet been attained shall not constitute a First Commercial Sale under this Agreement.
- 1.60 <u>Force Majeure</u>" means any event beyond the reasonable control of the affected Party including: embargoes; war or acts of war, including terrorism; insurrections, riots, or civil unrest; strikes, lockouts or other labor disturbances; epidemics, fire, floods, earthquakes or other acts of nature; or acts, omissions or delays in acting by any governmental authority (including the refusal of the competent government agencies to issue required Regulatory Approvals due to reasons other than the affected Party's negligence or willful misconduct or any other cause within the reasonable control of the affected Party), and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence

8

CONFIDENTIAL TREATMENT REQUESTED

that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances).

- 1.61 "FTE" means eighteen hundred (1800) hours of work per full Calendar Year (or equivalent pro-rata portion thereof for a period less than twelve (12) months) devoted to or in support of the Development of the applicable Products in accordance with the Research Plans or the Manufacturing of a Product or the provision of Research Support (but excluding, for clarity, time spent travelling to and attending meetings under this Agreement and scientific and medical conferences), that is carried out by one or more qualified scientific or technical employees or contract personnel of Takeda or its Affiliates, as such hours are measured in accordance with Takeda's normal time allocation practices. For the avoidance of doubt, FTE only applies to employees of a Party, and does not apply to contractors of Takeda.
- 1.62 "FTE Cost" means, for any period, the FTE Rate multiplied by the number of FTEs in such period.
- 1.63 "FTE Rate" means a rate of [***] per FTE per Calendar Year (pro-rated for the period beginning on the Effective Date and ending at the end of the first Calendar Year) for personnel engaged in Development activities. Such rate shall be adjusted annually, with each annual adjustment effective as of January 1 of each calendar year (with the first such annual adjustment to be made as of January 1, 2018) to correspond with the total percentage change in the Consumer Price Index for All Urban Consumers (CPI-U) for the U.S. City Average, 1982-84 = 100, calculated by the U.S. Bureau of Labor Statistics over the twelve (12)-month period preceding each such January 1.
- 1.64 "GAAP" means generally accepted accounting principles current in the U.S.
- 1.65 "Generic Competition Percentage" means, with respect to any Product in a given country in the Territory or Takeda Territory (as applicable), all units of the Generic Product(s) for such Product, sold in the aggregate in such country divided by the sum of: (a) all units of the Product sold in such country, and (b) all units of the Generic Product(s) sold in the aggregate in such country, where, in each case, the number of units of a Product and each Generic Product sold shall be based on the average of the monthly IMS data (or IMS-equivalent data if IMS data are not available).
- 1.66 "Generic Product" means, on a Product-by-Product and country-by-country basis, any pharmaceutical product sold by a Third Party, other than as a sublicensee to this Agreement that:
- (a) contains the same active ingredients as the applicable Product, in the same dosage form (e.g., oral) as the applicable Product; or (b) is A/B Rated with respect to such Product or otherwise approved by the Regulatory Authority in such country as a substitutable generic for such Product; or (c) is approved in the applicable field by a Regulatory Authority pursuant to an NDA filed by a Third Party under Section 505(b)(2) or 505(j)(2) of the FFDCA (or an equivalent Regulatory Approval Application filed outside the U.S.), contains the active ingredients in the Product, and relies on the finding of safety and/or effectiveness in the Regulatory Approval of the Product. For the purposes of this definition, "A/B Rated" means, inside the U.S., "therapeutically equivalent" as determined by the FDA, applying the definition of

9

CONFIDENTIAL TREATMENT REQUESTED

"therapeutically equivalent" set forth in the preface to the then-current edition of the FDA publication "Approved Drug Products With Therapeutic Equivalence Evaluations and, outside the U.S., such equivalent determination by the applicable Regulatory Authorities as is necessary to permit pharmacists or other individuals authorized to dispense pharmaceuticals under Applicable Law to substitute one product for another product in the absence of specific instruction from a physician or other authorized prescriber under Applicable Law."

- 1.67 "Good Clinical Practices", "GCP" or "cGCP" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines adopted by the International Conference on Harmonization ("ICH"), titled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," (or any successor document) including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time.
- 1.68 "Good Laboratory Practices", "GLP", or "cGLP" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in 21 C.F.R. Part 58 (or any successor statute or regulation), including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable guidelines promulgated under the ICH.
- 1.69 "Good Manufacturing Practices", "GMP", or "cGMP" means the then-current good manufacturing practices required by the FDA, as set forth in the FFDCA, as amended, and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable Applicable Law related to the manufacture and testing of pharmaceutical materials in jurisdictions outside the U.S., including the quality guideline promulgated by the ICH designated ICH Q7A, titled "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients" and the regulations promulgated thereunder, in each case as they may be updated from time to time.
- 1.70 "Governmental Authority" means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).
- 1.71 "Hatch-Waxman Act" means the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. 355, as amended
- 1.72 "House Mark" means the trademark that a Party uses to identify its commercial operations.
- 1.73 "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules promulgated thereunder.
- 1.74 "HSR Conditions" means the following conditions, collectively: (a) the waiting period under the HSR Act shall have expired or earlier been terminated; (b) no injunction (whether

10

CONFIDENTIAL TREATMENT REQUESTED

temporary, preliminary or permanent) prohibiting consummation of the transaction contemplated by this Agreement or any material portion hereof shall be in effect; (c) no judicial or administrative proceeding opposing consummation of all or any part of this Agreement shall be pending; and (d) no requirements or conditions shall have been imposed by the United States Department of Justice or Federal Trade Commission (as applicable) in connection with the filings by the Parties under the HSR Act, other than requirements or conditions that are satisfactory to the Party on whom such requirements or conditions are imposed.

- 1.75 "HSR Filing" means filings with the United States Federal Trade Commission and the Antitrust Division of the United States 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 subject matter of this Agreement, together with all required documentary attachments thereto.
- 1.76 "IFRS" means the International Financial Reporting Standards as promulgated by the International Standards Accounting Board and as they may be updated for time to time.
- 1.77 "IND" means an Investigational New Drug application as defined in the FFDCA, as amended, and applicable regulations promulgated hereunder by the FDA, or a clinical trial authorization application for a product filed with a Regulatory Authority in any other regulatory jurisdiction outside the U.S., the filing of which is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.
- 1.78 "IND Date" means the date on which ownership of Product INDs is transferred or a right of reference is granted pursuant to Section 9.2(a)(i), in the case of transfers or grants to Ultragenyx, or pursuant to Section 9.2(b)(i), in the case of transfers to Takeda..
- 1.79 "Indemnifying Party" has the meaning set forth in Section 17.3(a).
- 1.80 "Indemnitee" has the meaning set forth in Section 17.3(a).
- 1.81 "Information" means information, Inventions, discoveries, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, trade secrets, technology, techniques, designs, drawings, correspondence, computer programs, documents, apparatus, results, strategies, regulatory documentation, information and submissions pertaining to, or made in association with, filings with any Regulatory Authority or patent office, data, including pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions, devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable.
- 1.82 "<u>Initial [***] Development Plan</u>" means the plan (including timeline and budget) covering preliminary Development activities to be completed by Ultragenyx and Takeda (to the extent expressly provided in such plan) for a Licensed [***] Product in the Licensed Field attached

11

CONFIDENTIAL TREATMENT REQUESTED

hereto as Exhibit 1.82, as such plan may be amended from time to time pursuant to Section 2.1(a)(v).

- 1.83 "<u>Inventions</u>" means any and all inventions, discoveries and developments, whether or not patentable, made, conceived or reduced to practice in the course of performance of this Agreement, whether made, conceived or reduced to practice solely by, or on behalf of, Takeda, Ultragenyx, the Parties jointly, or any Affiliate of the same.
- 1.84 "Joint Know-How" means all Information included in the Joint Inventions.
- 1.85 "Joint Intellectual Property" means, collectively, Joint Know-How and Joint Patents.
- 1.86 "Joint Invention" has the meaning set forth in Section 12.1(b).
- 1.87 "Joint Patents" has the meaning set forth in Section 12.3(c).
- 1.88 "Joint Research Committee" or "JRC" has the meaning set forth in Section 2.2(a).
- 1.89 "Joint Steering Committee" or "JSC" has the meaning set forth in Section 2.1(a).
- 1.90 "Knowledge" means, as applied to a Party, that such Party shall be deemed to have knowledge of a particular fact or other matter to the extent that a person within the Knowledge Group knew of such fact or other matter.
- 1.91 "Knowledge Group" means, with respect to each Party, the individuals holding the positions listed on Exhibit 1.91; provided that if one or more of the individuals listed on Exhibit
- 1.191 no longer holds the same position or title set forth opposite his/her name, (a) such person shall continue to be considered part of the Knowledge Group, and (b) his/her replacement shall also be considered part of the Knowledge Group.
- 1.92 "<u>Labeling</u>" means the healthcare professional information or patient information used in the Territory that is part of the Product Regulatory Approval including the package insert, medication guides, company core safety information (CCSI) and company core data sheet (CCDS).
- 1.93 "Lead Regulatory Party" has the meaning set forth in Section 9.1.
- 1.94 "Licensed [***] Compound" means [***] as further described on, and with the chemical structure set forth in, Exhibit 1.94.
- 1.95 "<u>Licensed [***] Know-How</u>" means Information related to the (a) Licensed [***] Compound, Controlled by Takeda as of the Execution Date or during the Term, and/or (b) Licensed Analog Compound specified in the Agreement Controlled by Takeda as of the Execution Date, in each case including data, reports, and materials related to preclinical studies, regulatory filings/correspondence, and chemistry, manufacturing and controls and necessary or

12

CONFIDENTIAL TREATMENT REQUESTED

reasonably useful for the Exploitation of a Licensed [***] Compound or a Licensed Analog Compound.

- 1.96 "<u>Licensed [***] Patent</u>" means the Patent that is Controlled by Takeda as of the Execution Date identified as the Licensed [***] Patent on <u>Exhibit 1.168</u>, and all Patents Controlled by Takeda during the Term that claim priority to such Patent.
- 1.97 "<u>Licensed [***] Product</u>" means any pharmaceutical product that contains the Licensed [***] Compound, including all forms, presentations, strengths, doses and formulations (including any method of delivery).
- 1.98 "Licensed [***] Technology" means the Licensed [***] Patent and Licensed [***] Know-How.
- 1.99 "<u>Licensed Analog Compounds</u>" means (a) the compounds with the chemical structures listed on <u>Exhibit 1.99</u> and (b) any structures defined by [***] where approved by the JSC pursuant to Section 2.1(a)(iii)) [***], that are disclosed in the Licensed [***] Patent and that are developed pursuant to, and as specified in, a mutually agreed research plan conducted by Ultragenyx involving modifications to such structures. <u>Exhibit 1.99</u> shall be updated from time to time to include those chemical structures described in the foregoing subclause (b).
- 1.100 "<u>Licensed Analog Product</u>" means any pharmaceutical product that contains a Licensed Analog Compound, including all forms, presentations, strengths, doses and formulations (including any method of delivery).
- 1.101 "Licensed Field" means [***].
- 1.102 "<u>Licensed Option Product</u>" means any Option Product for which the Parties have executed an Option Product License Agreement.
- 1.103 "<u>Licensed Product</u>" means the Licensed [***] Products and Licensed Analog Products, as applicable.
- 1.104 "<u>Licensed Product Improvement</u>" means any Invention related to the Licensed [***] Compound, Licensed Analog Compounds, or Licensed Products made (a) solely by, or on behalf of, Ultragenyx or its Affiliates or sublicensees under this Agreement or (b) solely by Takeda or its Affiliates under this Agreement. For clarity, (i) employees of Ultragenyx or its Affiliates or sublicensees, or their respective agents or independent contractors receiving consideration from Ultragenyx or its Affiliates or sublicensees in the course of conducting activities under this Agreement, shall be considered "solely by, or on behalf of" pursuant to this Section 1.104, and
- (ii) neither Takeda nor any of its Affiliates shall, under any circumstances under this Agreement, be considered an agent or independent contractor of Ultragenyx or any of its Affiliates or sublicensees for purposes of this Section 1.104.

13

CONFIDENTIAL TREATMENT REQUESTED

- 1.105 "<u>Licensed Product Improvement Patents</u>" means Patents that Cover Licensed Product Improvements that do not claim priority (in accordance with Section 1.129) to the Licensed [***] Patent.
- 1.106 "<u>Licensed Product Royalty Term</u>" means, on a country-by-country and Licensed Product- by-Licensed Product basis, the period commencing on the First Commercial Sale of such Licensed Product in such country in the Territory and ending upon the later of (a) ten (10) years after First Commercial Sale of such Licensed Product in such country, (b) the expiration in such country of the last Valid Claim from the Licensed [***] Patent that Covers the composition, or method of making or using, such Licensed Product, or (c) the expiration of the applicable Regulatory Exclusivity of a Licensed Product.
- 1.107 "<u>Listed Compounds</u>" has the meaning set forth in Section 6.1.
- 1.108 "Loss" has the meaning set forth in Section 17.1.
- 1.109 "<u>Marketing Authorization Application</u>" or "<u>MAA</u>" means an application for Regulatory Approval (but excluding Pricing Approval) in any particular jurisdiction other than the U.S.
- 1.110 "Manufacture" means all activities related to the manufacturing of a Finished Product or Bulk Drug Product, including the manufacture of any ingredient used therein, for Development or Commercialization in the Territory, packaging, in-process and Product testing, validation, release of Product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of Product, ongoing stability tests, Packaging of Bulk Drug Product into Finished Product and regulatory activities related to any of the foregoing.
- 1.111 "NDA" means a New Drug Application or supplemental New Drug Application as contemplated by Section 505(b) of the FFDCA, as amended, and the regulations promulgated thereunder, submitted to the FDA pursuant to Part 314 of Title 21 of the U.S. Code of Federal Regulations, including any amendments thereto.
- 1.112 "Net Sales" means, with respect to any Product and calculated in accordance with Accounting Standards consistently applied across Products, the gross revenue recognized by a Party, its Affiliates and sublicensees for sales of such Product to Third Parties, less the following deductions, to the extent such deductions are paid, incurred or otherwise taken, reasonable and customary, provided to Third Parties, and actually allowed with respect to such sales:
- (a) reasonable cash, trade or quantity discounts, charge-back payments, and rebates actually granted to trade customers, managed health care organizations, pharmaceutical benefit managers, group purchasing organizations and national, state, or local government; and
- (b) credits, rebates or allowances actually allowed upon prompt payment or on account of claims, damaged goods, rejections or returns of such Product, including in connection with recalls, and the actual amount of any write-offs for bad debt (not to exceed one percent (1%)) (provided that an amount subsequently recovered will be treated as Net Sales)

CONFIDENTIAL TREATMENT REQUESTED

(c)	inventory management fees and costs of freight, carrier insurance, and other transportation charges directly							
related to the distribution of such	related to the distribution of such Product; and							
9	taxes, duties or other governmental charges (including (i) any tax such as a value added or similar tax, other than (ii) any payments made to the Pharmaceutical and Medical Device Agency (" <i>Kiko</i> ") based on Section 19 or 22 nd Medical Devices Agency (Act No.192 of 2002)") directly levied on or measured by the billing amount for such nd refunds.							
its Affiliates or sublicensees for or invoiced by a Party, its Affilia	mounts received or invoiced by a Party, its Affiliates or sublicensees for the sale of such Product among a Party, resale shall not be included in the computation of Net Sales hereunder. In any event, any amounts received tes and sublicensees shall be accounted for only once. For purposes of determining Net Sales, a Product shall be come generated from such sale is recognized in accordance with the Accounting Standards. Each Party shall record							

such Net Sales as the "principal" and not the "agent" as defined under the Accounting Standards. For clarity, a particular deduction may only be accounted for once in the calculation of Net Sales and no deductions may be made for the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended). Net Sales shall exclude any samples of a Product transferred

The Net Sales of any Combination Product:

or disposed of at no cost for promotional, Development or educational purposes.

(i) for which the Product(s) and other active ingredient(s) of such Combination Product are sold separately by a Party, or any of its Affiliates or sublicensees, in such country, then Net Sales for such Combination Product in such country shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/(A+B), where A is the average Net Sales price of the Product as the only active ingredient(s), as sold separately by a Party or any of its Affiliates or sublicensees in such country, and B is the average net sales (calculated in a manner analogous to the manner in which Net Sales are calculated as set forth above) price of the other active ingredient(s) in the Combination Product as sold separately by a Party or any of its Affiliates or sublicensees in such country;

(ii) for which the (A) Licensed Product of such Combination Product is/are sold separately by a Party or any of its Affiliates or sublicensees in such country and (B) the other active ingredient(s) in the Combination Product is/are not sold separately by a Party or any of its Affiliates or sublicensees in such country, then Net Sales for such Combination Product in such country shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/D, where A is the average Net Sales price of the Licensed Product as the only active ingredient(s), as sold separately by a Party or any of its Affiliates or sublicensees in such country, and D is the average Net Sales price of the Combination Product as sold separately by a Party or any of its Affiliates or sublicensees in such country; and

(iii) for which neither clause (i) nor clause (ii) above is applicable, the Parties shall determine Net Sales for such Combination Product in such country by mutual agreement

15

CONFIDENTIAL TREATMENT REQUESTED

based on the re	elative contributi	on of the License	d Product and tl	he other active i	ingredient(s)	in the Co	mbination Product.

- 1.113 "Neutral Expert" has the meaning set forth in Section 16.3(a).
- 1.114 "Non-breaching Party" has the meaning set forth in Section 15.2(a).
- 1.115 "Notice Date" has the meaning set forth in Section 16.3(a).
- 1.116 "Option Negotiation Period" has the meaning set forth in Section 6.12(a).
- 1.117 "Option Notice" has the meaning set forth in Section 6.12(a).
- 1.118 "Option Product" means (a) a Candidate Product selected pursuant to Section 6.10 or (b) a [***] Product, as applicable.
- 1.119 "Option Product Improvements" means any Invention related to a [***] Product or another Research Product made (a) solely by, or on behalf of, Ultragenyx or its Affiliates or sublicensees under this Agreement, or (b) solely by Takeda or its Affiliates under this Agreement. For clarity,
- (i) employees of Ultragenyx or its Affiliates or sublicensees, or their respective agents or independent contractors receiving consideration from Ultragenyx or its Affiliates or sublicensees in the course of conducting activities under this Agreement, shall be considered "solely by, or on behalf of" pursuant to this Section 1.119, and (ii) neither Takeda nor any of its Affiliates shall, under any circumstances under this Agreement, be considered an agent or independent contractor of Ultragenyx or any of its Affiliates or sublicensees for purposes of this Section 1.119.
- 1.120 "Option Product Improvement Patents" means Patents Covering Option Product Improvements.
- 1.121 "Option Product Key Terms" has the meaning set forth in Section 6.10(a).
- 1.122 "Option Product Know-How" means all Information Controlled by Takeda as of the Execution Date and during the Term that is necessary or reasonably useful for, as applicable, (a) Ultragenyx to evaluate whether to exercise the Ultragenyx Option or (b) Ultragenyx to Exploit an Option Product solely in accordance with the activities to be performed by Ultragenyx or its Affiliates or sublicensees under the Option Product Research Plan.
- 1.123 "Option Product License Agreement" has the meaning set forth in Section 6.12(a).
- 1.124 "Option Product Patents" means all Patents Controlled by Takeda as of the Execution Date and during the Term that are necessary or reasonably useful for the Exploitation of the Option Product(s) in the Ultragenyx Field in the Territory.
- 1.125 "Option Product Research Plan" has the meaning set forth in Section 6.10(a).
- 1.126 "Option Product Technology" means the Option Product Patents and Option Product Know-How.

CONFIDENTIAL TREATMENT REQUESTED

- 1.127 "Packaging" means all activities related to the preparation of Bulk Drug Product into Finished Product, including application of the approved Labeling. "Packaged" means that Bulk Drug Product has been subject to complete Packaging.
- 1.128 "Party" has the meaning set forth in the preamble.
- 1.129 "<u>Patents</u>" means all patents, including any utility or design patent, and all applications thereof, including any provisional application, whether in the Territory or any other jurisdiction; any other patent or patent application claiming priority to (a) any such specified patent or patent application or (b) any patent or patent application from which such specified patent or patent application claim priority; and (c) all divisionals, continuations, continuations in-part, registrations, reissues, re-examinations, renewals, supplemental protection certificates, or extensions of (a) or (b).
- 1.130 "Patent Term Extension" means any term extensions, supplementary protection certificates and equivalents thereof offering Patent protection beyond the initial term with respect to any issued Patents.
- 1.131 "Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.
- 1.132 "Phase I Trial" means a clinical trial of a Product with the endpoint of determining initial tolerance, safety, pharmacokinetic or pharmacodynamic information in single dose, single ascending dose, multiple dose and/or multiple ascending dose regimens.
- 1.133 "Phase II Trial" means a clinical trial of a Product on patients, including possibly pharmacokinetic, pharmacodynamic and doseranging studies, the principal purposes of which are to make a preliminary determination that such product is safe for its intended use and to obtain sufficient information about such product's efficacy or dose-response information to permit the design of further clinical trials.
- 1.134 "Phase III Trial" means a pivotal clinical trial of a Product on a sufficient number of patients, which trial is designed to (a) establish that a product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed; and (c) pivotal to support submission of a Regulatory Approval Application for such product.
- 1.135 "Phase IV Trial" means a clinical trial of a Product, including pharmacokinetic studies, which trial (a) is not required in order to obtain Regulatory Approval of an indication; and (b) either (i) is required by the Regulatory Authority as mandatory to be conducted on or after the Regulatory Approval of an indication, or (ii) is conducted voluntarily to enhance marketing or scientific knowledge of the product (e.g., providing additional drug profile, outcomes research, safety data or marketing support information, or supporting expansion of product labeling).

CONFIDENTIAL TREATMENT REQUESTED

- 1.136 "PMDA" means Japan's Pharmaceuticals and Medical Devices Agency and any successor agency(ies) or authority having substantially the same function.
- 1.137 "<u>Preexisting Third Party IP</u>" means those intellectual property rights owned or controlled by Third Parties as of the Execution Date that are necessary or reasonably useful for the Exploitation of Licensed Products and which are set forth in <u>Exhibit 1.137</u>.
- 1.138 "<u>Pricing Approval</u>" means governmental approval, agreement, determination or decision establishing prices that can be charged and/or reimbursed for a Product in a jurisdiction where the applicable Governmental Authority or Regulatory Authority approves or determines the pricing of pharmaceutical products.
- 1.139 "Product" means any Licensed [***] Product, Licensed Analog Product, Licensed Option Product or Ultragenyx Pipeline Product, as applicable.
- 1.140 "Product Complaint" means all data, which come to the attention of either Party, its Affiliates or its sub-licensees, concerning any dissatisfaction regarding a Product of such a nature and magnitude that it is required under Applicable Laws to be collected, maintained and reported to a Regulatory Authority, including reports of actual or suspected product tampering, contamination, mislabeling or inclusion of improper ingredients.
- 1.141 "<u>Product IND</u>" means any IND filed in the Territory related to a Product, whether in existence as of the Effective Date or filed with the FDA during the Term, including any supplements or amendments thereto. The Product INDs as of the Execution Date are set forth on Exhibit 1.141.
- 1.142 "Product Liabilities" means all losses, damages, fees, costs and other liabilities incurred by a Party, its Affiliate or its sublicensee and resulting from or relating to the any use of a Compound and/or a Product in a human (including in Clinical Trials and/or pursuant to Commercialization) in the Territory, other than any losses, damages, fees, costs and other liabilities that are a result of a Party's, its Affiliates' or its sublicensee's negligence, willful misconduct or breach of such Party's representations and warranties made hereunder. For the avoidance of doubt, Product Liabilities include, reasonable attorneys' and experts' fees and costs relating to any claim or potential claim against a Party, its Affiliate, or its sublicensee and all losses, damages, fees, costs. Product Liabilities shall not include liabilities associated with recalls and/or the voluntary or involuntary withdrawal of the Compound and/or a Product.
- 1.143 "<u>Promotional Materials</u>" means all written, printed, graphic, electronic, audio or video presentations of information, including journal advertisements, sales visual aids, formulary binders, reprints, direct mail, direct-to-consumer advertising, disease awareness materials, internet postings, broadcast advertisements and sales reminder aides (for example, note pads, pens and other such items, if appropriate) intended for use or used by or on behalf of a Party, its Affiliates or its sublicensees in connection with the Commercialization of a Product in the Territory.

- 1.144 "<u>Product Regulatory Approval</u>" means any Regulatory Documentation filed in the Territory which is related to a Product in the Licensed Field, whether in existence as of the Effective Date or filed with the applicable Regulatory Authority during the Term, including any supplements or amendments thereto.
- 1.145 "Product Trademarks" has the meaning set forth in Section 5.5(a).
- 1.146 "PVA" has the meaning set forth in Section 9.8(a)(i).
- 1.147 "Receiving Party" has the meaning set forth in Section 14.1.
- 1.148 "Regulatory Approval" means any approval or authorization, including Pricing Approvals, of any Regulatory Authority that is necessary for the Manufacture, use, storage, import, transport and/or sale of a Product in accordance with Applicable Laws.
- 1.149 "Regulatory Approval Application" means an NDA or BLA, or any corresponding application for Regulatory Approval in the Territory, including: (a) with respect to the European Union, an MAA filed with the EMA pursuant to the Centralized Approval Procedure or with the applicable Regulatory Authority of a country in Europe with respect to the decentralized procedure, mutual recognition or any national approval procedure; and (b) an MAA filed with the PMDA, including, in each case, all supplements, amendments, variations, extensions and renewals thereof.
- 1.150 "Regulatory Authority" means any applicable Governmental Authority involved in granting Regulatory Approval in a country or jurisdiction in the Territory, including in the U.S., the FDA and any other applicable Governmental Authority in the U.S. having jurisdiction over a Product; in the EU, the EMA or any competent Government Authority in the EU; in Japan, the PMDA; and any other applicable Governmental Authority having jurisdiction over a Product.
- 1.151 "Regulatory Documentation" means, with respect to each Research Product or Licensed Product, all: (a) Regulatory Materials, including all data contained therein and all supporting documents created for, submitted to or received from an applicable governmental agency or Regulatory Authority relating to such Regulatory Materials; and (b) other documentation or Information Controlled by a Party which is necessary or reasonably useful in order to Exploit such Product in the applicable Field in the Territory, including any registrations and licenses, regulatory drug lists, advertising and promotion documents shared with Regulatory Authorities, adverse event files, complaint files and Manufacturing records.
- 1.152 "Regulatory Exclusivity" means any exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a Product in a country or jurisdiction in the Territory, other than a Patent right, including orphan drug exclusivity, pediatric exclusivity, rights conferred in the U.S. under the Hatch Waxman Act, in the EU under Directive 2001/83/EC, as amended, and Regulation (EC) No. 1901/2006, as amended, or in the Biologics Price Competition Act as set forth in the Patient Protection & Affordable Care Act, or rights similar thereto in other countries or regulatory jurisdictions in the Territory.

CONFIDENTIAL TREATMENT REQUESTED

- 1.153 "Regulatory Materials" means, with respect to each Product, all documentation, correspondence, submissions and notifications submitted to or received from a Regulatory Authority that are necessary or reasonably useful in order to Exploit such Product in the applicable field in the Territory. For the avoidance of doubt, Regulatory Materials shall include, with respect to each Product, all INDs, Regulatory Approval Applications, Regulatory Approvals, Pricing Approvals and amendments and supplements for any of the foregoing, as well as the contents of any minutes from meetings (whether in person or by audio conference or videoconference) with a Regulatory Authority.
- 1.154 "Representative Expert" has the meaning set forth in Section 16.3(b).
- 1.155 "Research Materials" has the meaning set forth in Section 6.6(a).
- 1.156 "Research Plan" means a [***] Research Plan or Option Product Research Plan, as applicable.
- 1.157 "Research Product," means a [***] Product, Candidate Product or Option Product, as applicable.
- 1.158 "Research Support" has the meaning set forth in Section 7.1.
- 1.159 "Senior Officer" means the Head of Research & Development or his or her designee, in the case of Takeda and, the Chief Executive Officer or his or her designee, in the case of Ultragenyx.
- 1.160 "Takeda [***] License" means the licenses granted to Takeda in Section 3.2.
- 1.161 "Takeda Field" means [***].
- 1.162 "<u>Takeda Indemnitee</u>" has the meaning set forth in Section 17.1.
- 1.163 "<u>Takeda Option</u>" has the meaning set forth in Section 8.1.
- 1.164 "<u>Takeda Option Field</u>" means all human indications other than the Takeda Field for Licensed [***] Products, and all human indications for Licensed Analog Products, Licensed Option Products and Ultragenyx Pipeline Products.
- 1.165 "<u>Takeda Option Negotiation Period</u>" has the meaning set forth in Section 8.2(d).
- 1.166 "<u>Takeda Option Notice</u>" has the meaning set forth in Section 8.2(c).
- 1.167 "<u>Takeda Option Term</u>" means the period beginning on the Effective Date and ending on the earlier of (a) [***] after the Effective Date or (b) with respect to a Licensed [***] Product, Licensed Analog Product, Licensed Option Product, or Ultragenyx Pipeline Product, as

CONFIDENTIAL TREATMENT REQUESTED

the case may be: (i) [***] after Takeda's receipt of the applicable Final Phase II Data Package for the applicable Licensed [***] Product, Licensed Analog Product or Licensed Option Product, (ii) [***] after Takeda's receipt of the Final Phase II Data Package (or Final Phase III Data Package in the case of [***]) for the applicable Ultragenyx Pipeline Product (other than [***]) and (iii) [***] after Takeda's receipt of the Final Phase II Data Package for [***]. Notwithstanding the foregoing, (a) in the event of a [***] of Ultragenyx [***], the Takeda Option Term will expire with respect to all applicable products (i.e., any Licensed [***] Product, Licensed Analog Product, Licensed Option Term will expire with respect to all applicable products (i.e., any Licensed [***] Product, Licensed Analog Product, Licensed Option Product, or Ultragenyx Pipeline Product) [***] after the closing of such [***].

- 1.168 "<u>Takeda Patents</u>" means the Licensed [***] Patent and any Patent that claims priority (in accordance with Section 1.129) to the Licensed [***] Patent during the Term, and the Ultragenyx Pipeline Improvement Patents Controlled by Takeda or its Affiliates. The Takeda Patents as of the Execution Date are set forth on Exhibit 1.168.
- 1.169 "<u>Takeda Product Infringement</u>" has the meaning set forth in Section 12.6(b)(i).
- 1.170 "<u>Takeda ROFN Territory</u>" means Japan.
- 1.171 "<u>Takeda Royalty Term</u>" means, on a country-by-country and Exercised Product-by- Exercised Product basis, the period commencing on the First Commercial Sale of such Exercised Product in a country in the Takeda Territory by Takeda, its Affiliates, or sublicensees that occurs after Takeda's exercise of the Takeda Option and ending upon the later of (a) ten (10) years after First Commercial Sale of such Exercised Product, (b) the expiration of the last Valid Claim that Covers the composition, or method of making or using, such Exercised Product and issued from the following, as applicable to the particular Exercised Product: a (i) Licensed [***] Patent, (ii) Option Product Patent that Covers a Licensed Option Product that is subject to an active Option Product License Agreement or (iii) Ultragenyx Pipeline Patent that Covers an Ultragenyx Pipeline Product, or (c) the expiration of the applicable Regulatory Exclusivity for such Exercised Product.
- 1.172 "<u>Takeda Territory</u>" means, (i) with respect to Licensed Products and Licensed Option Products, Japan and Asia and (ii) with respect Ultragenyx Pipeline Products, Japan.
- 1.173 "<u>Tax Conditions</u>" means, with respect to the premium being paid by Takeda to Ultragenyx under the Common Stock Purchase Agreement, Ultragenyx's confirmation of receipt of the tax residence certificate (IRS Form 6166) from the U.S. Internal Revenue Service specified in Section 11.11(c) and appropriate submission of such certificate and required forms and information with the Osaka Regional Taxation Bureau.

21

CONFIDENTIAL TREATMENT REQUESTED

- 1.174 "Term" has the meaning set forth in Section 15.1.
- 1.175 "<u>Terminated Product</u>" means any: (a) Option Product for which an Option Product License Agreement has not been executed during the Option Negotiation Period in accordance with Section 6.12(a); (b) Research Product terminated pursuant to Section 6.7(d) or 18.5; (c) Licensed [***] Compound or Licensed [***] Product that reverts to Takeda pursuant to Section 4.3(f); or (d) Licensed Product or Research Product terminated pursuant to Section 15.2, 15.4 or 15.5.
- 1.176 "<u>Territory</u>" means worldwide.
- 1.177 "Third Party" means a Person other than Takeda and Ultragenyx and their respective Affiliates.
- 1.178 "<u>Ultragenyx [***] Know-How</u>" means all Information related to the Licensed [***] Compound Controlled by Ultragenyx during the Term.
- 1.179 "<u>Ultragenyx</u> [***] <u>License</u>" means the licenses granted to Ultragenyx in Section 3.1.
- 1.180 "<u>Ultragenyx [***] Patents</u>" means all Patents Controlled by Ultragenyx or its Affiliates as of the Execution Date or during the Term that are necessary or reasonably useful for the Exploitation of the Licensed [***] Compound or Licensed Analog Compound in the Licensed Field in the Territory, but expressly excluding any Licensed Product Improvement Patents. The Ultragenyx [***] Patents as of the Execution Date are set forth on <u>Exhibit 1.188</u>.
- 1.181 "<u>Ultragenyx [***] Technology</u>" means the Ultragenyx [***] Patents and Ultragenyx [***] Know-How.
- 1.182 "<u>Ultragenyx Field</u>" means the Licensed Field, excluding the Takeda Field.
- 1.183 "<u>Ultragenyx In-License Agreement</u>" means [***] and (g) any other applicable agreement between Ultragenyx (or its Affiliates) and a Third Party under which Takeda is granted a sublicense or other right under this Agreement.
- 1.184 "<u>Ultragenyx Indemnitee</u>" has the meaning set forth in Section 17.2.
- 1.185 "<u>Ultragenyx Know-How</u>" means all Information Controlled by Ultragenyx during the Term that is necessary or reasonably useful to Exploit a Compound or a Product in the Licensed Field.

CONFIDENTIAL TREATMENT REQUESTED

- 1.186 "<u>Ultragenyx Intellectual Property</u>" means, collectively, Ultragenyx Know-How and Ultragenyx Patents.
- 1.187 "<u>Ultragenyx Option</u>" has the meaning set forth in Section 6.11.
- 1.188 "<u>Ultragenyx Patents</u>" means all Ultragenyx [***] Patents, Licensed Product Improvement Patents Controlled by Ultragenyx or its Affiliates, Option Product Improvement Patents Controlled by Ultragenyx or its Affiliates and Ultragenyx Pipeline Patents. The Ultragenyx Patents as of the Execution Date are set forth on <u>Exhibit 1.188</u>.
- 1.189 "<u>Ultragenyx Pipeline Compound</u>" means the active ingredient in an Ultragenyx Pipeline Product.
- 1.190 "<u>Ultragenyx Pipeline Improvements</u>" means any Invention related to an Ultragenyx Pipeline Product made (a) solely by, or on behalf of, Takeda or its Affiliates or sublicensees under this Agreement or (b) solely by Ultragenyx or its Affiliates under this Agreement. For clarity, (i) employees of Takeda or its Affiliates or sublicensees, or their respective agents or independent contractors receiving consideration from Takeda or its Affiliates or sublicensees in the course of conducting activities under this Agreement, shall be considered "solely by, or on behalf of" pursuant to this Section 1.190, and (ii) neither Ultragenyx nor any of its Affiliates shall, under any circumstances under this Agreement, be considered an agent or independent contractor of Takeda or any of its Affiliates or sublicensees for purposes of this Section 1.190.
- 1.191 "<u>Ultragenyx Pipeline Improvement Patents</u>" means Patents that Cover Ultragenyx Pipeline Improvements.
- 1.192 "<u>Ultragenyx Pipeline Patents</u>" means all Patents Controlled by Ultragenyx as of the Execution Date and during the Term that: (a) claim the composition of matter of, or the method of making or using an Ultragenyx Pipeline Product; or (b) are otherwise necessary or reasonably useful to Exploit an Ultragenyx Pipeline Product in the Licensed Field. The Ultragenyx Pipeline Patents for the Takeda Territory as of the Execution Date are set forth on Exhibit 1.188.
- 1.193 "<u>Ultragenyx Pipeline Products</u>" means all products that have entered into Clinical Trials and are Controlled by Ultragenyx or its Affiliates during the Collaboration Term and that Ultragenyx or its Affiliates have rights to Commercialize in the Takeda ROFN Territory, [***]. For purposes of this Section 1.193, "Controlled" shall not include [***]

CONFIDENTIAL TREATMENT REQUESTED

[***].	
1.194	" <u>Ultragenyx Product Infringement</u> " has the meaning set forth in Section 12.6(b)(i).
1.195	" <u>UX[***</u>]" means the compound having Ultragenyx reference number UX[***] as further described on <u>Exhibit 1.195</u> .
1.196	" $\underline{UX[***]}$ " means the compound having Ultragenyx reference number $UX[***]$ as further described on $\underline{Exhibit\ 1.195}$.
1.197	" $\underline{UX[***]}$ " means the compound having Ultragenyx reference number $\underline{UX[***]}$ as further described on $\underline{Exhibit\ 1.195}$.
1.198	" $\underline{UX[***]}$ " means the compound having Ultragenyx reference number $UX[***]$ as further described on $\underline{Exhibit\ 1.195}$.
1.199	" $\underline{UX[***]}$ " means the compound having Ultragenyx reference number $\underline{UX[***]}$ as further described on $\underline{Exhibit\ 1.195}$.
agency of comp	"Valid Claim" means a claim of an issued and unexpired Patent included within the Takeda Patents, the Ultragenyx Patent ents, to the extent such claim has not been revoked, held invalid or unenforceable by a patent office, court or other governmenta etent jurisdiction in a final order, from which no further appeal can be taken, and which claim has not been disclaimed, denied invalid or unenforceable through reissue, re-examination or disclaimer.
1.201	"Validation Research Plan" has the meaning set forth in Section 6.2(b).

ARTICLE 2 – OVERVIEW; MANAGEMENT

Joint Steering Committee for Licensed Products.

2.1

- (a) **Formation and Purpose**. Within thirty (30) days after the Effective Date, the Parties shall promptly establish and convene a Joint Steering Committee (the "Joint Steering Committee" or "JSC") in accordance with Section 2.3(c)(i) that will direct and oversee activities relating to the Licensed Products under this Agreement. The JSC shall consist of representatives and operate by the procedures in accordance with Section 2.3. Except as otherwise provided herein, the role of the Joint Steering Committee shall be:
- (i) to encourage and facilitate ongoing communication and cooperation between the Parties with respect to the Exploitation by the Parties of Licensed Products in the Licensed Field;

24

CONFIDENTIAL TREATMENT REQUESTED

(ii) Party relating to additional compounds Covered by t	to serve as a forum for sharing discoveries and exchanging data and results generated by each he Licensed $[***]$ Patent;
(iii) compounds that are Covered by the Licensed [**	to evaluate and approve the inclusion as Licensed Analog Compounds of additional *] Patent but that do not meet the definition of Licensed Analog Compounds [***];
(iv) of additional compounds that are Covered by the L	to evaluate and approve the exclusion from the definition of Licensed Analog Compounds icensed [***] Patent [***];
(v)	to review and discuss [***] Development Plans and any proposed amendments or revisions to

- the [***] Development Plans;
- (vi) to review and discuss Commercialization Plans including the review and discussion of any amendments to such Commercialization Plans;
- (vii) to review and discuss Licensed Product regulatory issues, including those raised by the joint regulatory affairs working group established pursuant to Section 2.1(a)(viii) and Section 9.4(a);
- (viii) to establish other such working groups or subcommittees, as needed to further the purposes of the Agreement relating to Licensed Products, as mutually agreed by the Parties in writing;
 - (ix) to resolve any disputes referred to the JSC; and
 - (x) to approve or decide such other matters as provided in this Agreement.

(b) JSC Decisions; Final Decision Authority.

- (i) The JSC will make good faith efforts to make all decisions by consensus. Except as set forth in Section 2.1(b)(ii), actions to be taken by the Joint Steering Committee shall be taken only following unanimous vote, with each Party's representatives collectively having one (1) vote. If the Joint Steering Committee fails to reach unanimous agreement on a matter before it for decision for a period in excess of fifteen (15) days from the date first presented to the JSC in writing, either Party may submit such matter for resolution to the Senior Officers of the Parties for attempted resolution by good faith negotiation within thirty (30) days after such notice is received by the Senior Officers.
- (ii) If the Senior Officers of the Parties are unable to resolve such dispute within such thirty (30) day period, such dispute shall be resolved during the Term as follows. For the avoidance of doubt, the right of a Party to make final decisions with respect to any issue

25

CONFIDENTIAL TREATMENT REQUESTED

shall not otherwise diminish or eliminate such Party's obligations under this Agreement, including its obligation to exercise Commercially Reasonable Efforts where required herein.

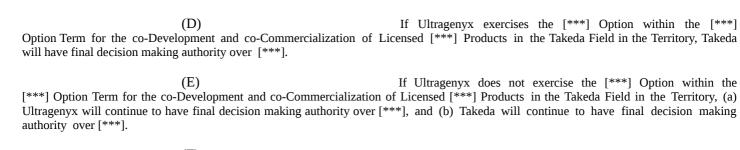
(A) Subject to Sections 2.1(b)(ii)(D) and 2.1(b)(ii)(E) and provided that such decision does not result in an increase in the scope of work or costs associated with the performance of any activities by Takeda under this Agreement, Ultragenyx will have final decision making authority over [***]; and

(B) Takeda will have final decision making authority over [***].

(C) Takeda will have final decision making authority over [***].

26

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(F) Takeda shall have final decision making authority over [***];

(G) Ultragenyx shall have final decision making authority over [***].

(iii) Neither Party shall have the final decision making authority for any other matter under the purview of the JSC and not covered by subsections (A)-(G), and the status quo shall persist with respect to such matter if the Parties are unable to agree. For clarity, the Parties anticipate that Licensed Option Products and Exercised Products will be governed by separate committees and final decision making authority to be established pursuant to the applicable Option Product License Agreement or Exercised Product License Agreement, respectively.

(c) **Discontinuation of JSC.** Upon the second (2nd) anniversary of the Effective Date or any time thereafter, Ultragenyx shall have the right, upon written notice to Takeda, to

27

CONFIDENTIAL TREATMENT REQUESTED

discontinue its participation in the JSC. Once Ultragenyx has provided such notice to Takeda, the JSC shall have no further obligations under this Agreement and, thereafter, Takeda shall have final decision making authority with respect to the topics that were otherwise determined by the JSC, subject to the other terms and conditions of this Agreement.

2.2 Joint Research Committee for Collaboration Activities.

(a) **Formation and Purpose**. Within thirty (30) days after the Effective Date, the Parties shall promptly establish and convene a Joint Research Committee (the "<u>Joint Research Committee</u>" or "<u>JRC</u>") in accordance with Section 2.3(c)(i) for the overall coordination and oversight of the Collaboration Activities. The JRC shall consist of representatives and operate by the procedures in accordance with Section 2.3. Except as otherwise provided herein, the Joint Research Committee shall be responsible for supporting the [***] in assessing, prioritizing, and advancing Takeda's rare genetic disease products, including the following specific activities (collectively, "<u>Collaboration Activities</u>"):

(í۱	review and approve the Validation Research Plan and	any amondments thereto:
ı	IJ	i) ieview and approve the vandation Research Plan and	any amendments mereto,

- (ii) review and approve the Option Product Research Plans and any amendments thereto;
- (iii) review and approve any amendments to the [***] Research Plan;
- (iv) evaluate and prioritize [***];
- (v) support the overall direction of Candidate Product and Option Product strategy;

(vi) identify, define, and support collaborations with key experts and investigators and other third parties in support of the prioritized Candidate Products, Option Products and related indications;

- (vii) identify and implement opportunities [***];
- (viii) determine the [***]; and
- (ix) oversee and manage the secondee program provided for in Section 2.6.

(b) **Termination of Responsibilities.** Upon execution of an Option Product License Agreement for an Option Product, the JRC will no longer have any responsibility over or decision making authority relating to such Option Product.

28

CONFIDENTIAL TREATMENT REQUESTED

(C) JRC Decisions; Final Decision Authority.

- (i) The JRC will make good faith efforts to make all decisions by consensus Except as set forth in Section 2.2(c)(ii), actions to be taken by the Joint Research Committee shall be taken only following unanimous vote, with each Party's representatives collectively having one (1) vote. If the Joint Research Committee fails to reach unanimous agreement on a matter before it for decision for a period in excess of fifteen (15) days from the date first presented to the JRC in writing, either Party may submit such matter for resolution to the Senior Officers of the Parties for attempted resolution by good faith negotiation within thirty (30) days after such notice is received among the Senior Officers.
- (ii) If the Senior Officers of the Parties are unable to resolve such dispute within such thirty (30) day period, such dispute shall be resolved during the Collaboration Term as follows. For the avoidance of doubt, the right of a Party to make final decisions with respect to any issue shall not otherwise diminish or eliminate such Party's obligations under this Agreement, including its obligation to exercise Commercially Reasonable Efforts where required herein.
 - (A) Ultragenyx will have final decision making authority over [***];
 - (B) The Parties must mutually agree on the scope of Research Support to be provided by Takeda. If the Parties are unable to unanimously agree on the scope of the Research Support to be provided, then no Research Support shall be provided;
 - (C) Takeda will have final decision making authority over [***]; and
 - (D) Neither Party shall have the final decision making authority for any other matter under the purview of the JRC and not covered by subsections (A)-(C), and the status quo shall persist with respect to such matter if the Parties are unable to agree. For clarity, the Parties anticipate that Licensed Option Products will be governed by a separate committee and final decision making authority to be established pursuant to the Option Product License Agreement.

2.3 Committee Membership and Procedures.

(a) **Membership.** Takeda and Ultragenyx shall each designate an equal number of representatives to serve on the JSC and the JRC (each, a "<u>Committee</u>") by written notices to the other Party. Promptly after the Effective Date, each Party shall designate three (3)

29

CONFIDENTIAL TREATMENT REQUESTED

representatives for the JSC and three (3) representatives for the JRC. Each Committee may elect to vary the number of representatives from time to time during the Term; provided that each Committee shall maintain an equal number of representatives from each Party. Each representative shall have the appropriate level of experience in the subject area of the Committee, and at least one (1) representative shall have sufficient seniority within the applicable Party's organization to have the necessary decision-making authority in order for the Committee to fulfill its responsibilities. Either Party may designate substitutes for its Committee representatives if one (1) or more of such Party's designated representatives is unable to be present at a meeting. From time to time each Party may replace its Committee representatives by written notice to the other Party specifying the prior representative(s) and their replacement(s).

(b) Chairperson. Each Committee will have two chairpersons, one designated by each of the Parties. The chairpersons shall be responsible for calling and convening meetings, but shall have no special authority over the other members of the Committee, and shall have no additional voting rights. The chairpersons (or their designates) shall jointly: (i) prepare and circulate an agenda reasonably in advance of each upcoming meeting; and (ii) prepare and issue minutes of each Committee meeting within thirty (30) days thereafter. Such minutes shall not be finalized until each Committee representative reviews and approves such minutes in writing; provided that any minutes shall be deemed approved unless a member of such Committee objects to the accuracy of such minutes within fifteen (15) days after the circulation of the minutes.

(c) Meetings.

(i) Committee Meetings. Each Committee shall meet at least once each Calendar Quarter. Additional meetings of the Committees may be held with the consent of each Party (such consent not to be unreasonably withheld, conditioned or delayed), as required under this Agreement. In the case of any dispute referred to a Committee, such meeting shall be held within five (5) Business Days following referral to the Committee, or as soon as reasonably possible.

(ii) **General Requirements.** Meetings of a Committee shall be effective only if a majority of representatives of each Party are present or participating. Other than the initial meeting, which shall be held in person, a Committee may meet either (A) in person at either Party's facilities or at such locations as the Parties may otherwise agree; or (B) by audio or video teleconference. Additional non-members of a Committee having relevant experience may from time to time be invited to participate in a Committee meeting, provided that such participants shall have no voting rights or powers. Non-member participants who are not employees of a Party or its Affiliates shall only be allowed to attend if: (i) the other Party's representatives have consented to the attendance (such consent not to be unreasonably withheld, conditioned or delayed); and (ii) such non-member participant is subject to confidentiality and non-use obligations at least as restrictive as those set forth in this Agreement. Each Party shall be responsible for all of its own expenses incurred in connection with participating in the Committees including all travel and all expenses associated with an initial alliance kick-off meeting. All other expenses incurred by a Committee in furtherance of a meeting, such as expenses associated with off-site meetings, shall be shared equally by the Parties.

30

CONFIDENTIAL TREATMENT REQUESTED

- **Alliance Managers**. Promptly following the Effective Date, each Party shall designate in writing an Alliance Manager to serve as the primary point of contact for the Parties regarding all collaboration and transition activities contemplated under this Agreement. Each Alliance Manager shall facilitate communication and coordination of the Parties' activities under this Agreement relating to the Products and shall plan the Committee meetings. The Alliance Managers shall be allowed to attend Committee meetings as non-voting observers.
- 2.5 **Authority**. The Parties agree that, in voting on matters as described in this ARTICLE 2, it shall be conclusively presumed that unless otherwise explicitly stated, each voting member of a Committee has the authority and approval of such member's respective senior management in casting his or her vote. Each Committee shall have only the powers assigned expressly to it in this ARTICLE 2 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement.
- **Takeda Secondee.** Takeda shall have the right, at its own expense, to place one employee of Takeda or its Affiliates, who is reasonably acceptable to Ultragenyx, as a secondee with Ultragenyx at any time during the Collaboration Term; provided that such secondee shall enter into a confidentiality agreement with Ultragenyx prior to placement. Takeda may, one or more times during the Collaboration Term, substitute such employee with another employee of Takeda or its Affiliates.

ARTICLE 3 - LICENSES FOR [***] AND ANALOGS

- 3.1 **Licenses from Takeda to Ultragenyx.** Subject to the terms and conditions of this Agreement, Takeda hereby grants to Ultragenyx in the Territory during the Term:
- (a) an exclusive (even as to Takeda and its Affiliates, subject to the retention of rights to conduct activities under the [***] Development Plan) license, with the right to grant sublicenses solely in accordance with Section 3.3, under the Licensed [***] Technology, Licensed Product Improvements Controlled by Takeda or its Affiliates, Licensed Product Improvement Patents Controlled by Takeda or its Affiliates, and Joint Intellectual Property to Exploit the Licensed [***] Products in the Ultragenyx Field;
- (b) a co-exclusive license, without the right to grant sublicenses, under the Licensed [***] Technology, Licensed Product Improvements Controlled by Takeda or its Affiliates, Licensed Product Improvement Patents Controlled by Takeda or its Affiliates, and Joint Intellectual Property to conduct activities under the [***] Development Plan in the Takeda Field in the Territory; and
- (c) an exclusive (even as to Takeda and its Affiliates) license, including the right to grant sublicenses solely in accordance with Section 3.3, under the Licensed [***] Technology, Licensed Product Improvements Controlled by Takeda or its Affiliates, Licensed Product Improvement Patents Controlled by Takeda or its Affiliates, and Joint Intellectual Property to Exploit the Licensed Analog Compounds and Licensed Analog Products in the Licensed Field in the Territory; provided, however, that, notwithstanding the licenses granted in this Section 3.1(c), at any time during the Term Ultragenyx shall not, and shall cause its Affiliates not to (i)

31

CONFIDENTIAL TREATMENT REQUESTED

directly or indirectly Exploit any Licensed Analog Product in the Takeda Field or (ii) license, authorize, appoint, or otherwise enable any Third Party to, directly or indirectly, Exploit any Licensed Analog Product in the Takeda Field.

- 3.2 **Licenses from Ultragenyx to Takeda.** Subject to the terms and conditions of this Agreement, Ultragenyx hereby grants to Takeda in the Territory during the Term:
- (a) an exclusive (even as to Ultragenyx and its Affiliates, subject to the retention of rights to conduct activities under the [***] Development Plan) license, with the right to grant sublicenses under multiple tiers solely in accordance with Section 3.3, under the Ultragenyx [***] Technology, Licensed Product Improvements Controlled by Ultragenyx or its Affiliates, Licensed Product Improvement Patents Controlled by Ultragenyx or its Affiliates, and Joint Intellectual Property to (i) Exploit the Licensed [***] Products in the Takeda Field in the Territory, and (ii) Exploit any structures Covered by the Licensed [***] Patent, other than with respect to Licensed Analog Compounds, in the Takeda Field in the Territory.
- (b) a co-exclusive license, without the right to grant sublicenses, under the Ultragenyx [***] Technology, Licensed Product Improvements Controlled by Ultragenyx or its Affiliates, Licensed Product Improvement Patents Controlled by Ultragenyx or its Affiliates, and Joint Intellectual Property to conduct activities under the [***] Development Plan in the Ultragenyx Field in the Territory and to perform the activities under the [***] Development Plan.
- Sublicensing. Each Party shall have the right to grant sublicenses, through multiple tiers, of the rights granted to such Party under Sections 3.1(a) and 3.1(c) (in the case of Ultragenyx) and Section 3.2(a) (in the case of Takeda), to its Affiliates and to Third Parties; provided, however that (a) subject to Section 5.2, Ultragenyx shall not grant a sublicense of the rights granted to it under (i) Section 3.1(a) to a Third Party without the prior written consent of Takeda (not to be unreasonably withheld, conditioned or delayed) or (ii) Section 3.1(c) in the Takeda Field and (b) Takeda shall not grant a sublicense of the rights granted to it under Section 3.2(a) to a Third Party without the prior written consent of Ultragenyx (not to be unreasonably withheld, conditioned or delayed). Each sublicense shall refer to and be subordinate to this Agreement and, except to the extent the Parties otherwise agree in writing, any sublicense must be consistent in all material respects with the terms and conditions of this Agreement. Upon termination of this Agreement, any sublicense granted by Ultragenyx to a Third Party shall continue and be transferred to Takeda and any sublicense granted by Takeda to a Third Party shall continue and be transferred to Ultragenyx; provided that such sublicenses comply with the requirements of this Section 3.3. Each Party shall remain responsible for the performance of this Agreement and the performance of its sublicensees hereunder.
- 3.4 **No Implied Licenses**. No license or other right is or shall be created or granted hereunder by implication, estoppel, or otherwise. All licenses and rights are or shall be granted only as expressly provided in this Agreement. All rights not expressly granted by a Party under this Agreement are reserved by the Party and may not be used by the other Party for any purpose.

32

CONFIDENTIAL TREATMENT REQUESTED

ARTICLE 4 - LICENSED PRODUCT DEVELOPMENT

4.1 **Overview of Product Development**. The Parties desire and intend to collaborate with respect to the Development of the Licensed Product in the Licensed Field in the Territory, to the extent set forth in this Agreement. Takeda's Development of the Licensed [***] Products in the Takeda Field and Ultragenyx's Development of the Licensed [***] Products in the Ultragenyx Field and Licensed Analog Products in the Licensed Field shall be conducted in a manner consistent with the [***] Development Plans and using Commercially Reasonable Efforts.

4.2 Transition and Exchange of Know-How

- (a) Transition from Takeda to Ultragenyx. As soon as practicable after the Effective Date, the Parties will cooperate and act in good faith to support the transition of the Licensed [***] Product from Takeda to Ultragenyx in the Ultragenyx Field and, solely for purposes of Ultragenyx's performance of its obligations under Section 4.3(a)(ii), in the Takeda Field, at no additional consideration payable to Takeda, including the (i) transition and, to the extent appropriate, assignment of Regulatory Materials and Regulatory Approvals covering the Licensed [***] Product in the Ultragenyx Field and, solely for purposes of Ultragenyx's performance of its obligations under Section 4.3(a)(ii), in the Takeda Field, from Takeda to Ultragenyx, (ii) sharing of the Licensed [***] Know-How with Ultragenyx to the extent necessary or reasonably useful for the use of the Licensed [***] Product and the Licensed Analog Products for and implementation of the Initial [***] Development Plan, and (iii) transferring to Ultragenyx, at no cost to Ultragenyx, those biological materials or chemical compounds related to the Licensed [***] Product Controlled by Takeda as of the Execution Date as are necessary for Ultragenyx to perform the activities allocated to it under the Initial [***] Development Plan. Takeda will also use Commercially Reasonable Efforts, at Ultragenyx's sole cost and expense, to assign or sublicense to Ultragenyx any existing Third Party agreements that are necessary or reasonably useful for the Exploitation of a Licensed [***] Product in the Ultragenyx Field in the Territory. Within forty-five (45) days after the receipt of an invoice from Takeda reflecting the costs and expenses of such assignment or sublicense, Ultragenyx shall pay the invoiced amounts to Takeda.
- (b) Know-How Sharing by Ultragenyx. Ultragenyx shall provide to Takeda, promptly after the Effective Date and during the Term upon Ultragenyx Know-How being obtained or generated by Ultragenyx, at no additional cost or expense to Takeda, all such Ultragenyx Know-How as is necessary or reasonably useful to enable Takeda: (a) to perform its obligations under this Agreement; (b) to Exploit the Licensed [***] Product in the Takeda Field, and (c) to Exploit any structures Covered by the Licensed [***] Patent, other than with respect to Licensed Analog Compounds, in the Takeda Field in the Territory.

4.3 **Development Activities**.

(a) Throughout the Term, Ultragenyx will use Commercially Reasonable Efforts to
(i) Exploit a Licensed [***] Product or Licensed Analog Product in the Ultragenyx Field in the Territory and (ii) complete Development activities for a Licensed [***] Product in the Takeda

33

CONFIDENTIAL TREATMENT REQUESTED

(b) If the Parties mutually agree to conduct other Development activities with respect to a Licensed [***] Product other than as set forth in the Initial [***] Development Plan, then the Parties shall prepare a plan (including timeline and budget) covering the Development activities to be completed, the Party responsible for completing such activities, and the Party responsible for the associated costs (together with the Initial [***] Development Plan, the "[***] Development Plans").

Field, in each case at Ultragenyx's sole expense and pursuant to the Initial [***] Development Plan.

(c) If Ultragenyx elects to pursue Development of a Licensed Analog Product, Ultragenyx will use Commercially Reasonable Efforts to Exploit such Licensed Analog Product in the Ultragenyx Field in the Territory at Ultragenyx's sole expense and pursuant to a [***] Development Plan for such Licensed Analog Product.

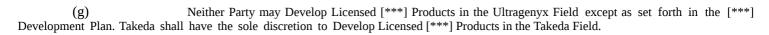
(d) At Ultragenyx's sole expense, Takeda, using Commercially Reasonable Efforts, will (i) conduct initial manufacturing process development and scale-up activities for the Licensed Products as set forth in the Initial [***] Development Plan and in accordance with the agreed upon budget contained therein, (ii) will work with Ultragenyx to transfer Licensed [***] Know-How as necessary or reasonably useful for Development and for the purposes of completing Regulatory Applications, initiating Clinical Trials and for transitioning manufacturing activities to Ultragenyx, and (iii) conduct such other Development and Manufacturing activities as may be mutually agreed by the Parties.

(e) Each Party shall conduct its activities under this Agreement in good scientific manner and in compliance in all material respects with all Applicable Laws, including, GCP, GLP, and GMP.

(f) If Ultragenyx breaches its obligations under Section 4.3(a) or 4.3(c) or is otherwise no longer actively conducting Development of a Licensed [***] Compound and Licensed [***] Product in any indication in the Ultragenyx Field, then [***] of the date Ultragenyx stopped actively conducting such Development, the Ultragenyx [***] License for the Licensed [***] Compound and Licensed [***] Product shall terminate and, [***] of such event, such license shall revert to Takeda and the terms of Section 15.7(c) shall apply with respect to such Compound and Product; provided, that, upon the reversion of rights to Takeda, Takeda shall not develop such Product in the Ultragenyx Field except in accordance with Takeda's exercise of the Takeda Option or right of first negotiation pursuant to ARTICLE 8. If, prior to the effective date of such reversion, Ultragenyx determines it wishes to license such Compound or Product from Takeda in the Ultragenyx Field, Ultragenyx may provide written notice to Takeda. Following receipt of such notice, Takeda and Ultragenyx will negotiate in good faith such license agreement for a period of [***] thereafter, which period may be extended by mutual agreement. Any resulting license agreement will be subject to Takeda's exercise of the Takeda Option or right of first negotiation pursuant to ARTICLE 8.

34

CONFIDENTIAL TREATMENT REQUESTED



4.4 Clinical Trial Registry.

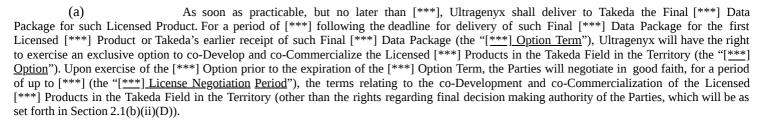
- (a) Ultragenyx shall be responsible for registering any Clinical Trial performed pursuant to the [***] Development Plans in the appropriate clinical trial registry (e.g., clinicaltrials.gov) and posting the results of such Clinical Trials as required by Applicable Laws.
- (b) The posting of any results to a clinical trial registry in accordance with this Section 4.4 shall be considered a "publication" and subject to the Parties' obligations set forth in Section 14.9.
- 4.5 Records; Disclosure of Data and Results. In conformity with standard pharmaceutical industry practices and the terms and conditions of this Agreement, each Party shall prepare and maintain, or shall cause to be prepared and maintained, complete and accurate written records, accounts, notes, reports and data with respect to activities conducted pursuant to the [***] Development Plans for a minimum of three (3) years following the end of the Calendar Year to which they pertain (or such longer period as may be required by Applicable Laws) and, upon the other Party's reasonable written request, shall send legible copies (in English and in electronic format) of the aforesaid to the other Party, to the extent not already provided, throughout the Term and for a minimum of twelve (12) months following the Term. Upon reasonable advance notice, at the request of the JSC, each Party agrees to make its employees and consultants reasonably available at their respective places of employment to consult with the other Party on issues arising in connection with the [***] Development Plans. In accordance with the reporting format and schedule approved by the JSC, each Party shall promptly and fully disclose to the other Party in writing all data, including preclinical data, Clinical Trial data, formulation data and manufacturing data, generated by or on behalf of such Party with respect to the Products in the Licensed Field. Without limiting the foregoing: (a) Ultragenyx shall keep Takeda regularly and fully informed by reporting to the JSC on a quarterly basis regarding the Development of Licensed Products in the Ultragenyx Field in the Territory by Ultragenyx, its Affiliates and sublicensees, including information regarding the status of Clinical Trials, filing of Regulatory Materials and receipt of Regulatory Approval with respect to the Products in the Ultragenyx Field in the Territory; (b) on at least an annual basis (but in any event, no later than December 1 of each Calendar Year), each Party, as applicable, shall submit to the JSC proposed updates and amendments, as appropriate, to the [***] Development Plans; and (c) Takeda shall keep Ultragenyx regularly informed by reporting to the JSC on a quarterly basis regarding the Development of Licensed Products in the Takeda Field by Takeda, its Affiliates and sublicensees, including information regarding the status of any Clinical Trials, filing of Regulatory Materials and receipt of Regulatory Approval with respect to the Products in the Takeda Field in the Territory.

ARTICLE 5- [***] CO-DEVELOPMENT AND CO-COMMERCIALIZATION

5.1 Co-Development and Co-Commercialization Negotiation for Takeda Field.

35

CONFIDENTIAL TREATMENT REQUESTED



- (b) If Ultragenyx exercises the [***] Option within the [***] Option Term and the Parties reach agreement regarding the co-Development and co-Commercialization of the Licensed [***] Product in the Takeda Field within the [***] License Negotiation Period, such agreement, including any needed modification to the Ultragenyx [***] License and Takeda [***] License, will be entered into by the Parties or their designated Affiliates. Such agreement shall provide that, if Ultragenyx terminates the Development of Licensed [***] Products in the Ultragenyx Field, then Ultragenyx shall have the right to terminate such co-Development and co-Commercialization of Licensed [***] Products in the Takeda Field upon providing Takeda with the following prior written notice: (i) if the Licensed [***] Product is in Development at the time of termination, [***], and (ii) if the Licensed [***] Product is being Commercialized at the time of termination, [***].
- (c) If Ultragenyx exercises the [***] Option within the [***] Option Term and the Parties fail to reach an agreement regarding the co-Development and co-Commercialization of the Licensed [***] Product in the Takeda Field within the [***] License Negotiation Period, then Takeda and Ultragenyx shall have the right to submit their proposed terms for such co-Development and co-Commercialization of the Licensed [***] Products in the Takeda Field in the Territory to binding arbitration as set forth in Section 16.3; provided, however, that the rights regarding the final decision making authority of the Parties as set forth in Section 2.1(b)(ii)(D) will not be subject to modification in such arbitration.
- 5.2 **Takeda Right of First Negotiation for the Ultragenyx Field.** Notwithstanding Ultragenyx's right to sublicense under Section 3.3, Ultragenyx does not have the right to enter into an agreement with any Third Party for the co-Development and/or co-Commercialization (including co-promotion) of the Licensed Product in the Ultragenyx Field except in accordance with the terms of this Section 5.2. If Ultragenyx intends to co-Develop and/or co-Commercialize (including co-promote) with a Third Party a Licensed Product in the Ultragenyx Field, Ultragenyx will provide Takeda with prior written notice of such intent and, for a period of [***] after receipt of such notice, Takeda will have a right of first negotiation to enter into a definitive agreement with Ultragenyx for such co-Development and/or co-Commercialization (including co-promotion). If the Parties fail to enter into a definitive

36

CONFIDENTIAL TREATMENT REQUESTED

agreement prior to the expiration of [***], Ultragenyx will have the right to enter into a definitive agreement with a Third Party (including via sublicensing as set forth in Section 3.3) for the co-Development and/or co-Commercialization (including co- promotion) of the Licensed Product in the Ultragenyx Field; provided, that, [***], Ultragenyx shall not enter into such a definitive agreement with a Third Party on terms, when viewed as a whole, that are less favorable to Ultragenyx than the terms last offered to Ultragenyx by Takeda.

5.3 **Commercialization Plans.** Each Party shall submit a Commercialization Plan to the JSC for discussion no less [***] prior to the anticipated date of such Party obtaining Regulatory Approval for a Licensed Product. Thereafter, each Party shall provide a copy of the thencurrent Commercialization Plan to the JSC at least once each Calendar Year during the Licensed Product Royalty Term and Takeda Royalty Term, as applicable.

5.4 Commercialization Activities.

- (a) Ultragenyx Commercialization. Ultragenyx shall use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Ultragenyx Field in the Territory throughout the Term. Subject to any modifications based on agreements reached pursuant to Sections 5.1 and 5.2, Ultragenyx's Commercially Reasonable Efforts requirements and the provisions of Section 2.1(b), Ultragenyx has sole discretion relating to all aspects of the Commercialization of Licensed Products in the Ultragenyx Field in the Territory. As between the Parties, Ultragenyx shall bear all of the costs and expenses incurred in connection with all such Commercialization activities. On an annual basis, and no later than March 1 of each Calendar Year following the First Commercial Sale of a Licensed Product in the Ultragenyx Field in the Territory, Ultragenyx shall present a reasonably detailed written report to the JSC summarizing Ultragenyx's overall Commercialization activities undertaken during the previous Calendar Year with respect to the Licensed Products in the Ultragenyx Field.
- (b) **Takeda Commercialization**. Subject to any modifications based on agreements reached pursuant to Sections 5.1 and 5.2 and the provisions of Section 2.1(b), Takeda has sole discretion relating to the Commercialization of Licensed [***] Products in the Takeda Field in the Territory. As between the Parties, Takeda shall bear all of the costs and expenses incurred in connection with all such Commercialization activities.

5.5 Trademarks.

- (a) **Ownership.** Each Party shall own, throughout the world, each Product trademark that it develops for a Product in its Field in the Territory (each a "Product Trademark"). All goodwill attributable to a Party's Product Trademark generated by the Commercialization of a Product bearing such mark shall inure to the benefit of such Party.
- (b) Use. Neither Party shall be obligated to use the other Party's Product Trademark or House Marks except to the extent required by Applicable Law or regulatory requirement. Neither Party shall, during the Term or thereafter, adopt, register or use any trademark, trade

37

CONFIDENTIAL TREATMENT REQUESTED

name, brand name, symbol or logo that is identical, or confusingly similar, to the other Party's Product Trademarks.

(c) **Filing; Maintenance.** Each Party shall solely be responsible for, and shall solely bear all costs associated with maintenance and enforcement of, such Party's Product Trademark.

ARTICLE 6 - RESEARCH COLLABORATION

6.1 **Research Collaboration Generally**. The Parties will conduct research of Takeda's [***] Compound and Candidate Products as set forth in this Agreement. As further described below, the Candidate Products will be selected from the Takeda-Controlled compounds listed on <u>Exhibit</u> attached hereto, as may be amended from time to time by Takeda in its sole discretion (the "<u>Listed Compounds</u>").

6.2 Nomination of Candidate Products and Validation Research.

- (a) **Nomination**. Either Party may nominate compounds from the Listed Compounds for consideration and approval by the JRC as candidate products under this Agreement (upon such approval, each such Listed Compound shall thereafter be a "<u>Candidate Product</u>"). The JRC may select up to five (5) Candidate Products for validation pursuant to Section 6.2(b) at any one time. If five (5) Candidate Products have been selected at any one time, neither Party may nominate any additional Listed Compound to be considered as a Candidate Product unless and until the Parties determine, after the completion or termination of research activities under the applicable Validation Research Plan, that a Candidate Product will not be nominated as an Option Product.
- (b) Validation Research Plan. Takeda will design, with input from Ultragenyx, a research plan and budget for the initial validation for each Candidate Product (each, a "Validation Research Plan"), with each such Validation Research Plan intended to sufficiently include the activities required to provide information and data necessary for the JRC to determine whether to nominate a Candidate Product as an Option Product. Each Validation Research Plan will be submitted to the JRC for approval (for which Takeda will have final decision-making authority in accordance with Section 2(c)(ii)(C)) and will be funded by Takeda and performed by or on behalf of Takeda, in Takeda's sole discretion.

6.3 [***] Research Plan and Transition

(a) During the Collaboration Term with respect to the [***] Products, the Parties will use Commercially Reasonable Efforts to Exploit the [***] Products, at Ultragenyx's sole expense, pursuant to the initial research plan and budget for the [***] Products attached hereto as <u>Exhibit 6.3(a)</u> (the "[***] Research Plan"). Pursuant to the [***] Research Plan and in accordance with the associated budget, at Ultragenyx's sole expense, Takeda will use Commercially Reasonable Efforts to conduct initial Manufacturing process development and scale-up of the [***] Products, as agreed by the Parties. For clarity, there will not be any Validation Research Plan for the [***] Products.

38

CONFIDENTIAL TREATMENT REQUESTED

(b)	During the Collaboration Term with respect to the [***] Products, the Parties shall cooperate and act in good
faith to support the transition of	f the [***] Products from Takeda to Ultragenyx in the Licensed Field to the extent necessary or reasonably
useful for Ultragenyx to perform	the [***] Research Plan, including the transition of Option Product Know-How with respect to the [***]
Products. [***].	

<u>6.4</u> **Option Product Research Plan.** During the Collaboration Term with respect to each Option Product for which there is an agreed Option Product Research Plan, Ultragenyx will use Commercially Reasonable Efforts to Exploit each Option Product in accordance with the applicable Option Product Research Plan.

6.5 Limited Licenses During the Collaboration Term.

(a) License to Ultragenyx.

- (i) Upon selection of a Candidate Product as an Option Product by the JRC and as of the Effective Date with respect to [***] Products, Takeda hereby grants to Ultragenyx a limited, co-exclusive (with Takeda and its Affiliates), non-transferable, non-sublicensable, royalty-free license under the Option Product Technology, Option Product Improvements Controlled by Takeda or its Affiliates, Option Product Improvement Patents Controlled by Takeda or its Affiliates, and Joint Intellectual Property to Exploit the Option Product solely in accordance with the activities to be performed by Ultragenyx under the Option Product Research Plan.
- (ii) The foregoing license under Section 6.5(a)(i) will continue on an Option Product-by-Option Product basis until the earlier of (A) execution of an Option Product License Agreement, (B) failure by the Parties to enter into an Option Product License Agreement by the expiration of the applicable Option Negotiation Period, or (C) expiration or termination of the Collaboration Term, at which time such Option Product shall be a Terminated Product and all rights to such Option Product will revert to Takeda in accordance with Section 15.7(c); provided that, if in the case of (C), an Option Negotiation Period is then ongoing, the Collaboration Term with respect to such Option Product will automatically extend until the earlier of (1) expiration of such Option Negotiation Period or (2) execution of the applicable Option Product License Agreement.
- (b) License to Takeda. During the Collaboration Term, with respect to each Research Product, Ultragenyx hereby grants to Takeda a limited, non-exclusive, non- transferable, non-sublicensable, royalty-free license, under all Ultragenyx Intellectual Property, Option Product Improvements Controlled by Ultragenyx and Joint Intellectual Property for use in the Licensed Field in the Territory solely to perform its obligations under each Research Plan and to the extent necessary or reasonably useful for Takeda to evaluate a Candidate Product.
- (c) **No Implied Licenses**. No license or other right is or shall be created or granted hereunder during the Collaboration Term with respect to any Research Product by implication,

39

CONFIDENTIAL TREATMENT REQUESTED

estoppel, or otherwise. All rights not expressly granted by a Party under this Agreement are reserved by such Party and may not be used by the other Party for any purpose.

6.6 **Research Materials Transfer**.

- (a) In order to facilitate the activities contemplated by this Agreement, Takeda shall transfer to Ultragenyx, at no cost to Ultragenyx (i) those quantities of [***] Compound Controlled by Takeda as of the Execution Date as are necessary for Ultragenyx to perform the activities allocated to it under the [***] Research Plan and (ii) reasonable quantities of biological materials or chemical compounds Controlled by Takeda at the time a Candidate Product becomes an Option Product for Development of such Option Product (collectively, the "Research Materials") by Ultragenyx in furtherance of the applicable Research Plans. Such transfer shall be pursuant to a mutually agreed upon Research Materials transfer plan and schedule (including, as necessary, a separate agreement with respect to such transfer which the Parties shall enter as soon as practicable (A) after the Effective Date in the case of the foregoing clause (i) or (B) after a Candidate Product becomes an Option Product in the case of the foregoing clause (ii)). Except as otherwise provided for under this Agreement, all such Research Materials will remain the sole property of Takeda, will be used only in furtherance of the activities conducted in accordance with the applicable Research Plans, without the prior written consent of Takeda, and will be used in compliance with Applicable Law. The Research Materials supplied under this Agreement must be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. Takeda will provide Ultragenyx the most current material safety data sheet for the Research Materials upon transfer of any Research Materials.
- (b) Except as expressly set forth in this Agreement, THE RESEARCH MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE RESEARCH MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

6.7 General Terms Applicable to Research Plans and Research Activities.

- (a) Annual Review of Research Plans. On an annual basis, the Parties, through the JRC, shall review, and as necessary, update and amend the then-current Research Plans, provided that either Party may at any time between annual updates recommend updates or amendments of the then-current plans and associated budget for consideration by the JRC.
- (b) **Performance Obligations**. With respect to each Research Plan, Ultragenyx and Takeda shall each use Commercially Reasonable Efforts to execute and perform the activities assigned to it and cooperate with the other Party in the performance of such activities. Each Party shall conduct the activities assigned to it under the Research Plan in a good scientific manner and in compliance in all material respects with Applicable Law, including applicable

40

CONFIDENTIAL TREATMENT REQUESTED

national and international (e.g., ICH, GCP, GLP, and GMP) guidelines. If a Research Plan provides for Clinical Trials, the sponsor of such trial shall register and post the results of such trial.

- Records; Disclosure of Data and Results. Each Party shall prepare and maintain, or shall cause to be prepared and maintained, complete and accurate written records, accounts, notes, reports and data with respect to its activities conducted pursuant to a Research Plan in conformity with Applicable Law and standard pharmaceutical industry practices; provided that in no case shall such records be maintained for less than three (3) years following the Calendar Year to which such records pertain (or such longer period as may be required by Applicable Laws). Upon the other Party's written request, the Party receiving such written request shall send legible copies of the aforesaid to the other Party throughout the Term with respect to such Research Product and for a minimum of twelve (12) months following such Term. Upon reasonable advance notice, at the request of the JRC, each Party agrees to make its employees and consultants reasonably available at their respective places of employment to consult with the other Party on issues arising in connection with each Research Plan. In accordance with the reporting format and schedule approved by the JRC, each Party shall promptly disclose to the other Party in writing all data, including preclinical data, clinical trial data (if any), formulation data and Manufacturing data, generated by or on behalf of such Party with respect to a Research Product in the Licensed Field in the Territory.
- (d) **Termination of Research Plan**. In the event the activities under a Research Plan are terminated for any reason, all research thereunder shall cease and the applicable Option Product or [***] Product will be deemed to be a Terminated Product. All Terminated Products shall revert to Takeda pursuant to Section 15.7(c). For clarity, such termination shall not terminate the Collaboration Term for any other purpose under this Agreement.

6.8 Research Program Expenses.

- (a) **Nomination Evaluation**. Each Party shall be responsible for its own FTEs and any Third Party expenses, in each case, incurred with respect to the nomination, evaluation and selection of Candidate Products in accordance with Section 6.2(a).
- (b) [***] Research Plan. Ultragenyx shall reimburse Takeda for Takeda's FTE Costs and out-of-pocket Third Party expenses, in each case, incurred by Takeda in furtherance of the completion of those activities assigned to it under the [***] Research Plan and in accordance with the applicable budget, subject to a maximum reimbursement obligation of [***] of such budget or such greater amount as Ultragenyx may approve in advance.
- (c) Validation Research Plan. Takeda shall be responsible for its own FTEs and any Third Party expenses incurred by Takeda with respect to a Validation Research Plan.
- (d) Option Product Research Plan. Ultragenyx shall reimburse Takeda for Takeda's FTE Costs and out-of-pocket Third Party expenses, in each case, incurred by Takeda in furtherance of the completion of those activities assigned to it under an Option Product Research Plan and in accordance with the applicable budget, subject to a maximum reimbursement

41

CONFIDENTIAL TREATMENT REQUESTED

obligation of [***] of such budget or such greater amount as Ultragenyx may approve in advance.

6.9 **Invoices**. Within forty-five (45) days after the end of each Calendar Quarter, Takeda will provide a written report and invoice to Ultragenyx setting forth in reasonable detail its FTEs and its Third Party expenses recorded in furtherance the [***] Research Plan and Option Product Research Plans. Within sixty (60) days after the receipt of such invoice, Ultragenyx shall pay the undisputed portion of any such invoice. For clarity, making such a payment does not preempt Ultragenyx's audit rights under Section 11.12, which remain in full force and effect. If Ultragenyx in good faith identifies items in an invoice which are disputed, Ultragenyx will notify Takeda in writing, noting its objection to the disputed item(s) with specificity, within ten (10) business days of receipt of the invoice. Takeda will respond to such written notification within ten (10) days of receipt of the disputed notification. Thereafter, the Parties shall negotiate in good faith to resolve the dispute with either Takeda supplying Ultragenyx documentation justifying the charge or reducing or deleting the disputed amount. Any dispute over invoiced amounts due that cannot be resolved by direct good faith negotiation between the Parties shall be resolved in accordance with ARTICLE 16 (Dispute Resolution) of this Agreement; provided further, if the Dispute is not resolved pursuant to Section 16.2, the Parties agree that such Dispute shall be resolved pursuant to Section 16.3.

6.10 **Option Products.**

- (a) At any time during the Collaboration Term after the completion of research activities under a Validation Research Plan, either Ultragenyx or Takeda may, through the JRC, nominate a Candidate Product for selection as an Option Product, and the JRC will promptly consider such request. In order for a Candidate Product to become an Option Product, the JRC must agree (by mutual agreement of the Parties' representatives on the JRC) to (i) the selection of the Candidate Product as an Option Product, (ii) a research plan, and budget that identifies the research and development activities which shall be performed and paid for entirely by Ultragenyx (each, an "Option Product Research Plan"), and (iii) key terms, including the territory, field of use, development and commercial responsibilities and financial terms (the "Option Product Key Terms") to serve as the basis for an Option Product License Agreement. For clarity, the Option Product Research Plan for [***] Products is the [***] Research Plan.
- (b) The [***] Products are designated as Option Products as of the Effective Date. The Option Product Key Terms for [***] Products are attached hereto as Exhibit 6.10(b).
- 6.11 **The Ultragenyx Option.** Takeda hereby grants to Ultragenyx, during the applicable Collaboration Term, the exclusive option to obtain, on a product-by-product basis, an exclusive license, with the right to grant sublicenses through multiple tiers, under the Option Product Technology and Joint Intellectual Property to Exploit (a) the [***] Products and (b) up to five (5) other Option Products in the Licensed Field in the Territory (the "<u>Ultragenyx Option</u>"), subject to the terms and conditions set forth in this Agreement including ARTICLE 8.

6.12 Exercising the Option.

42

CONFIDENTIAL TREATMENT REQUESTED

- (a) At any time during the Collaboration Term, Ultragenyx may exercise the Ultragenyx Option regarding an Option Product by notifying Takeda in writing of its intent to exercise the Option with respect to a specific Option Product and negotiate the terms of a license agreement (the "Option Notice"). During the period of time beginning on the effective date of each such Option Notice and ending [***] thereafter, which period may be extended by mutual agreement (the "Option Negotiation Period"), the Parties will conduct good faith negotiations with the intent to agree upon license terms and conclude a definitive license agreement (the "Option Product License Agreement") in accordance with the applicable Option Product Key Terms and other terms that reflect the expected commercial opportunity and development stage of the Option Product. Any such Option Product License Agreement will include provisions to address approvals of any Governmental Authority which are required before effectiveness of such Option Product License Agreement.
- (b) If the Parties cannot conclude an Option Product License Agreement during the Option Negotiation Period, Takeda and Ultragenyx shall each have the right to submit the Option Product Key Terms and other terms for a final decision regarding the terms of the Option Product License Agreement pursuant to binding arbitration under Section 16.3. All rights to any Option Product for which the Parties do not enter into an Option Product License Agreement shall revert to Takeda and such Option Product shall be deemed a Terminated Product subject to Section 15.7(c).

ARTICLE 7 - TAKEDA RESEARCH SUPPORT

- Research Support. During the Collaboration Term and upon mutual agreement of the Parties, Takeda may provide research support as set forth in this Section 7.1 ("Research Support") to Ultragenyx, at Ultragenyx's sole cost. Such Research Support shall be related to the development of Ultragenyx Pipeline Products (in each case, other than Exercised Products) or Licensed Option Products (in each case, in connection with an Option Product License Agreement), and shall include medicinal chemistry, testing of compounds in disease animal models, drug formulation and clinical development support. If Ultragenyx and Takeda agree that Takeda should provide such Research Support, the confidentiality obligations, access to premises, and other details related to Takeda personnel providing such Research Support to Ultragenyx shall be addressed in a separate agreement between the Parties and such personnel.
- Expenses and Invoices. Ultragenyx shall reimburse Takeda for Takeda's FTE Costs and out-of-pocket Third Party expenses, in each case, incurred by Takeda for the provision of the Research Support and in accordance with the applicable budget, subject to a maximum reimbursement obligation of [***] of such budget or such greater amount as Ultragenyx may approve in advance. Within forty-five (45) days after the end of each Calendar Quarter, Takeda will provide a written report and invoice to Ultragenyx setting forth in reasonable detail its FTEs and its Third Party expenses recorded for the Research Support. Within sixty (60) days after the receipt of such invoice, Ultragenyx shall pay the undisputed portion of any such invoice. For clarity, making such a payment does not preempt Ultragenyx's audit rights under Section 11.12, which remain in full force and effect. If Ultragenyx in good faith identifies items in an invoice which are disputed, Ultragenyx will notify Takeda in writing,

43

CONFIDENTIAL TREATMENT REQUESTED

noting its objection to the disputed item(s) with specificity, within ten (10) business days of receipt of the invoice. Takeda will respond to such written notification within ten (10) days of receipt of the disputed notification. Thereafter, the Parties shall negotiate in good faith to resolve the dispute with either Takeda supplying Ultragenyx documentation justifying the charge or reducing or deleting the disputed amount. Any dispute over invoiced amounts due that cannot be resolved by direct good faith negotiation between the Parties shall be resolved in accordance with ARTICLE 16 (Dispute Resolution) of this Agreement; provided further, if the Dispute is not resolved pursuant to Section 16.2, the Parties agree that such dispute shall be resolved pursuant to Section 16.3.

7.3 **Patent Ownership.** If Research Support is provided pursuant to Section 7.1 related to an Ultragenyx Pipeline Product (other than an Exercised Product), then, notwithstanding Section

12.1 or any other separate written agreement between the Parties with respect to such Research Support, as between the Parties and regardless of inventorship, Ultragenyx shall own all right, title and interest in and to any Patents related to such Ultragenyx Pipeline Product (other than an Exercised Product in the Exercised Countries) that arise out of such Research Support. For purposes of clarity, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of activities of the type covered by the definition of Research Support related to the Product(s) that are the subject of the applicable license agreement.

ARTICLE 8 - TAKEDA'S LICENSE OPTION

- 8.1 **The License Option.** In partial consideration for the premium paid by Takeda to Ultragenyx under the Common Stock Purchase Agreement, Ultragenyx hereby grants to Takeda during the applicable Takeda Option Term, the exclusive option to obtain (the "<u>Takeda Option</u>"), on a product-by-product and country-by-country basis, an exclusive license (even as to Ultragenyx and its Affiliates) to (a) any or all of the Licensed Products in the Ultragenyx Field,
- (b) any or all Licensed Option Products in the Licensed Field, and (c) one (1) Ultragenyx Pipeline Product in the Licensed Field, in each case in any or all of the countries in the Takeda Territory. For clarity, if Takeda elects not to exercise the Takeda Option with respect to (i) any Licensed [***] Product, Licensed Analog Product, Licensed Option Product, or Ultragenyx Pipeline Product, or (ii) any country in the Takeda Territory, as the case may be, prior to the expiration of the Takeda Option Term with respect to such Product and/or such country, as applicable, then Takeda shall no longer have any rights under the Takeda Option with respect to such Product and/or such country, as applicable.

8.2 Exercising the License Option.

(a) Preparation and Delivery of the Data Packages. Ultragenyx shall prepare and deliver to Takeda as soon as reasonably practicable after completion of the applicable Clinical Trials (a) the Final Phase II Data Package for each Licensed [***] Product, Licensed Analog Product, Licensed Option Product and Ultragenyx Pipeline Product (other than [***]) and (b) the Final Phase III Data Package for [***].

44

CONFIDENTIAL TREATMENT REQUESTED

(b) Takeda Review of Research Data Package. Following Takeda's receipt of the applicable Data Package pursuant to Section 8.2(a) and during the applicable Takeda Option Term, Takeda may review and assess the Data Package to determine whether it will submit the Takeda Option Notice. During this review period, upon Takeda's reasonable request, Ultragenyx shall promptly make available to Takeda: (i) its employees, consultants and independent contractors (subject to the availability of any independent contractors) who performed the activities on behalf of Ultragenyx, including the preparation of the Data Package; and (ii) any additional Information under Ultragenyx's possession and Control related to the applicable products that is reasonably useful in evaluating the Data Package.
(c) Takeda Option Exercise Mechanics. Takeda may exercise the Takeda Option for one or more Licensed [***] Products, one or more Licensed Analog Products, one or more Licensed Option Products, and one Ultragenyx Pipeline Product on a country-by-country basis in the Takeda Territory at any time during the applicable Takeda Option Term by providing written notice to Ultragenyx (the "Takeda Option Notice") identifying the applicable Products ("Exercised Products") and countries ("Exercised Countries"); provided, however, that Takeda may exercise the Takeda Option with respect to each Licensed Product only once (i.e., if the Takeda Option is exercised with respect to a particular Licensed Product for fewer than all applicable countries, then additional countries may not be added by additional exercises of the Takeda Option with respect to that particular Licensed Product).
(d) During the period of time beginning on the effective date of the Takeda Option Notice and ending [***], which period may be extended by mutual agreement (the " <u>Takeda Option Negotiation Period</u> "), the Parties will conduct good faith negotiations to conclude a definitive license agreement (the " <u>Exercised Product License Agreement</u> "). Such Exercised Product License Agreement shall include the following:
(i) the following license grant with respect to the Exercised Products in the Exercised Countries, which, to the extent of any conflict, shall supersede the Ultragenyx [***] License and Takeda [***] License and the terms of any Option Product License Agreement: Ultragenyx hereby grants to Takeda an exclusive license (even as to Ultragenyx and its Affiliates), with the right to grant sublicenses through multiple tiers, under the Ultragenyx Intellectual Property and Joint Intellectual Property, to Exploit the Exercised Products in the Ultragenyx Field (where such Exercised Product is a Licensed Product) or the Licensed Field (where such Exercised Product is a Licensed Countries;
(ii) financial terms in ARTICLE 11 (and related definitions) applicable to Exercised Products (and no other consideration payable by Takeda);
(iii) provisions to address approvals of any Governmental Authority which are required before effectiveness of the Exercised Product License Agreement;
(iv) provisions to address the prosecution, enforcement and defense of Patents that cover Exercised Products similar to those contained in ARTICLE 12;

45

(v) the right for Takeda to terminate for convenience upon [***] written notice;

(vi) the right for Takeda to, in lieu of termination for Ultragenyx's material breach or insolvency, receive rights on the basis set forth in Section 15.7(a)(ii)(B);

- (vii) provisions that upon the expiration of the Takeda Royalty Term for each Exercised Product in each Exercised Country, Takeda shall have a non-exclusive, fully-paid up and irrevocable license under the Ultragenyx Intellectual Property with respect to such Exercised Product in such Exercised Country in the Ultragenyx Field (for Exercised Products that are Licensed Products) and in the Licensed Field (for Exercised Products that are Option Products or Ultragenyx Products); and ARTICLE 18.
 - (viii) to the extent applicable, Miscellaneous provisions as contained in
- (e) If the Parties cannot conclude the Exercised Product License Agreement during the Takeda Option Negotiation Period, Takeda and Ultragenyx shall each have the right to submit the terms for a final decision regarding the terms (other than those specified in Section 8.2(d)) of the Exercised Product License Agreement pursuant to binding arbitration under Section 16.3. For clarity, the terms set forth in Section 8.2(d) must be included within the Exercised Product License Agreement and are not subject to arbitration and Ultragenyx shall be required to enter into an Exercised Product License Agreement including those terms if the Takeda Option is exercised pursuant to Section 8.2(c).
- Takeda Right of First Negotiation on Ultragenyx Pipeline Products. As additional consideration for the premium being paid by Takeda to Ultragenyx under the Common Stock Purchase Agreement, and notwithstanding anything to the contrary contained in this Agreement, if, during the [***] period following expiration of the applicable Takeda Option Term, Ultragenyx intends to license (all or a subset of all rights) or otherwise transfer any Ultragenyx Pipeline Product to a Third Party in the Takeda ROFN Territory, Ultragenyx will provide Takeda with prior written notice of such intent and, for a period of [***] after receipt of such notice, Takeda will have a right of first negotiation to enter into a definitive agreement with Ultragenyx for such license (of all or a subset of all rights) or other transfer in the Takeda ROFN Territory. If the Parties fail to enter into a definitive agreement prior to the expiration of the [***] period, Ultragenyx will have the right to enter into a definitive agreement with a Third Party for the license (of all or a subset of all rights) or other transfer of such Ultragenyx Pipeline Product in the Takeda ROFN Territory.
- 8.4 **Transition of Responsibilities After Exercise of the Takeda Option**. Ultragenyx shall, in accordance with a transition plan set forth in the Exercised Product License Agreement, transfer to Takeda all activities and responsibilities related to the Exercised Products in the Exercised Countries. The Parties shall exercise Commercially Reasonable Efforts to complete the transfer in accordance with such transition plan. Any dispute between the Parties regarding the transition shall be resolved as set forth in the Exercised Product License Agreement.

46

CONFIDENTIAL TREATMENT REQUESTED

8.5	Development and Commercialization After Exercise of the Takeda Option. After exercise of the Takeda Option, Takeda will us
Commercially	Reasonable Efforts to Exploit the Exercised Products in the Takeda Option Field in the Exercised Countries at its sole cost are
expense; prov	ided, however, notwithstanding the above, Takeda's financial commitment toward global Development costs for Licensed Optic
Products and	an Ultragenyx Pipeline Products will be in accordance with the terms set forth in Section 8.6.

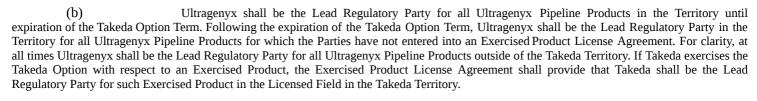
- 8.6 **Cost Sharing for Development Activities in Takeda Territory**. After exercise of the Takeda Option with respect to a Licensed Option Product and/or an Ultragenyx Pipeline Product:
- (a) the Parties will share the costs of future global Development activities for such Licensed Option Product or Ultragenyx Pipeline Product, as applicable, including costs for Clinical Trials and clinical drug supply and chemistry, manufacturing and controls-related activities in accordance with mutually agreed upon Development plans, budgets and cost sharing structures; provided that Takeda shall only be required to share global Development costs where the Development activities are necessary or reasonably useful to support the Development, Regulatory Approval and Commercialization of such product in the Takeda Territory, in which case Takeda will contribute [***]. For clarity, Takeda will not be required to share in the costs of future global Development activities where the Development activities, including Clinical Trials, are not necessary and are not used to support the Development, Regulatory Approval and Commercialization of such product in the Takeda Territory; and
- (b) Notwithstanding the foregoing, Takeda shall be solely responsible for all Development costs where the Development activities are required specifically and solely for Regulatory Approval of a Licensed Option Product or Ultragenyx Pipeline Product, as applicable, in the Takeda Territory. If such Development activities are also necessary or reasonably useful for Regulatory Approval of a Licensed Product, Licensed Option Product or Ultragenyx Pipeline Product, as applicable, outside the Takeda Territory, the Parties will negotiate in good faith to agree upon an equitable sharing of costs for such Development activities.

ARTICLE 9 - REGULATORY

- **Lead Regulatory Party**. Primary regulatory responsibility under this Agreement shall be assigned to one of the Parties (such Party, the "<u>Lead Regulatory Party</u>") as set forth in this Section 9.1.
- (a) Ultragenyx shall be the Lead Regulatory Party for all Licensed Products until expiration of the [***] Option Term. Following expiration of the [***] Option Term, whether or not Ultragenyx has exercised the [***] Option (i) Takeda shall be the Lead Regulatory Party for Licensed [***] Products in the Takeda Field unless otherwise agreed by the Parties, and (ii) Ultragenyx shall be the Lead Regulatory Party for Licensed [***] Products in the Ultragenyx Field and shall be the Lead Regulatory Party for Licensed Analog Products in the Ultragenyx Field.

47

CONFIDENTIAL TREATMENT REQUESTED



- The Parties will agree as to which Party shall be the Lead Regulatory Party for the [***] Products and each Candidate Product prior to the expiration of the Collaboration Term; provided, however, that Takeda shall be the Lead Regulatory Party (i) if the Parties are unable to agree, (ii) at any time after Ultragenyx provides Takeda written notice that it will not exercise the Ultragenyx Option with respect to the [***] Products and (iii) for the planned Scientific Advice with the Dutch Medicines Evaluation Board and US Orphan Drug Designation follow-up (as needed) for [***]. Ultragenyx shall be the Lead Regulatory Party for each Option Product for which the Parties have entered into an Option Product License Agreement and Takeda shall be the Lead Regulatory Party for each Option Product for which the Parties have not entered into an Option Product License Agreement.
- (d) In accordance with the foregoing, upon entering into an Option Product License Agreement or Exercised Product License Agreement, it is understood that the terms of such Option Product License Agreement or Exercised Product License Agreement will govern with respect to such Option Product covered by such Option Product License Agreement or Exercised Product covered by such Exercised Product License Agreement, as applicable.

9.2 Initial Transfer of Data and Regulatory Materials.

(a) Transfer to Ultragenyx

(i) As soon as practicable after the Effective Date, but in any event no later than sixty (60) days after the Effective Date, Takeda shall timely transfer to Ultragenyx copies of (A) all Regulatory Materials (in electronic or other format) in its possession related to the use of the Licensed [***] Products in the Ultragenyx Field (and, solely for purposes of Ultragenyx's performance of its obligations under Section 4.3(a)(ii), in the Takeda Field) and (B) the briefing book, FDA meeting minutes, Takeda meeting minutes, and FDA correspondence associated with [***], the US Orphan Drug Designation Request and subsequent regulatory correspondence, and the briefing book and correspondence for Scientific Advice with the Dutch Medicines Evaluation Board, in each case for the [***] Products in the Licensed Field and existing as of such date of transfer. Following each such transfer and at a time to be mutually agreed by the Parties, the Parties shall take all steps necessary (a) for Ultragenyx to own or have the right of reference to the INDs and Regulatory Approvals necessary to conduct Development of the Licensed [***] Product in the Ultragenyx Field and (b) for Takeda to own or have the right of reference to the INDs and Regulatory Approvals necessary to conduct Development of the Licensed [***] Product in the Takeda Field.

48

CONFIDENTIAL TREATMENT REQUESTED

(ii) Within sixty (60) days after the Effective Date, Takeda shall make available to Ultragenyx separate copies (in electronic or other format) of the study reports from all non-clinical trials and Clinical Trials in the Territory, in each case, whether completed as of the Effective Date or then in-progress, that are Controlled by Takeda (to the extent not previously provided to Ultragenyx), as such reports become available to Takeda, and to the extent that they relate to the use of the Licensed [***] Products for the Territory.

(b) Transfer to Takeda

(i) As soon as practicable after the effective date of an Exercised Product License Agreement for a given Exercised Product, but in any event no later than sixty (60) days after such date, Ultragenyx shall timely transfer to Takeda copies of all Regulatory Materials (in electronic or other format) in its possession related to the use of the Exercised Product in the Exercised Countries and which support the Product INDs, the Product Regulatory Approvals and associated correspondence, existing as of such date of transfer. Promptly after such transfer, Ultragenyx shall take all steps necessary to transfer ownership of all such Product INDs and Product Regulatory Approvals in the Takeda Territory to Takeda, including, if applicable, submitting to the PMDA a letter or other necessary documentation (with a copy to Takeda) notifying the PMDA of the transfer of such ownership. From time to time after the IND Date, and solely to the extent not previously disclosed, Ultragenyx shall, and shall cause its Affiliates to, without additional compensation, disclose and make available to Takeda, in whatever form Takeda may reasonably request, all Regulatory Materials Controlled by Ultragenyx and related to the use of an Exercised Product in the Exercised Countries.

(ii) Within sixty (60) days after the Parties enter into an Exercised Product License Agreement for a given Exercised Product, Ultragenyx shall make available to Takeda separate copies (in electronic or other format) of the study reports from all non-clinical trials and Clinical Trials in the Territory, in each case, whether completed as of the Effective Date, that are Controlled by Ultragenyx (to the extent not previously provided to Takeda), as such reports become available to Ultragenyx, and to the extent that they relate to the use of the Exercised Products in the Exercised Countries.

9.3 Preparation of Regulatory Materials.

(a) After the Effective Date (or, as applicable, the IND Date), the Lead Regulatory Party shall have the sole right and responsibility, and shall exercise Commercially Reasonable Efforts, to prepare, obtain, and maintain, as applicable, the Regulatory Materials, including the Product INDs, the Product Regulatory Approvals, and other submissions, and to conduct communications with the FDA, for the relevant Products in the applicable indication in the Territory or applicable portion thereof, except in the case of Licensed [***] Products from the Effective Date until expiration of the [***] Option Term, during which time Takeda shall hold the IND and Ultragenyx (i.e., the Lead Regulatory Party) shall receive a right of reference from Takeda. Except with respect to Licensed [***] Products from the Effective Date until expiration of the [***] Option Term, all Product INDs and Product Regulatory Approvals generated after the Effective Date, including any supplements or amendments to those Product INDs and Product Regulatory Approvals in existence as of the Effective Date, with respect to such Products in the

49

CONFIDENTIAL TREATMENT REQUESTED

applicable indication in the Territory or applicable portion thereof under this Agreement shall be owned by, and shall be the sole property and held in the name of, Lead Regulatory Party or its designee.

- (b) Other than the Scientific Advice Briefing Book for the [***] Products which has been prepared as of the Execution Date but not yet been submitted, the Lead Regulatory Party shall provide the other Party with an opportunity to review and comment on all material Regulatory Materials submitted by the Lead Regulatory Party to a Regulatory Authority after the Effective Date, in each case reasonably in advance of when the Lead Regulatory Party intends to submit such Regulatory Materials to the applicable Regulatory Authority. The other Party shall provide its comments within [***], or such other period of time mutually agreed to by the Parties. The Lead Regulatory Party shall consider in good faith any such comments of the other Party. The Lead Regulatory Party shall provide the other Party with a copy in electronic form of all material Regulatory Materials filed with the Regulatory Authority related to the use of the relevant Products.
- (c) The Lead Regulatory Party shall notify the other Party within no less than [***] of any request for a meeting or substantive telephone conference call with a Regulatory Authority with respect to any Product IND or Product Regulatory Approval. Upon the other Party's request, the Lead Regulatory Party shall request that the FDA or other Regulatory Authority permit at least [***] of the other Party's employees to attend any such meeting or conference call. To the extent permitted by the FDA or other Regulatory Authority, the other Party shall have the right to participate in any such meeting or conference call. The foregoing rights and obligations apply with respect to meetings or conferences initiated by the Lead Regulatory Party or by a Regulatory Authority. The Lead Regulatory Party shall promptly furnish the other Party with copies of all substantive correspondence related to the relevant Product the Lead Regulatory Party has had with the Regulatory Authority, and contact reports concerning substantive conversations or minutes from any substantive meetings with a Regulatory Authority related to such Product.
- (d) Notwithstanding the foregoing, Takeda, in consultation with Ultragenyx, shall be responsible for the preparation of any components of Regulatory Materials to be filed by Ultragenyx that relate to the Manufacture of a Licensed Product or Option Product. Takeda shall use Commercially Reasonable Efforts to prepare such components in a timely manner and provide such components to Ultragenyx with sufficient time for Ultragenyx to review and comment on such components; provided, however, that Takeda may use an alternative arrangement (such as a drug master file) to preserve the confidentiality of such components to the extent required by any Third Party agreements or, in Takeda's reasonable discretion, if otherwise necessary to protect Takeda confidential information and such alternative arrangement is permissible under Applicable Laws; provided, further, that if Ultragenyx reasonably requests additional information with respect to the Development or Commercialization of a Licensed Product or Option Product otherwise treated as confidential in such alternative arrangement (such as a drug master file), Takeda shall reasonably consider such request. In the event that Ultragenyx elects to Manufacture a Licensed Product or Option Product, Ultragenyx shall notify Takeda of such election and, to the extent covered by the license rights granted in Sections 3.1(a)

50

CONFIDENTIAL TREATMENT REQUESTED

and 3.1(c) (for Licensed Products) or Section 6.5(a) (for Option Products), Takeda shall promptly transfer to Ultragenyx or its Third Party designee all Regulatory Materials, processes and technical information Controlled by Takeda or its Affiliates that are reasonably necessary and useful for the Manufacture of such Licensed Product or Option Product, and thereafter Ultragenyx shall be responsible for the preparation of any components of Regulatory Materials to be filed related to the Manufacture by Ultragenyx or its Third Party designee of such Licensed Product or Option Product.

9.4 Cooperation, Consultation and Review.

- (a) The Parties shall cooperate with each other to achieve the regulatory objectives contemplated herein in a timely, accurate and responsive manner and shall assist the other Party as reasonably requested in connection with the preparation and filing of Regulatory Materials in the Licensed Field, whether in or outside of the Territory. The Parties shall establish a joint regulatory working group to manage Licensed Product regulatory activities and issues. It is the intention of the Parties that the joint regulatory working group shall meet (in person or via teleconference) on an as-needed basis after the Effective Date and throughout the Term, but at a minimum on a quarterly basis. The Parties agree and acknowledge that the activities of Ultragenyx with respect to (i) Licensed [***] Products in the Ultragenyx Field and (ii) Licensed Analog Products in the Licensed Field and the activities of Takeda with respect to (A) Licensed [***] Products in the Takeda Field and (B) Licensed Products outside of the Licensed Field, shall be coordinated such that they are consistent with the overall objective of facilitating Regulatory Approvals.
- (b) The other Party shall assist the Lead Regulatory Party, as is reasonably necessary, in order for the Lead Regulatory Party to obtain and maintain the Product INDs and the Product Regulatory Approvals, including in connection with the preparation and filing of Regulatory Materials necessary to maintain such Product INDs and Product Regulatory Approvals.
- 9.5 **Regulatory Costs and Expenses**. Each Party shall bear its own costs and expenses incurred related to the preparation, maintenance, formatting and filing of the Regulatory Materials.
- 9.6 **Rights of Reference to Regulatory Materials**. Each Party hereby grants to the other Party a right of reference to all Regulatory Materials, including any data relied on in support of such Regulatory Materials, solely for the purpose of seeking, obtaining and maintaining Regulatory Approvals for the Products, consistent with the roles of the Parties set forth in this Agreement.
- 9.7 **Labeling Information Exchange/Labeling Agreement**. The Parties shall cooperate to develop methods and/or procedures for sharing information related to Labeling. Specific details regarding the management of Labeling information, including CCDS will be delineated in a separate Labeling agreement that shall be agreed upon by the Parties.
- 9.8 Adverse Event Reporting and Safety Data Exchange.

51

CONFIDENTIAL TREATMENT REQUESTED

(a) Safety Information Exchange; Pharmacovigilance Agreement.

(i) The Parties shall cooperate to develop methods and/or procedures for sharing information relating to the clinical experiences in accordance with safety reporting requirements of the respective Regulatory Authorities and as necessary for a Party to comply with Applicable Laws. Specific details regarding the management of safety information including adverse events reports related to the Development and the Commercialization of the Products will be delineated in a separate global pharmacovigilance agreement (the "PVA") that shall be agreed to by the Parties as soon as reasonably practicable, but in any event not later than [***] of the Effective Date. The Lead Regulatory Party shall be responsible for the compliance and filing of all required safety reports to the Regulatory Authorities in the Territory, including annual safety reports, throughout the Term.

(ii) The PVA shall provide as follows:

- (A) Unless otherwise agreed by the Parties, the Lead Regulatory Party shall maintain the global safety database for the Products, and mirror databases will be maintained by the other Party; provided, however, that Takeda shall maintain the global safety database regarding Licensed [***] Products, and Ultragenyx shall maintain the global safety database regarding Licensed Analog Products. For clarity, to the extent a Party is no longer actively Developing or Commercializing a Licensed [***] Product, then the global safety database shall be transferred to the Party that continues to actively Develop or Commercialize such Licensed [***] Product.
- (B) Each Party shall timely report to the other Party all clinical experiences, safety monitoring, and pharmacovigilance surveillance observed in the Territory, which in all cases shall be (i) for clinical studies: as soon as practicable, [***] and (ii) for commercial Products: [***]; exchange of information shall be on a Council for International Organizations of Medical Sciences Suspect Adverse Reaction Report Form ("CIOMS Form").
- (C) The other Party shall prepare and provide to the Lead Regulatory Party on a timely basis safety updates in order for the Lead Regulatory Party to meet the safety report submission requirements necessary to maintain the Product INDs and the Product Regulatory Approvals.
- (b) Regulatory Reporting of Safety Information. The Parties shall work together to achieve consensus with respect to safety issues related to the Products, including urgent safety information, and to report said opinion to safety boards, investigators, and to applicable Regulatory Authorities. In the event that, after reasonable medical and scientific consultation, the Parties cannot achieve consensus with respect to safety issues to be reported to any applicable Regulatory Authority, the Lead Regulatory Party shall have final decision making 52

CONFIDENTIAL TREATMENT REQUESTED

authority with respect to the Products in the Licensed Field in the Territory. Notwithstanding anything to the contrary in this Agreement, either Party may report safety matters to a Regulatory Authority that it reasonably determines are necessary to report prior to the conclusion of the dispute resolution procedure.

- Regulatory Authority Communications Received by a Party. Each Party shall inform the other Party in a timely manner, not to exceed [***], of the notification of any action by, or notification or other information which it receives (directly or indirectly) from any Regulatory Authority which: (i) raises any material concerns regarding the safety or efficacy of a Product; (ii) indicates or suggests a potential material liability of either Party to Third Parties in connection with a Product; (iii) is reasonably likely to lead to a recall or market withdrawal of a Product; or (iv) relates to expedited reports of adverse events with respect to a Product, or Product Complaints, and which may have a material impact on obtaining or maintaining Regulatory Approval or the continued Commercialization of a Product, as then conducted. The other Party will fully cooperate with and assist such Party in complying with regulatory obligations and communications, including by providing to such Party, in a timely manner after a request, such information and documentation in the other Party's possession as may be necessary or helpful for the Party to prepare a response to an inquiry from a Regulatory Authority. Each Party will provide the other Party in a timely manner with a copy of all correspondence received from a Regulatory Authority specifically regarding the matters referred to above.
- 9.10 Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party's facility or a facility under contract with such Party with regard to a Product in the Territory, then the audited Party shall notify the other Party as soon as practicably possible after receipt of such notification of such audit or inspection and provide copies of any materials provided to it by the applicable Regulatory Authority; provided, that the audited Party shall not be required to notify the other Party of audits or inspections that are of a routine nature or that do not relate to a Product, except where such audits result in communications or actions of such Regulatory Authority which have a direct impact upon a Product. In addition, if a Regulatory Authority conducts an unannounced inspection or audit of a Party's facility or a facility under contract with such Party with regard to a Product in the Territory, then the audited Party shall notify the other Party within [***] of commencement of such audit or inspection. The audited Party shall cooperate, and shall use reasonable efforts to cause the contract facility to cooperate, with such Regulatory Authority and the other Party during such inspection or audit. Following receipt of the inspection or audit observations of such Regulatory Authority (a copy of which the audited Party will immediately provide to the other Party), the audited Party will also provide the other Party with copies of any written communications received from Regulatory Authorities with respect to such facilities in a timely manner after receipt, to the extent such written communications relate directly to a Product or the Manufacture thereof, and will prepare the response to any such observations. The audited Party will provide the other Party with a copy of any proposed response to such communications and will consider in good faith such other Party's reasonable comments with respect to such proposed response. The audited Party agrees to conform its activities under this Agreement to any commitments made in such a response.

53

CONFIDENTIAL TREATMENT REQUESTED

Recalls and Voluntary Withdrawals. Each Party shall notify the other Party promptly but in no event later than [***] following its determination that any event, incident, or circumstance has occurred that may result in the need for a recall, market suspension, or market withdrawal of a Product under any MAA or Regulatory Approval for the Product held by such Party and filed with Regulatory Authorities in the Territory, and shall include in such notice the reasoning behind such determination, and any supporting facts. Such Party shall have the sole right to make the final determination whether to voluntarily implement any such recall, market suspension, or market withdrawal, in the Territory; provided that prior to any implementation of such a recall, market suspension, or market withdrawal, the such Party shall, to the extent practical, consult with the other Party and shall consider the other Party's comments in good faith. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 9.11, such Party shall be solely responsible for the execution thereof, and the other Party shall reasonably cooperate in all such recall efforts. Subject to ARTICLE 17, such Party shall be responsible for all costs of any such recall, market suspension, or market withdrawal; provided that, the other Party shall be responsible for the costs of any recall, market suspension, or market withdrawal with respect to a Product in the Territory to the extent such recall, market suspension, or market withdrawal is attributable to the other Party's breach of its obligations hereunder or its negligence, recklessness or willful misconduct.

ARTICLE 10 - MANUFACTURING AND SUPPLY

10.1 **Supply Agreement**. The Parties shall enter into mutually agreeable supply agreements as soon as appropriate after the Effective Date covering the manufacture and research supply (other than as provided in Section 6.6), clinical supply or Commercial supply of Compounds or Products needed for Development or Commercialization.

ARTICLE 11 - PAYMENT

11.1 Licensed Product Development Milestones Payable to Takeda.

(a) Ultragenyx shall pay to Takeda a milestone payment within forty-five (45) days after the first achievement of each of the following milestones for each Licensed Product, calculated as follows:

(i) [***];

(ii) upon Regulatory Approval of [***];

(iii) upon both (A) Regulatory Approval of [***] and (B) Pricing Approval [***]

(iv) [***];

54

CONFIDENTIAL TREATMENT REQUESTED

		(vi)	upon both (A) Regulatory Approval of [***] and (B) Pricing Approval [***]	
milestone Licensed l			ilestone payment in this Section 11.1 shall be payable only upon the first achievement and no amounts shall be due for subsequent or repeated achievements of such milestone for	
11.2	Licensed	Product Sales Miles	tones Payable to Takeda.	
following	(a) milestone	9	eyx shall pay to Takeda a milestone payment within [***] after the first achievement of eac annual Net Sales of all Licensed Products, calculated as follows:	ch of the
and Sublic	censees in	(i) a given Calendar Year	upon the Net Sales in the Territory of all Licensed Products made by Ultragenyx, its requaling or exceeding [***];	Affiliates

upon Regulatory Approval of [***]; and

(ii) upon the Net Sales in the Territory of all Licensed Products made by Ultragenyx, its Affiliates and Sublicensees in a given Calendar Year equaling or exceeding [***]; and

(iii) upon the Net Sales in the Territory of all Licensed Products made by Ultragenyx, its Affiliates and Sublicensees in a given Calendar Year equaling or exceeding [***].

(b) Each milestone payment in this Section 11.2 shall be payable only upon the first achievement of such milestone for all Licensed Products in aggregate and no amounts shall be due for subsequent or repeated achievements of such milestone. If two or more milestone events are achieved in the same Calendar Year, Ultragenyx shall pay to Takeda each milestone payment corresponding to the respective milestone event.

11.3 **Licensed Product Royalties Payable to Takeda.** Subject to Section 11.8 below, and during the applicable Licensed Product Royalty Term, Ultragenyx shall pay to Takeda, on a Licensed Product-by-Licensed Product basis, a running royalty at the following incremental royalty rates, on Net Sales of each Licensed Product in the Territory in a Calendar Year:

Net Sales in the Territory

Royalty Rate

For that portion of annual Net Sales less than \$[***]

For that portion of annual Net Sales greater than or

[***]%

(v)

55

CONFIDENTIAL TREATMENT REQUESTED

equal to \$[***] but less than \$[***]	
For that portion of annual Net Sales greater than or equal to \$[***] but less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***]	[***]%

11.4 Exercised Product Milestones and Fees Payable to Ultragenyx.

- (a) Pursuant to the applicable Exercised Product License Agreement, Takeda shall pay to Ultragenyx a milestone payment of [***] within [***] after the first Regulatory Approval in the first indication in Japan for [***] if such product is an Exercised Product that has not been terminated at the time of such Regulatory Approval. The milestone payment in this Section 11.4(a) shall be payable only upon the first achievement of such milestone for each such Exercised Product and no amounts shall be due for subsequent or repeated achievements of such milestone for such Exercised Product. For clarity, the maximum aggregate amount payable by Takeda for each Exercised Product pursuant to this Section 11.4(a) is [***].
- (b) For all Ultragenyx Pipeline Products other than [***], during the Takeda Option Negotiation Period for such Ultragenyx Pipeline Products, the Parties will negotiate in good faith (for inclusion in the applicable Exercised Product License Agreement) commercially reasonable financial terms in addition to the royalties contemplated in Section 11.6 (such as one or more of the following: option exercise fees, sales and development milestones, reimbursement for historical research and development costs allocable to Japan, and milestones due to Third Party licensors) for such Ultragenyx Pipeline Products, taking into consideration factors such as the investment in the collaboration under this agreement already made by Takeda, including the premium paid by Takeda to Ultragenyx under the Common Stock Purchase Agreement. If the Parties cannot reach agreement on such commercially reasonable financial terms during the Takeda Option Negotiation Period, either Takeda or Ultragenyx may seek a final decision regarding the commercially reasonable financial terms pursuant to binding arbitration as set forth in Section 16.3.
- 11.5 **Licensed Product Royalties Payable to Ultragenyx for the Exercised Countries**. Subject to Section 11.8 below, and during the applicable Licensed Product Royalty Term, pursuant to the applicable Exercised Product License Agreement, Takeda shall pay to Ultragenyx, on a Licensed Product-by-Licensed Product basis, a running royalty at the following incremental royalty rates, on aggregate, Net Sales of each Exercised Product that is a Licensed Product in the Exercised Countries in a Calendar Year:
- (a) If the Takeda Option for such Licensed Product is exercised by Takeda prior to Takeda's receipt of the Final Phase II Data Package for such Licensed Product:

56

CONFIDENTIAL TREATMENT REQUESTED

Net Sales in the Exercised Countries	Royalty Rate
For that portion of annual Net Sales less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***] but less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***] but less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***]	[***]%

(b) If the Takeda Option for such Licensed Product is exercised by Takeda after Takeda's receipt of the Final Phase II Data Package for such Licensed Product:

Net Sales in the Exercised Countries	Royalty Rate
For that portion of annual Net Sales less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***] but less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***] but less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***]	[***]%

- 11.6 Licensed Option Product and Ultragenyx Pipeline Product Royalties Payable to Ultragenyx for the Exercised Countries. During the Takeda Option Negotiation Period for a Licensed Option Product or Ultragenyx Pipeline Product, the Parties will negotiate in good faith (for inclusion in the applicable Exercised Product License Agreement) tiered royalty rates on annual Net Sales of such Licensed Option Product or Ultragenyx Pipeline Product to be paid by Takeda to Ultragenyx during the Takeda Royalty Term. If the Parties cannot reach agreement on such tiered royalty rates during the Takeda Option Negotiation Period, either Takeda or Ultragenyx may seek a final decision regarding the royalty rates pursuant to binding arbitration as set forth in Section 16.3.
- 11.7 **Royalty Reduction for Generic Product Entry in a Country**. On a Licensed Product- by-Licensed Product basis, the royalty rates set forth in Sections 11.3 and 11.5 for Net Sales of a Product in a country shall be reduced by [***] in each Calendar Quarter during which the Generic Competition Percentage with respect to such Licensed Product in such country in such Calendar Quarter is greater than or equal to [***].

11.8 Payment for Third Party Licenses.

- (a) Each Party will be responsible for paying all Third Party license fees, royalties, and/or milestones, with respect to Third Party licenses entered into by such Party or its Affiliates prior to or on the Effective Date or during the Term, for intellectual property that is necessary or reasonably useful for the Exploitation of any Licensed Product. For such Third Party licenses to Preexisting Third Party IP, the paying Party will be entitled to deduct up to [***] of such amounts due to any such Third Party from royalties payable to the other Party hereunder on such Licensed Product. For such Third Party licenses obtained during the Term, the paying Party will be entitled to deduct [***] of such amounts due to any such Third Party from royalties payable to the other Party hereunder on such Licensed Product. Notwithstanding the foregoing, in no event shall such royalty payable to Takeda in any Calendar Quarter as a result of this reduction be less than [***] of the amount that would otherwise be due.
- (b) Ultragenyx shall be responsible for paying all Third Party license fees, royalties, and/or milestones, with respect to Third Party licenses for intellectual property that is necessary or reasonably useful for the Exploitation of any Ultragenyx Pipeline Product, where such licenses are entered into (i) prior to or on the Effective Date or (ii) unless and until such Ultragenyx Pipeline Product is an Exercised Product, during the Term. Each Party will be responsible for paying all Third Party license fees, royalties, and/or milestones, with respect to Third Party licenses for intellectual property that is necessary or reasonably useful for the Exploitation of any Ultragenyx Pipeline Product that is an Exercised Product entered into by such Party or its Affiliates on or after the date on which it becomes an Exercised Product. For such Third Party licenses obtained by Takeda or its Affiliates, Takeda will be entitled to deduct [***] of such amounts due to any such Third Party from royalties payable to Ultragenyx on such Exercised Product. Notwithstanding the foregoing, in no event shall the royalty payable to Ultragenyx in any Calendar Quarter on such Exercised Product as a result of this reduction be less than [***] of the amount that would otherwise be due.
- (c) Notwithstanding the foregoing, for intellectual property held by a Third Party that is necessary or reasonably useful for the Exploitation of any Exercised Products in both the Exercised Countries and other countries in the Territory, the Parties will coordinate license negotiations with such Third Party for rights in both the Exercised Countries and other countries in the Territory.
- Manner of Royalty Payment. Each Party will calculate and report royalty payments due by such Party to the other Party under Section 11.3 or 11.5, as applicable, each Calendar Quarter. Each Party shall pay all royalty payments due under Section 11.3 or 11.5, as applicable, within sixty (60) days after the end of each Calendar Quarter and shall include with each payment a report containing the following information for the applicable Calendar Quarter: (a) the amount of gross sales (in U.S. dollars) of the Products in the Territory; (b) an itemized calculation of Net Sales in the Territory showing deductions, to the extent applicable, provided for in the definition of "Net Sales"; (c) a calculation of the royalty payment due on such sales;

(d) an accounting of the number of units and prices for the Products sold; and (e) application of

58

CONFIDENTIAL TREATMENT REQUESTED

the reductions, if any, made in accordance with the terms of Section 11.7 and 11.8. Within twenty (20) Business Days after the end of each Calendar Quarter, each Party shall provide a preliminary report as described above for the most recent Calendar Quarter then ended. Each Party shall reasonably cooperate to reconcile any deviations and confirm the accuracy to the extent necessary under Applicable Laws, GAAP or IFRS.

11.10 **Exchange Rate**. The rate of exchange to be used in computing the amount of currency equivalent in U.S. Dollars owed to a Party under this Agreement shall be equal to the weighted average exchange rate, over the applicable Calendar Quarter, between each currency of origin and U.S. Dollars as reported by OANDA (www.oanda.com), or an equivalent resource as agreed by the Parties, on the last Business Day of the Calendar Quarter in which the applicable Net Sales were made.

11.11 Taxes

- (a) Cooperation and Coordination. The Parties acknowledge and agree that it is their mutual objective and intent to appropriately calculate, to the extent feasible and legal, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use all commercially reasonable efforts to cooperate and coordinate with each other to achieve such objective. Ultragenyx shall cooperate with Takeda in seeking any tax exemption or credits that may be available to Takeda with respect to any research which Takeda or its affiliates perform or fund under this Agreement, including any credits under section 45C of the U.S. Internal Revenue Code of 1986, as amended.
- (b) Payment of Tax. A Party receiving a payment pursuant to this ARTICLE 11 shall pay any and all taxes levied on such payment. A Party making a payment pursuant to this ARTICLE 11 shall make a reasonable effort to obtain the lowest tax rate under Applicable Laws for taxes required to be deducted and withheld. If Applicable Laws require that taxes be deducted and withheld from a payment made pursuant to this ARTICLE 11, after a Party making a payment makes a reasonable effort to obtain the lowest tax rate, the remitting Party shall: (i) deduct those taxes from the payment; (ii) pay the taxes to the proper taxing authority; and (iii) send evidence of the obligation together with proof of payment to the other Party within sixty (60) days following that payment.
- (c) Tax Residence Certificate. A Party receiving a payment pursuant to this ARTICLE 11 shall provide the remitting Party appropriate certification from relevant revenue authorities that such Party is a tax resident of that jurisdiction, if such receiving Party wishes to claim the benefits of an income tax treaty to which that jurisdiction is a party. Upon the receipt thereof, any deduction and withholding of taxes shall be made at the appropriate treaty tax rate.
- (d) Assessment. Either Party may, at its own expense, protest any assessment, proposed assessment, or other claim by any Governmental Authority for any additional amount of taxes, interest or penalties or seek a refund of such amounts paid if permitted to do so by Applicable Laws. The Parties shall cooperate with each other in any protest by providing records and such additional information as may reasonably be necessary for a Party to pursue such protest.

59

CONFIDENTIAL TREATMENT REQUESTED

- (e) Withholding. If a Party that owes a payment under this Agreement assigns its rights and obligations to any Person and if, solely as a result of such assignment, the withholding or deduction of tax required by Applicable Laws with respect to payments under this Agreement is increased, then, subject to Section 11.11(f), any amount payable under this Agreement shall be increased to take into account such withheld or deducted taxes as may be necessary so that, after making all required withholdings and deductions (including withholdings and deductions on amounts payable under this Section 11.11(e)), the payee receives an amount equal to the sum it would have received had no such increased withholding or deduction been made. For the avoidance of doubt, if a payee under this Agreement assigns its rights and obligations under this Agreement, the payee shall not be entitled to any additional payments with respect to Taxes arising as a result of such payee's assignment.
- (f) Credit. To the extent a payee obtains any credit for Taxes for which it has received a payment pursuant to Section 11.11(e) against any liability for tax in the year in which the receipt is taxable, any preceding years, or any succeeding years within the term of this Agreement, thereby reducing out-of-pocket tax payments by the Section 11.11(e)-payee in such year or years, calculated on a "with and without" basis, the Section 11.11(e)-payee shall promptly reimburse the Section 11.11(e)-payor an amount equal to its tax savings resulting from such credit and the Section 11.11(e)-payee shall timely provide the Section 11.11(e)-payor with reasonable evidence as may reasonably be requested to determine whether any amounts are subject to reimbursement pursuant to this Section 11.11(f).
- Audit. Each Party will maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the calculation of royalty and other payments under this Agreement. Upon reasonable prior notice, such records shall be available during regular business hours for a period of three (3) years from the end of the Calendar Year to which they pertain for examination at the expense of the requesting Party, and not more often than once each Calendar Year, by an independent certified public accountant selected by the requesting Party and reasonably acceptable to the other Party, for the sole purpose of verifying the accuracy of the financial reports furnished by the other Party pursuant to this Agreement. Any such auditor shall not disclose the other Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the other Party or the amount of payments due by the other Party under this Agreement during the prior thirty six (36) months. Any amounts shown to be owed but unpaid shall be paid within thirty (30) days from the accountant's report, plus interest (as set forth in Section 11.13) from the original due date. Any amounts shown to have been overpaid shall be refunded within thirty (30) days from the accountant's report. The requesting Party shall bear the full cost of such audit unless such audit discloses an underpayment by other Party of more than five percent (5%) of the amount due, in which case the other Party shall bear the full cost of such audit.
- Manner of Payment, Late Payment. All payments due to a Party hereunder shall be made in U.S. Dollars by wire transfer of immediately available funds into an account designated by such Party. If a Party does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to such Party until the date of payment at the per annum rate of one percent (1%) over the then-current prime rate quoted by

60

CONFIDENTIAL TREATMENT REQUESTED

Citibank in New York City or the maximum rate allowable by Applicable Laws, whichever is lower.

11.14 **Finance and Accounting Working Group**. The Parties shall cooperate with each other to achieve the finance and accounting objectives contemplated herein in a timely, accurate and responsive manner. The Parties shall establish a finance and accounting working group to manage financial and accounting affairs related to the Products, which, for at least the first twelve (12) months after the Effective Date, shall meet monthly unless otherwise agreed upon by the Parties.

ARTICLE 12 – INTELLECTUAL PROPERTY MATTERS

12.1 **Ownership of Inventions**.

- (a) **Sole Ownership.** Subject to the terms of this Agreement, each Party shall own any Inventions made solely by its own employees, agents, or independent contractors or its Affiliate's or sublicensees' employees, agents, or independent contractors in the course of conducting its activities under this Agreement, together with all intellectual property rights therein.
- (b) **Joint Ownership**. The Parties shall jointly own any Inventions that are made jointly by employees, agents, or independent contractors of each Party or its Affiliates in the course of performing activities under this Agreement, together with all intellectual property rights therein (the "Joint Inventions").
- (c) **Inventorship.** For purposes of this Agreement, inventorship shall be determined in accordance with U.S. patent laws.

12.2 Assignment Obligation and Disclosure of Inventions.

- (a) Each Party shall cause all Persons who perform activities for such Party under this Agreement to be under an obligation to assign (or, if such Party is unable to cause such Person to agree to such assignment obligation despite such Party using commercially reasonable efforts to negotiate such assignment obligation, provide a license under) their rights in any Information and Inventions resulting therefrom to such Party, except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions which have standard policies against such an assignment (in which case a suitable license, or right to obtain such a license, shall be obtained).
- (b) Takeda will promptly disclose to Ultragenyx in writing, the conception, discovery, development or making of any Joint Inventions and any Inventions Covering Ultragenyx Pipeline Improvements by Persons who perform activities for Takeda under this Agreement.

61

CONFIDENTIAL TREATMENT REQUESTED

- (c) Ultragenyx will promptly disclose to Takeda in writing the conception, discovery, development or making of any Joint Inventions and any Inventions Covering Licensed Product Improvements, or Option Product Improvements.
- (d) Each Party will promptly disclose to the other Party in writing, the conception, discovery, development or making of any Joint Inventions by Persons who perform activities for it under this Agreement.

12.3 **Prosecution of Patents.**

(a) Licensed [***] Patents, Licensed Product Improvement Patents, and Joint Patents relating to Licensed **Products.** Except as otherwise provided in this Section 12.3(a), as between the Parties, Takeda shall have the sole right and authority to prepare, file, prosecute and maintain the Licensed [***] Patent, Licensed Product Improvement Patents, and, where relating to Licensed Products, Joint Patents (collectively, the "[***] Patent Prosecution") on a worldwide basis (including the right to defend in patent office proceedings such as inter partes reviews, post grant reviews and oppositions). Takeda shall bear all costs of preparation, filing, prosecution and maintenance of the [***] Patent Prosecution in the Territory. Provided that Ultragenyx's rights with respect to the applicable Licensed Product have not terminated, Takeda, upon Ultragenyx's request, shall provide Ultragenyx a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding the [***] Patent Prosecution and drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Takeda shall consider Ultragenyx's comments regarding such communications and drafts in good faith with a view to maximizing the Patent protection and scope in the Territory in the Ultragenyx Field. If Ultragenyx's rights with respect to the applicable Licensed Product have not terminated and Takeda determines in its sole discretion to abandon or not maintain any Licensed [***] Patent, Licensed Product Improvement Patent, or, where relating to Licensed Products, Joint Patent that is being prosecuted or maintained by Takeda in the Territory and that is applicable to the in the Ultragenyx Field, then Takeda shall provide Ultragenyx with written notice of such determination within a period of time reasonably necessary to allow Ultragenyx to determine, in its sole discretion, its interest in such Patent(s) (which notice by Takeda shall be given no later than sixty (60) days prior to the final deadline for any pending action or response that may be due with respect to such Patent(s) with the applicable patent authority). If Ultragenyx provides timely written notice expressing its interest in continuing to support such Patent(s), Ultragenyx shall have the right to pursue the filing or support the continued prosecution or maintenance of such Patents and Takeda shall provide to Ultragenyx, subject to reimbursement of Takeda's out-of-pocket costs, all unpublished patent applications and any other information and documents necessary to permit Ultragenyx to take such action to establish or preserve any such Patents. If Ultragenyx pursues the filing or support of such Patents and Takeda continues to pursue a Licensed [***] Product in the Takeda Field, it shall provide Takeda a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding such Patents and drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Ultragenyx shall consider Takeda's comments regarding such communications and drafts in good faith.

62

CONFIDENTIAL TREATMENT REQUESTED

Option Product Patents, Option Product Improvement Patents, and Joint Patents Relating to Research **Products.** Except as otherwise provided in this Section 12.3(b), as between the Parties, Takeda shall have the sole right and authority to prepare, file, prosecute and maintain the Option Product Patents, Option Product Improvement Patents and, where relating to Research Products, Joint Patents on a worldwide basis (including the right to defend in patent office proceedings such as inter partes reviews, post grant reviews and oppositions). Takeda shall bear all costs of preparation, filing, prosecution and maintenance of Option Product Patents, Option Product Improvement Patents and, where relating to Research Products, Joint Patents in the Territory. During the Collaboration Term, Takeda, upon Ultragenyx's request, shall provide Ultragenyx a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding Option Product Patents, Option Product Improvement Patents and, where relating to Research Products, Joint Patents and drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Takeda shall consider Ultragenyx's comments regarding such communications and drafts in good faith with a view to maximizing the Patent protection and scope in the Territory in the Licensed Field; provided that final decision making authority rests with Takeda. If, during the Collaboration Term, Takeda determines in its sole discretion to abandon or not maintain any Option Product Patent, Option Product Improvement Patent and, where relating to Research Products, Joint Patent that is being prosecuted or maintained by Takeda in the Territory, then Takeda shall provide Ultragenyx with written notice of such determination within a period of time reasonably necessary to allow Ultragenyx to determine, in its sole discretion, its interest in such Patent(s) (which notice by Takeda shall be given no later than sixty (60) days prior to the final deadline for any pending action or response that may be due with respect to such Patent(s) with the applicable patent authority). If Ultragenyx provides timely written notice expressing its interest in continuing to support such Patent(s), Ultragenyx shall have the right to pursue the filing or support the continued prosecution or maintenance of such Patents and Takeda shall provide to Ultragenyx, subject to reimbursement of Takeda's out- of-pocket costs, all unpublished patent applications and any other information and documents necessary to permit Ultragenyx to take such action to establish or preserve any such Patents. If Ultragenyx pursues the filing or support of such Patents, it shall provide Takeda a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding such Patents and drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Ultragenyx shall consider Takeda's comments regarding such communications and drafts in good faith. Notwithstanding the foregoing, following the execution of an Option Product License Agreement and/or Exercised Product License Agreement covering an Option Product, the terms of such license agreement(s) shall govern the handling of the preparation, filing, prosecution and maintenance of Patents covering the Option Product(s).

(c) Ultragenyx Pipeline Patents, Ultragenyx Pipeline Improvement Patents, Ultragenyx [***] Patents and Joint Patents Related to Ultragenyx Pipeline Products. Except as otherwise provided in this Section 12.3(c), as between the Parties, Ultragenyx shall have the sole right and authority to prepare, file, prosecute and maintain the Ultragenyx Pipeline Patents, Ultragenyx Pipeline Improvement Patents, Ultragenyx [***] Patents and, where relating to Ultragenyx Pipeline Products, the Patents included in the Joint Inventions (the "Joint Patents"),

63

CONFIDENTIAL TREATMENT REQUESTED

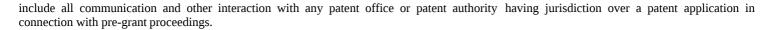
on a worldwide basis (including the right to defend in patent office proceedings such as inter partes reviews, post grant reviews and oppositions). Ultragenyx shall bear all costs of preparation, filing, prosecution and maintenance of Ultragenyx Pipeline Patents, Ultragenyx Pipeline Improvement Patents, Ultragenyx [***] Patents and, where relating to Ultragenyx Pipeline Products, Joint Patents in the Territory. During the Takeda Option Term, Ultragenyx, upon Takeda's request, shall provide Takeda a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding Ultragenyx Pipeline Patents, Ultragenyx Pipeline Improvement Patents, Ultragenyx [***] Patents and, where relating to Ultragenyx Pipeline Products, Joint Patents and drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Ultragenyx shall consider Takeda's comments regarding such communications and drafts in good faith with a view to maximizing the Patent protection and scope in the Territory; provided that final decision making authority rests with Ultragenyx. During the Takeda Option Term, if Ultragenyx determines in its sole discretion to abandon or not maintain any Ultragenyx Pipeline Patent, Ultragenyx Pipeline Improvement Patent, Ultragenyx [***] Patent and, where relating to Ultragenyx Pipeline Products, Joint Patent that is being prosecuted or maintained by Ultragenyx in the Takeda Territory, then Ultragenyx shall provide Takeda with written notice of such determination within a period of time reasonably necessary to allow Takeda to determine, in its sole discretion, its interest in such Patent(s) (which notice by Ultragenyx shall be given no later than sixty (60) days prior to the final deadline for any pending action or response that may be due with respect to such Patent(s) with the applicable patent authority). If Takeda provides timely written notice expressing its interest in continuing to support such Patent(s), Takeda shall have the right to pursue the filing or support the continued prosecution or maintenance of such Patents and Ultragenyx shall provide to Takeda, subject to reimbursement of Ultragenyx's out- of-pocket costs, all unpublished patent applications and any other information and documents necessary to permit Takeda to take such action to establish or preserve any such Patents. If Takeda pursues the filing or support of such Patents, it shall provide Ultragenyx a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding such Patents and drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Takeda shall consider Takeda's comments regarding such communications and drafts in good faith. Notwithstanding the foregoing, following the execution of an Exercised Product License Agreement covering an Ultragenyx Pipeline Product, the terms of such license agreement shall govern the handling of the preparation, filing, prosecution and maintenance of Patents covering such Ultragenyx Pipeline Product.

(d) Cooperation in Prosecution. Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts provided above in this Section 12.3, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution, as well as further actions as set forth below.

(i) The Parties shall respectively prepare, file, maintain and prosecute the Patents as set forth in this Section 12.3. As used herein, "prosecution" of such Patents shall

64

CONFIDENTIAL TREATMENT REQUESTED



(ii) All communications between the Parties relating to the preparation, filing, prosecution or maintenance of the Patents as set forth in this Section 12.3, including copies of any draft or final documents or any communications received from or sent to patent offices or patenting authorities with respect to such Patents, shall be considered Confidential Information and subject to the confidentiality provisions of ARTICLE 14.

12.4 Patent Term Extensions in the Territory.

- (a) The Parties will discuss and approve for which, if any, of the Patents under this Agreement the Parties should seek Patent Term Extensions in the Territory. If the Parties are unable to reach agreement for which, if any, of such Patents the Parties should seek Patent Term Extension, the final decision shall rest with the Party who first receives Regulatory Approval for the Licensed Product or Option Product, as applicable, with respect to which the Patent Term applies for such Party's territory. The Party with final decision-making authority shall act with reasonable promptness in light of the stage of the Products to apply for any such Patent Term Extensions, in accordance with such decision. The Party that does not apply for an extension hereunder will cooperate fully with the other Party in making such filings or actions, including making available all required Regulatory Materials (including underlying data) and Information and executing any required authorizations to apply for such Patent Term Extension. All expenses incurred in connection with activities of each Party with respect to the Patent(s) for which such Party seeks Patent Term Extensions pursuant to this 12.4 shall be entirely borne by the Party applying for such Patent Term Extension.
- 12.5 **Orange Book Listing.** The Party that is the NDA holder for the applicable Product shall be responsible for listing and maintaining all applicable Patents in the Orange Book, including payment of all costs and expenses related to such maintenance incurred after the Effective Date. The listing and maintaining Party shall provide the other Party with its planned listings in advance of their submission with sufficient time for the other Party to review and provide comments. The listing and maintaining Party shall consider any such comments in good faith. Upon request of the listing and maintaining Party, the other Party shall cooperate in the filing of appropriate information with the FDA listing such Patents in the Orange Book.

12.6 Infringement of Patents by Third Parties.

- (a) **Notification**. Each Party shall promptly notify the other Party in writing of any existing, alleged or threatened infringement of the Licensed [***] Patents, Licensed Product Improvement Patents, Ultragenyx [***] Patents, Option Product Improvement Patents, Ultragenyx Pipeline Improvement Patents, and Joint Patents in the Licensed Field in the Territory of which it becomes aware, and shall provide all Information in such Party's possession or control demonstrating such infringement.
 - (b) Infringement Action.

65

CONFIDENTIAL TREATMENT REQUESTED

(i) Takeda shall have the first right, but not the obligation, to bring an appropriate suit or other action against any Third Party engaged in any existing, alleged or threatened infringement related to the Joint Patents, Licensed [***] Patents, Licensed Product Improvement Patents, Ultragenyx [***] Patents, Option Product Patents, and Option Product Improvement Patents, in each case where relating to Licensed Products or Research Products (a "Takeda Product Infringement"), subject to Section 12.6(b)(ii) through 12.6(b)(iv); provided that if a Takeda Product Infringement concerns the enforcement of any Valid Claim against a Third Party making, using, selling, offering for sale, or importing solely within the Ultragenyx Field, Takeda must receive Ultragenyx's prior consent with respect to all strategic decisions in connection with such Takeda Product Infringement, such consent not to be unreasonably withheld, conditioned, or delayed; and provided further that if Takeda is not Developing or Commercializing the Licensed [***] Product in the Takeda Field, then the foregoing first right with respect to a Takeda Product Infringement shall become Ultragenyx's first right hereunder. Ultragenyx shall have the first right, but not the obligation, to bring an appropriate suit or other action against any Third Party engaged in any existing, alleged or threatened infringement related to the Joint Patents, Ultragenyx Pipeline Patents and Ultragenyx Pipeline Improvement Patents, in each case where relating to an Ultragenyx Pipeline Product (an "Ultragenyx Product Infringement"), subject to Section 12.6(b)(ii) through 12.6(b) (iv). Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of the infringement actions relating to the Patents covering such Licensed Option Product or Exercised Product, respectively, that is the subject of such license agreement.

(ii) The Parties shall discuss how to address each Takeda Product Infringement and Ultragenyx Product Infringement and the Party with the first right to enforce shall consider in good faith the input of the other Party in determining how to proceed. The Party with the first right to enforce shall notify the other Party of its election to take any action in accordance with Section 12.6(b) (i) within ten (10) Business Days before any time limit set forth in an Applicable Laws or regulation, including the time limits set forth under the Hatch Waxman Act. In the event such Party does not so elect, it shall so notify the other Party in writing, and the other Party shall have the right to commence a suit or take action to enforce the applicable Patent against such Third Party perpetrating such Takeda Product Infringement or Ultragenyx Product Infringement, as applicable, in the applicable portion of the Territory at its own cost and expense. If one Party elects to bring suit or take action against the Takeda Product Infringement or Ultragenyx Product Infringement, as applicable, then the other Party (at its expense) shall have the right, prior to commencement of the trial, suit or action, to join any such suit or action.

(iii) Each Party shall provide to the Party enforcing any such rights under this Section 12.6(b) reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by Applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any important aspects of such enforcement, including determination of litigation strategy and filing of important papers to the competent court.

66

CONFIDENTIAL TREATMENT REQUESTED

(iv)	Subject to this Section 12.6(b)(iv), the enforcing Party shall be solely responsible for all costs
and expenses arising from a suit or action against a	a Takeda Product Infringement or Ultragenyx Product Infringement, as applicable. For the
avoidance of doubt, the enforcing Party shall not be	responsible for the other Party's internal costs (e.g., FTEs) incurred as a result of the other
Party's cooperation with the enforcement action as	provided in Section 12.6(b)(iii). The Party not bringing an action with respect to the Takeda
Product Infringement or Ultragenyx Product Infringe	ement, as applicable, under this Section 12.6(b) shall be entitled to separate representation in
such matter by counsel of its own choice and at its	s own expense, but such Party shall at all times cooperate fully with the Party bringing such
action.	

- (c) Settlement. The enforcing Party may settle any claim, suit or action that it has brought under this Section 12.6 without the prior written consent of the other Party; provided that any such settlement does not negatively impact the non-enforcing Party's rights or interests in such non-enforcing Party's territory or field.
- (d) Allocation of Proceeds. If either Party recovers monetary damages from any Third Party in a suit or action brought under Sections 12.6(b), 12.6(c), or 12.8(b) or any royalties from a license agreement with a Third Party related to any alleged Takeda Product Infringement or Ultragenyx Product Infringement, as applicable, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such suit or action, and any remaining amounts shall be split as follows: (i) if such suit or action is initiated or defended by Ultragenyx, such amounts shall be retained by Ultragenyx, or (ii) if such suit or action was initiated or defended by Takeda, such amounts shall be retained by Takeda.

12.7 Infringement of Third Party Rights in the Territory.

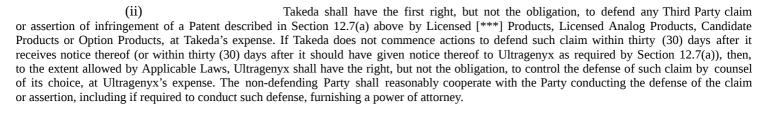
(a) **Notice.** If any Licensed Product used or sold by either Party, its Affiliates, licensees or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent granted in either Party's field or territory, the Party first having notice of the claim or assertion shall promptly notify the other Party, the Parties shall agree on and enter into an "identity of interest agreement" wherein such Parties agree to their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action.

(b) **Defense**.

(i) Ultragenyx shall have the first right, but not the obligation, to defend any Third Party claim or assertion of infringement of a Patent described in Section 12.7(a) above by Ultragenyx Pipeline Products, at Ultragenyx's expense. If Ultragenyx does not commence actions to defend such claim within thirty (30) days after it receives notice thereof (or within thirty (30) days after it should have given notice thereof to Takeda as required by Section 12.7(a)), then, to the extent allowed by Applicable Laws, Takeda shall have the right, but not the obligation, to control the defense of such claim by counsel of its choice, at Takeda's expense. The non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim or assertion, including if required to conduct such defense, furnishing a power of attorney.

67

CONFIDENTIAL TREATMENT REQUESTED



(iii) Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of the defense against infringement by Product(s) that are the subject of the applicable license agreement.

(c) Settlement; Licenses. Neither Party shall enter into any settlement of any claim described in this Section 12.7 that negatively affects the other Party's rights or interests without such other Party's written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Each Party shall have the right to decline to defend or to tender defense of any such claim to the other Party upon reasonable notice, including if the other Party fails to agree to a settlement that such Party proposes. In the event that it is determined by any court of competent jurisdiction that the Exploitation of a Product in the Licensed Field in the Ultragenyx Territory, conducted in accordance with the terms and conditions of this Agreement, infringes, or the JSC determines that such activities are likely to infringe, any patent, copyright, trademark, data exclusivity right or trade secret right arising under Applicable Laws of any Third Party, Ultragenyx shall use Commercially Reasonable Efforts to: (i) procure a license from such Third Party authorizing Ultragenyx to continue to conduct such activities; or (ii) modify such activities so as to render it non-infringing.

12.8 Patent Oppositions and Other Proceedings.

(a) Third-Party Patent Rights. If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, declaration for non-infringement, reexamination or other attack upon the validity, title or enforceability of a Patent owned or controlled by a Third Party and having one or more claims that covers a Product, or the use, sale, offer for sale or importation of a Product (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, a Third Party's claim or assertion of infringement under Section 12.7, in which case the provisions of Section 12.7 shall govern), such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. Ultragenyx shall have the exclusive right, but not the obligation, to bring at its own expense and in its sole control such action in the Territory with respect to Ultragenyx Pipeline Products. Takeda shall have the exclusive right, but not the obligation, to bring at its own expense and in its sole control such action with respect to Licensed [***] Products, Licensed Analog Products and Research Products in the Territory. If the

68

CONFIDENTIAL TREATMENT REQUESTED

Party with the first right does not bring such an action, within ninety (90) days of notification thereof pursuant to this Section 12.8(a) (or earlier, if required by the nature of the proceeding), then the other Party shall have the right, but not the obligation, to bring, at its sole expense, such action. The Party not bringing an action under this Section 12.8(a) shall be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense, and shall cooperate fully with the Party bringing such action. Any awards or amounts received in bringing any such action shall be first allocated to reimburse the initiating Party's expenses in such action and any remaining amounts shall be retained by such Party.

(b) Parties' Patent Rights. If any Licensed [***] Patents, Licensed Product Improvement Patent, Ultragenyx [***] Patents, Option Product Patent, Option Product Improvement Patent, Ultragenyx Pipeline Patent, Ultragenyx Pipeline Improvement Patent, or Joint Patent becomes the subject of any proceeding commenced by a Third Party within the Territory in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 12.6, in which case the provisions of Section 12.6 shall govern), then the Party responsible for filing, preparing, prosecuting and maintaining such Patent as set forth in Section 12.3, shall control such defense at its own cost and expense. The controlling Party shall permit the non-controlling Party to participate in the proceeding to the extent permissible under Applicable Laws, and to be represented by its own counsel in such proceeding, at the non-controlling Party's expense. If the controlling Party decides that it does not wish to defend against such action, then the other Party shall have a backup right to assume defense of such Third-Party action at its own expense. Any awards or amounts received in defending any such Third-Party action shall be allocated between the Parties as provided in Section 12.6(d).

ARTICLE 13 - REPRESENTATIONS AND WARRANTIES

- **Mutual Representations, Warranties and Covenants**. Each of the Parties hereby represents and warrants to the other Party as of the Execution Date and covenants that:
- (a) **Organization.** It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.
- (b) **Binding Agreement.** This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).
- (c) **Authorization.** The execution, delivery, and performance of this Agreement by such Party have been duly authorized by all necessary corporate action and do not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Laws or any order, writ, judgment, injunction, decree,

69

CONFIDENTIAL TREATMENT REQUESTED

determination, or award of any court or governmental body, or administrative or other agency presently in effect applicable to such Party.

- (e) **No Inconsistent Obligations.** Neither Party is under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.
- (f) Transparency Reporting. Each Party shall be responsible for tracking and reporting transfers of value initiated and controlled by its and its Affiliates' employees, independent contractors, and agents pursuant to the requirements of the marketing reporting laws of any Government Authority in the Territory, including Section 6002 of the Patient Protection and Affordable Care Act, commonly referred to as the "Sunshine Act."
- Regulatory Authorities in the Territory, and neither Party nor any of its Affiliates has been debarred by the FDA, is subject to any similar sanction of other Regulatory Authorities in the Territory, and neither Party nor any of its Affiliates has used, or will engage, in any capacity, in connection with this Agreement or any ancillary agreements (if any), any Person who either has been debarred by such a Regulatory Authority, or is the subject of a conviction described in Section 306 of the FFDCA. Each Party shall inform the other in writing promptly if it or any Person engaged by such Party or any of its Affiliates who is performing services under this Agreement or any ancillary agreements (if any) is debarred or is the subject of a conviction described in Section 306 of the FFDCA, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to such Party's Knowledge, is threatened, relating to the debarment or conviction of such Party, any of its Affiliates or any such Person performing services hereunder or thereunder.
- 13.2 **Additional Representations, Warranties and Covenants of Takeda**. Takeda represents and warrants as of the Execution Date and covenants to Ultragenyx that:
- (a) Takeda has all rights necessary to grant the options and licenses under the Licensed [***] Technology and Option Product Technology and rights of cross-reference under Regulatory Materials, in each case, existing as of the Execution Date that it grants to Ultragenyx in this Agreement. For the duration of the Term, Takeda shall not, and shall cause its Affiliates not to, grant to any Third Party rights in the Licensed Field or the Ultragenyx Field, as applicable, in the Territory that encumber, diminish or conflict with the rights granted to

70

CONFIDENTIAL TREATMENT REQUESTED

Ultragenyx hereunder with respect to the Licensed [***] Technology, Option Product Technology, Joint Intellectual Property or Regulatory Materials.
(b) (i) The Patents set forth in Exhibit 1.168 represent all Takeda Patents, (ii) to Takeda's Knowledge, the
Compounds set forth in Exhibit 13.2(b) represent all structures Controlled by Takeda that are [***], and
(i) to Takeda's Knowledge, the Compound set forth in Exhibit 1.94 represents the sole Licensed [***] Compound. Takeda (Y) is the sole and
exclusive owner of the entire right, title and interest in the Takeda Patents, and (Z) to Takeda's Knowledge, the sole and exclusive owner of the
entire right, title and interest in the Licensed [***] Compound and Licensed Analog Compounds, and in each of cases (Y) and (Z), free of any
encumbrance, lien, or claim of ownership by any Third Party.

- (c) To Takeda's Knowledge, there is no actual or threatened infringement or misappropriation of the Licensed [***] Technology and Option Product Technology by any Person in the Territory.
- (d) The Takeda Patents are being diligently prosecuted in the Territory in accordance with Applicable Laws. To Takeda's Knowledge, the Takeda Patents have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment.
- (e) To Takeda's Knowledge, each of the Takeda Patents properly identifies each and every inventor of the claims thereof as determined in accordance with Applicable Laws of the jurisdiction in which such Takeda Patent is issued or such application is pending.
- (f) To the extent permissible under Applicable Laws, all employees of Takeda or its Affiliates performing activities under this Agreement are and shall be under an obligation to assign all right, title and interest in and to their Inventions and intellectual property rights therein, to Takeda or its Affiliate(s) as the sole owner thereof. Ultragenyx shall have no obligation to contribute to any remuneration of any inventor employed or previously employed by Takeda or any of its Affiliates in respect of any such Inventions and intellectual property rights therein that are so assigned to Takeda or its Affiliate(s). Takeda will pay all such remuneration due to such inventors with respect to such Inventions and intellectual property rights therein.
- (g) The Inventions claimed or disclosed by the Takeda Patents (i) were not conceived, discovered, developed, or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the U.S. or any agency thereof, (ii) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(f), and (iii) are not otherwise subject to the provisions of the Bayh-Dole Act.
- (h) To Takeda's Knowledge, there are no material claims, judgments, or settlements against, or amounts with respect thereto, owed by Takeda or any of its Affiliates to any Third Parties relating to the Regulatory Materials, Licensed [***] Technology or Option Product Technology in the Territory.

CONFIDENTIAL TREATMENT REQUESTED

(i)	No claim or litigation in the Territory has been brought or, to Takeda's Knowledge, threatened by any Person
alleging, and Takeda has no l	Knowledge of any claim, whether or not asserted: (i) that any of the Takeda Patents is invalid or unenforceable, (ii)
that the Regulatory Materials	s, or the disclosing, copying, making, assigning, or licensing of the Regulatory Materials, violates, infringes, or
otherwise conflicts or interfer	res with, or would violate, infringe, or otherwise conflict or interfere with, any intellectual property or proprietary
right of any Person; or (iii)	related to the Development or Commercialization of the Licensed Products or Research Products, including any
claims of Product Liability.	

- (j) Takeda has no Knowledge of any material adverse information with respect to the safety and efficacy of any Licensed Product or Research Product that has not been disclosed to Ultragenyx, and all such information that has been disclosed is true, correct, and complete in all material respects.
- (k) To Takeda's Knowledge, Takeda and its Affiliates have generated, prepared, maintained, and retained all material Regulatory Materials in the Licensed Field that are required to be maintained or retained pursuant to and in accordance with GCP, GLP and other Applicable Laws, and all such information is true, complete and correct in all material respects and what it purports to be.
- (l) Takeda, without the prior written consent of Ultragenyx, during the Term, will not solicit, induce, encourage, or participate in soliciting, inducing, or encouraging any employee of Ultragenyx, or any of its Affiliates, to terminate his or her relationship with Ultragenyx or Ultragenyx's Affiliate. An offer of employment to an employee of Ultragenyx by Takeda which results directly from unsolicited responses to general advertisements for employment will not be deemed to be in violation of this provision.
- (m) In performing its obligations under this Agreement, Takeda shall, and shall cause its Affiliates to, comply with all Applicable Laws, including any applicable anti-corruption or anti-bribery laws or regulation, of any Governmental Authority with jurisdiction over the activities performed by Takeda or its Affiliates in furtherance of such obligations.
- 13.3 **Additional Representations, Warranties and Covenants of Ultragenyx**. Ultragenyx represents and warrants as of the Execution Date and covenants to Takeda that:
- (a) Ultragenyx and its Affiliates have provided or made available to Takeda prior to the Execution Date, true, complete, and correct copies (as of the Execution Date) of all Ultragenyx In-License Agreements.
- (b) Ultragenyx has all rights applicable necessary to grant the options and licenses under the Ultragenyx Intellectual Property and rights of cross-reference under Regulatory Materials, in each case, that it grants to Takeda in this Agreement. For the duration of the Term, Ultragenyx shall not, and shall cause its Affiliates not to, grant to any Third Party rights in the Takeda Field in the Territory or the Licensed Field in the Takeda Territory, as applicable, that encumber, diminish or conflict with the rights granted to Takeda hereunder with respect to the Ultragenyx Intellectual Property, Joint Intellectual Property or Regulatory Materials.

CONFIDENTIAL TREATMENT REQUESTED

(C) owner of the entire right, title a	The Patents set forth in Exhibit 1.188 represent all Ultragenyx Patents. Ultragenyx is the sole and exclusive and interest in the Ultragenyx Patents free of any encumbrance, lien, or claim of ownership by any Third Party.
(d) Intellectual Property by any Per	To Ultragenyx's Knowledge, there is no actual or threatened infringement or misappropriation of the Ultragenyx son in the Territory.
	The Ultragenyx Patents are being diligently prosecuted in the Territory in accordance with Applicable Laws and arrent prosecution practices. To Ultragenyx's Knowledge, the Ultragenyx Patents have been filed and maintained applicable fees have been paid on or before the due date for payment.
(f) claims thereof as determined in	To Ultragenyx's Knowledge, each of the Ultragenyx Patents properly identifies each and every inventor of the accordance with Applicable Laws of the jurisdiction in which such Ultragenyx Patent is issued or such application

- is pending.
- To the extent permissible under Applicable Laws, all employees of Ultragenyx or its Affiliates performing (g) activities under this Agreement shall be under an obligation to assign all right, title and interest in and to their Inventions, and intellectual property rights therein, to Ultragenyx or its Affiliate(s) as the sole owner thereof. Takeda shall have no obligation to contribute to any remuneration of any inventor employed or previously employed by Ultragenyx or any of its Affiliates in respect of any such inventions, Information and discoveries and intellectual property rights therein that are so assigned to Ultragenyx or its Affiliate(s). Ultragenyx will pay all such remuneration due to such inventors with respect to such Inventions and intellectual property rights therein.
- To Ultragenyx's Knowledge, the Inventions claimed or disclosed by the Ultragenyx Patents (i) were not conceived, discovered, developed, or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the U.S. or any agency thereof, (ii) are not a "subject invention" as that term is described in 35 Section 201(f), and (iii) are not otherwise subject to the provisions of the Bayh-Dole Act.
- To Ultragenyx's Knowledge, there are no material claims, judgments, or settlements against, or amounts with (i) respect thereto, owed by Ultragenyx or any of its Affiliates to any Third Parties relating to the Regulatory Materials or the Ultragenyx Intellectual Property in the Territory.
- (i) Ultragenyx has no Knowledge of any material adverse information with respect to the safety and efficacy of any Compound or Product that has not been disclosed to Takeda, and all such information that has been disclosed is true, correct, and complete in all material respects.
- No claim or litigation in the Territory has been brought or, to Ultragenyx's Knowledge, threatened by any Person (k) alleging, and Ultragenyx has no Knowledge of any claim, whether or not asserted: (i) that any of the Ultragenyx Patents is invalid or unenforceable, (ii) that the Regulatory Materials, the Ultragenyx Intellectual Property, or the disclosing, copying,

CONFIDENTIAL TREATMENT REQUESTED

making, assigning, or licensing of the Regulatory Materials or the Ultragenyx Intellectual Property, violates, infringes, or otherwise conflicts or interferes with, or would violate, infringe, or otherwise conflict or interfere with, any intellectual property or proprietary right of any Person; or (iii) related to the Development or Commercialization of the Products, including any claims of Product Liability.

- (l) In performing its obligations under this Agreement Ultragenyx shall, and shall cause its Affiliates to, comply with all Applicable Laws, including any applicable anti-corruption or anti-bribery laws or regulation, of any Governmental Authority with jurisdiction over the activities performed by Ultragenyx or its Affiliates in furtherance of such obligations.
- (m) Ultragenyx, without the prior written consent of Takeda, during the Term, will not solicit, induce, encourage, or participate in soliciting, inducing, or encouraging any employee of Takeda, or any of its Affiliates, to terminate his or her relationship with Takeda or Takeda's Affiliate. An offer of employment to an employee of Takeda by Ultragenyx which results directly from unsolicited responses to general advertisements for employment will not be deemed to be in violation of this provision.
 - (n) [***].
- (o) Ultragenyx has provided Takeda with true and correct copies (as of the Execution Date) of all Ultragenyx In-License Agreements in effect as of the Execution Date. None of Ultragenyx, its Affiliates and, to their Knowledge, any Third Party, is in breach of any Ultragenyx In-License Agreement and none of Ultragenyx, its Affiliates and, to their Knowledge, any other party to any Ultragenyx In-License Agreement has threatened to terminate, or has otherwise alleged any material breach under, such agreement and each Ultragenyx In-License Agreement is in full force and effect in accordance with its terms
- 13.4 No Other Representations or Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 13, THE PARTIES MAKE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, INCLUDING ANY EXPRESS OR IMPLIED WARRANTY OF QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT OR AS TO THE VALIDITY OF ANY PATENTS IN THE TERRITORY.

ARTICLE 14 - CONFIDENTIALITY

14.1 **Nondisclosure.** Each Party agrees that, during the Term and for a period of ten (10) years thereafter, a Party (the "<u>Receiving Party</u>") receiving Confidential Information of the other Party (the "<u>Disclosing Party</u>") 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, (b) not disclose such

74

CONFIDENTIAL TREATMENT REQUESTED

Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted
below, and (c) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this
Section 14.1 shall not create or imply any rights or licenses not expressly granted under this Agreement). Notwithstanding anything to the contrary
in the foregoing, the obligations of confidentiality and non-use with respect to any trade secret within such Confidential Information shall survive
such ten (10) year period for so long as such Confidential Information remains protected as a trade secret under Applicable Laws.

- such ten (10) year period for so long as such Confidential Information remains protected as a trade secret under Applicable Laws.

 14.2 **Exceptions.** The obligations in Section 14.1 shall not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent evidence:
- (a) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party hereunder;
- (b) is known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party;
- (c) is subsequently disclosed to the Receiving Party or any of its Affiliates on a non- confidential basis by a Third Party that, to the Receiving Party's Knowledge, is not bound by a similar duty of confidentiality or restriction on its use;
- (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, generally known or available, either before or after it is disclosed to the Receiving Party;
- (e) is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates without the use of or access to Confidential Information belonging to the Disclosing Party; or
 - (f) is the subject of written permission to disclose provided by the Disclosing Party.
- **Authorized Disclosure.** The Receiving Party may disclose Confidential Information belonging to the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances: filing or prosecuting Patents as permitted by this Agreement;
 - (b) filing Regulatory Materials in order to obtain or maintain Regulatory Approvals;
 - (c) prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation;
- (d) complying with Applicable Laws or regulations or court or administrative orders; or
- (e) to its Affiliates, sublicensees or prospective sublicensees, subcontractors or prospective subcontractors, payors, consultants, agents and advisors on a "need-to-know" basis

CONFIDENTIAL TREATMENT REQUESTED

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 by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than those set forth in this ARTICLE 14; provided, however, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 14.3 to treat such Confidential Information as required under this ARTICLE 14.

- (f) If and whenever any Confidential Information is disclosed in accordance with this Section 14.3, such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to clauses (a) through (d) of this Section 14.3, it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use not less than the same efforts to secure confidential treatment of such information as it would to protect its own confidential information from disclosure and shall be jointly and severally liable for any breach of this ARTICLE 14 by such Person.
- 14.4 **Terms of this Agreement.** The Parties acknowledge that this Agreement and all of the respective terms of this Agreement shall be treated as Confidential Information of both Parties.
- **Publicity.** The Parties shall make a joint public announcement of the execution of this Agreement in the form attached as Exhibit 14.5, which shall be issued at a time to be mutually agreed by the Parties. Each Party agrees not to issue any other press release or other public statement disclosing other information relating to this Agreement or the transactions contemplated hereby that contains information not previously publicly disclosed in accordance with this Section 14.5 without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed.
- Securities Filings. Notwithstanding anything to the contrary in this ARTICLE 14, in the event either Party proposes to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction a registration statement or any other disclosure document that describes or refers to the terms and conditions of this Agreement or any related agreements between the Parties, such Party shall notify the other Party of such intention and shall provide the other Party with a copy of relevant portions of the proposed filing at least ten (10) Business Days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto that refer to the other Party or the terms and conditions of this Agreement or any related agreements between the Parties. The Party making such filing shall cooperate in good faith with the other Party to obtain confidential treatment of the terms and conditions of this Agreement or any related agreements between the Parties that the other Party requests to be kept confidential or otherwise afforded confidential treatment, and shall only disclose Confidential Information that it is reasonably advised by outside counsel is legally required to be disclosed. No such notice and provision of a copy shall be required if the description of or reference to this Agreement or a related agreement

76

CONFIDENTIAL TREATMENT REQUESTED

between the Parties contained in the proposed filing has been included in any previous filing made by the either Party in accordance with this Section 14.6 or otherwise approved by the other Party.

- 14.7 **Relationship to Confidentiality Agreement.** As of the Effective Date, this Agreement supersedes the Confidentiality Agreement; provided however, that all "Confidential Information" disclosed or received by the Parties thereunder shall be deemed Confidential Information hereunder and shall be subject to the terms and conditions of this Agreement.
- **Equitable Relief.** Given the nature of the Confidential Information and the competitive damage that could 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 14. 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 14.
- Publications. All publications relating to the use of the Compound and/or a Product in the Licensed Field shall be prepared, presented and/or published in accordance with pharmaceutical industry accepted guidelines including: (a) International Committee of Medical Journal Editors (ICMJE) guidelines, (b) Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, (c) Pharmaceutical Research and Manufacturers of America (PhRMA) guidelines, and (d) Principles on Conduct of Clinical Trials. Each Party will have the right to publish summaries of results of all Clinical Trials conducted by such Party with respect to the use of a Product in the Licensed Field after the Effective Date; provided, however, that the other Party will have the right to review and comment on all proposed publications prior to submission of such publication. The publishing Party shall provide the other Party at least sixty (60) days prior notice to review and comment on the Clinical Trials results, or non-clinical study results to be published for the purposes of preparing any necessary Patent filings.
- Clinical Trial Transparency. Both Parties agree to collaborate to maintain compliance with all Applicable Laws related to clinical trial transparency, as well as any industry guidelines/codes of conduct, or other obligations that may apply to either the sponsor of any clinical trial and/or the owner of any Regulatory Approval, all as relates to any Research Product or Licensed Product. The Parties shall cooperate to maintain clinical trial transparency consistent with each sponsor's clinical trial registration, summary result, and data sharing transparency policies and will support disclosure of Information as needed based on the needs of the sponsors of the study or the Regulatory Approval holder with respect to any Research Product or Licensed Product.

ARTICLE 15 - TERM AND TERMINATION

15.1 **Term.** This Agreement shall become effective as of the Effective Date and shall continue in full force and effect, unless earlier terminated pursuant to this ARTICLE 15, until the later of the (a) expiration of the Collaboration Term, (b) the expiration of the Takeda Option Term, (c) the expiration of the Licensed Product Royalty Term with respect to all Licensed

77

CONFIDENTIAL TREATMENT REQUESTED

Products in the Territory, or (d) the expiration of the Takeda Royalty Term with respect to all Products the Takeda Territory (the "Term").

15.2 **Termination for Material Breach**.

- Either Party (the "Non-breaching Party") may terminate this Agreement in its entirety (except as otherwise provided in this Section 15.2(a)) if the other Party (the "Breaching Party") has materially breached this Agreement, and such material breach has not been cured within sixty (60) days after receipt of written notice of such breach by the Breaching Party from the Non-Breaching Party (the "Cure Period"); provided, however, that, notwithstanding the foregoing, termination pursuant to this Section 15.2(a) shall be on a Compound-by-Compound and Product-by-Product basis unless such material breach materially diminishes, or materially frustrates, the value of this Agreement to the Non-breaching Party, taken as a whole, in which case the Non-breaching Party may terminate this Agreement in its entirety. Any termination of this Agreement with respect to a Compound or Product, or in its entirety, pursuant to this Section 15.2(a) 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. The right of either Party to terminate this Agreement with respect to a Compound or Product, or in its entirety, as provided in this Section 15.2(a) 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.
- (b) If the Parties reasonably and in good faith disagree as to whether there has been a material breach, including whether such breach was material, the Party that disputes whether there has been a material breach may contest the allegation in accordance with ARTICLE 16. Notwithstanding anything to the contrary contained in Section 15.2(a), the Cure Period for any Dispute will run from the date that written notice was first provided to the Breaching Party by the Non-Breaching Party through the resolution of such Dispute pursuant to ARTICLE 16, and it is understood and acknowledged that, during the pendency of a Dispute pursuant to this Section 15.2(b), 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 under this Agreement.
- (C) Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of termination for material breach with respect to the activities that are the subject of such license agreement (which shall be on the basis of this Section 15.2) and any termination of this Agreement shall not affect the existence of such Option Product License Agreement or Exercised Product License Agreement.

15.3 **Termination for Safety Reasons.**

(a) Each Party shall have the right to terminate this Agreement on a Compound-by- Compound and Product-by-Product basis with respect to such Party's field and territory at any time upon providing ninety (90) days prior written notice to the other Party (i) if senior executives responsible for the terminating Party's pharmacovigilance and clinical science functions determine in good faith that the risk/benefit profile of the Compound or Product is such that the Compound or Product cannot continue to be Developed or administered to patients

78

CONFIDENTIAL TREATMENT REQUESTED

safely; or (b) upon the occurrence of	serious adverse	events r	elate	ed to the	use	of the	Con	npound o	or Prod	uct that	caus	e th	ie termii	nati	ng Part	y to
conclude that the continued use of the	e Compound or	Product	by	patients	will	result	in	patients	being	exposed	to	a p	product	in	which	the
isks outweigh the benefits.																

(b) Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of termination for safety reasons with respect to the activities that are the subject of such license agreement (which shall be on the basis of this Section 15.3) and any termination of this Agreement shall not affect the existence of such Option Product License Agreement or Exercised Product License Agreement.

15.4 Termination for Convenience.

- (a) Takeda shall have the right to terminate this Agreement with respect to the Takeda Option for any or no reason upon ninety (90) days written notice.
- (b) Provided that Ultragenyx has completed Development activities for a Licensed [***] Product in the Takeda Field as set forth in the Initial [***] Development Plan pursuant to Section 4.3(a), after the end of the Collaboration Term Ultragenyx shall have the right to terminate this Agreement with respect to any or all Licensed Products in any or all countries for which it has rights with respect to such Licensed Products for any or no reason upon ninety (90) days written notice.
- (c) Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of termination for convenience with respect to the activities that are the subject of such license agreement (which shall be on the basis of this Section 15.4) and any termination of this Agreement shall not affect the existence of such Option Product License Agreement or Exercised Product License Agreement.

15.5 **Termination for Patent Challenge**.

- (a) Takeda may terminate this Agreement with respect to the Licensed Products at any time upon providing written notice to Ultragenyx, if Ultragenyx, or any of Ultragenyx's Affiliates, directly, or indirectly through assistance granted to a Third Party, commences any interference or opposition proceeding, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to any Takeda Patent or any other Patent owned or controlled by Takeda that claims or discloses the composition of matter or the method of making or using a Licensed Product.
- (b) Takeda may terminate this Agreement with respect to all Candidate Products and/or Option Products at any time upon providing written notice to Ultragenyx, if Ultragenyx, or any of Ultragenyx's Affiliates, directly, or indirectly through assistance granted to a Third Party, commences any interference or opposition proceeding, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection

79

CONFIDENTIAL TREATMENT REQUESTED

certificate with respect to any Takeda Patent or any other Patent Controlled by Takeda that claims or discloses the composition of matter or the method of making or using a Candidate Product and/or Option Product.

- (c) Ultragenyx may terminate this Agreement with respect to an Ultragenyx Pipeline Product at any time upon providing written notice to Takeda, if Takeda, or any of Takeda's Affiliates, directly, or indirectly through assistance granted to a Third Party, commences any interference or opposition proceeding, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to any Ultragenyx Patent or any other Patent Controlled by Ultragenyx that claims or discloses the composition of matter or the method of making or using such Ultragenyx Pipeline Product.
- (d) Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of termination for patent challenge with respect to the activities that are the subject of such license agreement (which shall be on the basis of this Section 15.5) and any termination of this Agreement shall not affect the existence of such Option Product License Agreement or Exercised Product License Agreement.

15.6 **Termination for Insolvency**.

- (a) Either 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 an insolvency petition in bankruptcy, 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, and such proceeding or action remains un-dismissed or un-stayed for a period of more than ninety (90) days.
- (b) All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any other jurisdiction outside of the Territory (collectively, the "Bankruptcy Laws"), licenses of rights to "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided pursuant to such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee) shall perform all of the obligations in this Agreement intended to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided for under the Bankruptcy Laws, and the non-bankrupt Party elects to retain its rights hereunder as provided for under the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shall provide to the non-bankrupt Party copies of all Patents and Information necessary for the non-bankrupt Party to prosecute, maintain and enjoy its rights under the terms of this

CONFIDENTIAL TREATMENT REQUESTED

Agreement. All rights, powers and remedies of the non-bankrupt Party as 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 Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws. In particular, it is the intention and understanding of the Parties to this Agreement that the rights granted to the Parties under this Section 15.6 are essential to the Parties' respective businesses and the Parties acknowledge that damages are not an adequate remedy.

(c) Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of termination for insolvency with respect to the activities that are the subject of such license agreement (which shall be on the basis of this Section 15.6) and any termination of this Agreement shall not affect the existence of such Option Product License Agreement or Exercised Product License Agreement.

15.7 Effects of Termination.

(a) Effects of Termination of Agreement in its Entirety

(i) In the event of a termination of this Agreement in its entirety by Ultragenyx pursuant to Section 15.2 (Breach) and 15.6 (Insolvency), Ultragenyx may elect either of the following options (A) or (B) by providing written notice of its election with its notice of termination:

(A) to effectuate actual termination of this Agreement in its entirety, in which case the following shall apply:

(I) all rights and licenses granted to

Ultragenyx hereunder shall terminate immediately;

(II) all rights and licenses granted by Ultragenyx hereunder shall terminate immediately other than the Takeda [***] License, which license shall become non-exclusive under any intellectual property not assigned to Takeda pursuant to the remainder of this Section 15.7(a)(i)(A), and which license shall apply to the Licensed [***] Compound, Licensed Analog Compounds, Licensed Products and Research Products;

(III) Ultragenyx, as soon as reasonably practical after the effective date of such termination, shall provide to Takeda, as applicable and to the extent permitted under any applicable Third Party contract, (1) any Information, including copies of all Clinical Trial data and results, and the like developed by or for the benefit of Ultragenyx relating to a Licensed Product or Research Product, and (2) other documents to the extent relating to the Licensed [***] Compounds, Licensed Analog Compounds, [***] Compounds, Candidate Products, Licensed Products or Research Products that are necessary for their Exploitation. Ultragenyx will cooperate with Takeda to provide a transfer of such Information and documents at Takeda's expense. At Takeda's request, Ultragenyx shall assign to Takeda any and all agreements to which Ultragenyx, or its Affiliate, and a Third Party are parties, and that govern the Exploitation

81

CONFIDENTIAL TREATMENT REQUESTED

activities conducted in connection with such Compounds or Products prior to such termination, or, if such assignment is not permitted under the relevant agreement: (i) grant to Takeda other rights to provide to Takeda the benefit of such non-assignable agreement, at Takeda's expense, to the extent permitted under the terms of such non-assignable agreement; or (ii) to the extent not permitted under the terms of such non-assignable agreement, the Parties shall discuss in good faith an alternative solution to enable Takeda to receive, at Takeda's expense, the benefit of the terms of such non-assignable agreement. In addition to the actions contemplated in this Section 15.7(a)(i)(A)(III), Ultragenyx shall take such other actions and execute such other instruments, assignments and documents, at Takeda's expense, as may be necessary to effect the transfer of rights to such Compound(s) and Product(s) hereunder to Takeda;

(IV) Ultragenyx shall, at Takeda's expense, transfer to Takeda any and all Regulatory Documentation related to a Licensed Product or Research Product, including any Product INDs and Product Regulatory Approvals and, upon Takeda's request, shall make available to Takeda any other relevant information reasonably related to such Regulatory Documentation; and

(V) effective on the date of termination, Ultragenyx, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign) to Takeda all right, title and interest in and to any Licensed Product Improvements, Licensed Product Improvement Patents, Option Product Improvements, and Option Product Improvement Patents, in each case where Controlled by Ultragenyx or its Affiliates. Ultragenyx will, at Takeda's expense, execute and record assignments and other necessary documents consistent with such change in ownership; or

(B) in lieu of actual termination under (A) above, Ultragenyx may elect that all rights and licenses granted to Ultragenyx hereunder shall continue under this Agreement and any milestone or royalty payments that become due to Takeda by Ultragenyx with respect to Licensed Product after such termination shall be [***] and paid to Takeda in accordance with the payment provisions of this Agreement. This Section 15.7(a)(i)(B) may only be exercised once.

(ii) In the event of a termination of this Agreement in its entirety by Takeda pursuant to Section 15.2 (Breach) or 15.6 (Insolvency), Takeda may elect either of the following options (A) or (B) by providing written notice of its election with its notice of termination:

(A) which case the following shall apply:

to effectuate actual termination of this Agreement in its entirety, in

(I) all rights and licenses granted to Takeda hereunder shall terminate immediately, other than the Takeda [***] License, which license shall become non-exclusive under any intellectual property not assigned to Takeda pursuant to the remainder of this Section 15.7(a)(ii)(A), and which licenses shall apply to the

Licensed [***] Compound, Licensed Analog Compounds, Licensed Products and Research Products;

(II) all rights and licenses granted by Takeda hereunder

82

CONFIDENTIAL TREATMENT REQUESTED

(III) if not already completed and

provided, Ultragenyx shall complete and provide a report of the Development activities for the Licensed [***] Product in the Takeda Field as set forth in the Initial [***] Development Plan in accordance with Section 4.3(a);

(IV) Ultragenyx, as soon as reasonably

practical after the effective date of such termination, shall provide to Takeda, as applicable and to the extent permitted under any applicable Third Party contract, (1) any Information, including copies of all Clinical Trial data and results, and the like developed by or for the benefit of Ultragenyx relating to a Licensed Product or Research Product, and (2) other documents to the extent relating to the Licensed [***] Compounds, Licensed Analog Compounds, [***] Compounds, Candidate Products, Licensed Products or Research Products that are necessary for their Exploitation. Ultragenyx will cooperate with Takeda to provide a transfer of such material Information and documents at Ultragenyx's expense. At Takeda's request, Ultragenyx shall assign to Takeda any and all Patents and agreements to which Ultragenyx, or its Affiliate, and a Third Party are parties, and that govern the Exploitation activities conducted in connection with such Compounds or Products prior to such termination, or, if such assignment is not permitted under the relevant agreement: (i) grant to Takeda other rights to provide to Takeda the benefit of such non-assignable agreement, at Ultragenyx's expense, to the extent permitted under the terms of such non-assignable agreement; or (ii) to the extent not permitted under the terms of such non-assignable agreement. In addition to the actions contemplated in this Section 15.7(a)(ii)(A)(IV), Ultragenyx shall take such other actions and execute such other instruments, assignments and documents, at Ultragenyx's expense, as may be necessary to effect the transfer of rights to such Compound(s) and Product(s) hereunder to Takeda;

(V) Ultragenyx shall, at its expense,

transfer to Takeda any and all Regulatory Documentation related to a Licensed Product or Research Product, including any Product INDs and Product Regulatory Approvals and, upon Takeda's request, shall make available to Takeda any other relevant information reasonably related to such Regulatory Documentation; and

(VI) effective on the date of termination,

Ultragenyx, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign) to Takeda all right, title and interest in and to any Licensed Product Improvements, Licensed Product Improvement Patents, Option Product Improvements, and Option Product Improvement Patents, in each case where Controlled by Ultragenyx or its Affiliates. Ultragenyx will, at its expense, execute and record assignments and other necessary documents consistent with such change in ownership; or

(B) in lieu of actual termination under (A) above, Takeda may elect that all rights and licenses granted to Takeda hereunder shall continue under this Agreement and any milestones or royalty payments that become due to Ultragenyx by Takeda with respect to

83

CONFIDENTIAL TREATMENT REQUESTED

any Exercised Product after such termination shall be reduced by fifty percent (50%) and paid to Ultragenyx in accordance with the payment provisions of this Agreement. This Section 15.7(a)(ii)(B) may only be exercised once.
(iii) For clarity, an Exercised Product License Agreement or an Option Product License Agreement shall include termination provisions similar to this Section 15.7(a) and shall otherwise govern the effects of termination of such agreement in its entirety.
(b) Effects of Termination of a Compound or Product for Safety Reasons. In the event of a termination of this Agreement with respect to a particular Compound or Product pursuant to Section 15.3 (for the avoidance of doubt, not a Terminated Product) then:
(i) all license rights received by the terminating Party and all obligations of the terminating Party with respect to the terminated Compound or Product shall cease and, with respect to the terminating Party only, this Agreement shall automatically be deemed to be amended to exclude such rights and obligations of the terminating Party with respect to the terminated Compound or Product but shall otherwise survive and continue in effect for the remaining Compounds and Products; and
(ii) the non-terminating Party shall continue to have all rights and obligations under this Agreement with respect to the terminated Compound or Product (including the obligation to make royalty, milestone and other payments to the

(c) **Effects of Termination with Respect to a Terminated Product.** In the event of termination of this Agreement with respect to a Terminated Product (but not in the case of any termination of this Agreement in its entirety) then:

terminating Party) unless it also elects to terminate the particular Compound or Product pursuant to Section 15.3.

(i) all rights and licenses granted hereunder by either Party shall automatically be deemed to be amended to exclude the Terminated Product but shall otherwise survive and continue in effect for the remaining Compounds and Products;

(ii) in the case of termination for convenience pursuant to Section 15.4, if an Option Negotiation Period or Takeda Option Negotiation Period is then ongoing, the Term with respect to such Option Product or Exercised Product, as applicable, will automatically extend until the earlier of (A) expiration of such Option Negotiation Period or Takeda Option Negotiation Period, as applicable, or (B) execution of the applicable Option Product License Agreement or Exercised Product License Agreement;

(iii) if the Terminated Product is a Licensed Product, if not already completed and provided, Ultragenyx shall complete and provide a report of the Development activities for the Licensed [***] Product in the Takeda Field as set forth in the Initial [***] Development Plan in accordance with Section 4.3(a);

(iv) Ultragenyx, as soon as reasonably practical after the effective date of such termination, shall provide to Takeda, as applicable and to the extent permitted under any

84

CONFIDENTIAL TREATMENT REQUESTED

applicable Third Party contract, (A) any Information, including copies of all Clinical Trial data and results, and the like developed by or for the benefit of Ultragenyx relating to a Terminated Product, and (B) other documents to the extent relating to the Terminated Products that are necessary for their Exploitation. Ultragenyx will cooperate with Takeda to provide a transfer of such material Information and documents. Ultragenyx shall assign to Takeda any and all Patents and agreements to which Ultragenyx, or its Affiliate, and a Third Party are parties, and that govern the Exploitation activities conducted in connection with a Terminated Product prior to such termination, or, if such assignment is not permitted under the relevant agreement: (1) grant to Takeda other rights to provide to Takeda the benefit of such non-assignable agreement to the extent permitted under the terms of such non-assignable agreement; or (2) to the extent not permitted under the terms of such non-assignable agreement, the Parties shall discuss in good faith an alternative solution to enable Takeda to receive the benefit of the terms of such non-assignable agreement. In addition to the actions contemplated in this Section 15.7(c)(iv), Ultragenyx shall take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights to such Terminated Products hereunder to Takeda. Each Party shall bear its own expenses under this Section 15.7(c)(iv);

- (v) Ultragenyx shall transfer to Takeda any and all Regulatory Documentation directly and solely related to a Terminated Product, including any Product INDs and Product Regulatory Approvals and, upon Takeda's request, shall make available to Takeda any other relevant information reasonably related to such Regulatory Documentation;
- (vi) effective on the date of termination, Ultragenyx, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign) to Takeda all right, title and interest in and to any Licensed Product Improvements, Licensed Product Improvement Patents, Option Product Improvements, and Option Product Improvement Patents to the extent the foregoing Cover a Terminated Product and are Controlled by Ultragenyx or its Affiliates. Ultragenyx will execute and record assignments and other necessary documents consistent with such change in ownership; and
- (vii) Takeda shall have the right to assume all prosecution, maintenance, and enforcement activities with respect to Patents under this Agreement Covering the Terminated Products. Ultragenyx will cooperate with Takeda and provide Takeda with reasonable assistance and cooperation with the prosecution, maintenance, and enforcement activities with respect to such Patents.
- Effect of Termination on Ultragenyx's Put Rights under the Common Stock Purchase Agreement. Immediately upon (i) written notice of termination of this Agreement in its entirety pursuant to Section 15.2, or 15.6, (ii) written notice of termination of a Licensed Product or Research Product pursuant to Section 15.2, 15.3, 15.4, 15.5, 18.5 or (iii) upon the Ultragenyx [***] License terminating pursuant to Section 4.3(f), Ultragenyx's rights under the Common Stock Purchase Agreement to require the purchase of the Second Tranche Shares and Third Tranche Shares (as such terms are defined in the Common Stock Purchase Agreement) shall be suspended and such rights shall automatically terminate on the effective date of such termination, provided, however, there shall be no suspension or termination of such Ultragenyx

85

CONFIDENTIAL TREATMENT REQUESTED

rights under the Common Stock Purchase Agreement to the extent Ultragenyx terminates the Agreement, a Licensed Product or Research Product pursuant to Section 15.2. Where written notice of termination pursuant to Section 15.2 is provided by Takeda, and Ultragenyx cures all material breaches during the Cure Period, the suspension shall be removed on the effective date of such cure.

15.8 Effect of Expiration

- (a) **Expiration of Collaboration Term.** Upon expiration of the Collaboration Term for a given Research Product:
- (i) All rights to such Research Product shall revert to Takeda except for those rights, if any, granted to Ultragenyx under an Option Product License Agreement;
- (ii) As soon as reasonably practical after the effective date of expiration of the Collaboration Term for a given Research Product, Ultragenyx shall, except where otherwise provided under an Option Product License Agreement, provide to Takeda, as applicable and to the extent permitted under any applicable Third Party contract (1) any Information, including copies of all Clinical Trial data and results, and the like developed by or for the benefit of Ultragenyx relating to such Research Product and (2) other documents to the extent relating to such Research Product that are necessary for their continued Exploitation. Ultragenyx will cooperate with Takeda to provide a transfer of such material Information and documents. At Takeda's request, Ultragenyx shall assign to Takeda any and all Patents and agreements to which Ultragenyx, or its Affiliate, and a Third Party are parties, and that govern the Exploitation activities conducted in connection with such Research Product prior to such expiration, or if such assignment is not permitted under the relevant agreement: (i) grant to Takeda other rights to provide to Takeda the benefit of such non-assignable agreement to the extent permitted under the terms of such non-assignable agreement; or (ii) to the extent not permitted under the terms of such non-assignable agreement. In addition to the actions contemplated in this Section 15.8(a)(ii), Ultragenyx shall take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights to such Product to Takeda. Each Party shall bear its own expenses under this Section 15.8(a)(ii);
- (iii) Ultragenyx shall transfer to Takeda any and all Regulatory Documentation directly and solely related to such Research Product, including any Product INDs and Product Regulatory Approvals and, upon Takeda's request, shall make available to Takeda any other relevant information reasonably related to such Regulatory Documentation; and
- (iv) Takeda shall have the right to assume all prosecution, maintenance, and enforcement activities with respect to Patents under this Agreement Covering such Research Product. Ultragenyx will cooperate with Takeda and provide Takeda with reasonable assistance and cooperation with the prosecution, maintenance, and enforcement activities with respect to such Patents.

86

CONFIDENTIAL TREATMENT REQUESTED

- (b) **Expiration of Licensed Product Royalty Term.** Upon the expiration of the Licensed Product Royalty Term for each Licensed Product in each country in the Territory, Ultragenyx shall have a non-exclusive, fully-paid up and irrevocable license under the Licensed [***] Technology with respect to such Licensed Product in such country in the Ultragenyx Field for Licensed Products.
- (c) Expiration of Exercised Product License Agreement and Option Product License Agreement. Each Exercised Product License Agreement and Option Product License Agreement shall provide that, upon expiration of the applicable royalty term, Takeda shall have a non-exclusive, fully-paid up and irrevocable license with respect to the Exercised Products and Licensed Option Products, respectively.
- Remedies. Notwithstanding anything to the contrary in this Agreement, except as otherwise set forth in this Agreement, termination or expiration of this Agreement shall not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration, nor prejudice either Party's right to obtain performance of any obligation. Each Party shall be free, pursuant to ARTICLE 16, to seek, without restriction as to the number of times it may seek, damages, costs and remedies that may be available to it under Applicable Laws or in equity and shall be entitled to offset the amount of any damages and costs obtained against the other Party in a final determination under Section 16.4, against any amounts otherwise due to such other Party under this Agreement.
- Survival. The following provisions shall survive any expiration or termination of this Agreement for the period of time specified therein (or, if no such period is specified, indefinitely): ARTICLE 1 (Definitions); ARTICLE 16 (Dispute Resolution); and ARTICLE 17 (Indemnification); and Sections 4.5 (Records; Disclosure of Data and Results), 6.6(b) (Research Materials Transfer), 11.9, 11.10, 11.11, 11.12, 11.13 (Payment, Taxes, Audit); 12.1 (Ownership of Inventions); 14.1, 14.2, 14.3, 14.4, 14.5, 14.6, 14.7, 14.8 (Confidentiality); 15.7, 15.8, 15.9, 15.10 (Termination); 18.3, 18.7, 18.8, 18.9, 18.10, 18.14, 18.15, 18.16, and 18.17 (Miscellaneous).

ARTICLE 16 - DISPUTE RESOLUTION

- 16.1 **Exclusive Dispute Resolution Mechanism.** Except for disputes for which a Party has final decision making authority under this Agreement, including Sections 2.1(b)(ii), 2.2(c)(ii) and 12.4, the Parties agree that the procedures set forth in this ARTICLE 16 shall be the exclusive mechanism for resolving any dispute, controversy, or claim between the Parties that may arise from time to time pursuant to this Agreement relating to either Party's rights or obligations hereunder (each, a "<u>Dispute</u>", and collectively, the "<u>Disputes</u>") that is not resolved through good faith negotiation between the Parties.
- Resolution by Executive Officers. In the event of any Dispute, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within ten (10) Business Days after receipt of writing notice of such Dispute by a Party, either Party may, by written notice to the other Party, refer the Dispute to the Senior Officers of the other Party for

87

CONFIDENTIAL TREATMENT REQUESTED

attempted resolution by good faith negotiation within thirty (30) days after such notice is received. Except where exclusive decision-making authority rests with a Party under this Agreement (including Sections 2.1(b)(ii), 2.2(c)(ii) and 12.4), each Party may, in its sole discretion, seek resolution of any and all Disputes that are not resolved under this Section 16.2 using (a) arbitration pursuant Section 16.3 where arbitration pursuant to Section 16.3 is specifically provided for in this Agreement or (b) otherwise, pursuant to Section 16.4.

- **Baseball Arbitration.** Any Dispute for which arbitration pursuant to this Section 16.3 is specifically provided for in this Agreement shall be finally decided by expedited arbitration in accordance with the following abbreviated dispute resolution procedures:
- (a) If the Dispute is not resolved within thirty (30) days after referral to the Party's respective Senior Officers pursuant to Section 16.2, either Party may send the other Party a written notice that it wishes to resolve the Dispute by using a neutral Third Party who is an Expert with at least fifteen (15) years of experience in area of the Dispute (the "Neutral Expert"). The date of the other Party's receipt of such written notices shall be the "Notice Date."
- (b) Within fifteen (15) Business Days of the Notice Date, each Party shall notify the other Party in writing of its appointed Expert (each, a "Representative Expert"). The Representative Experts for each Party shall jointly appoint the Neutral Expert within fifteen (15) Business Days.
- (c) Within ten (10) Business Days after the appointment of the Neutral Expert, each Party shall submit to the other Party and the Neutral Expert a written summary regarding its position with respect to the Dispute. Contemporaneously with the submission of its written summary regarding its position, each Party shall provide the other Party and the Neutral Expert with copies of all documents it relied upon in its written summary; provided that each Party may redact any portion of such documents which are covered by an applicable privilege or do not relate to the subject matter of this Agreement. Within three (3) Business Days of receipt of the other Party's written summary regarding its position, each Party may submit an opposition statement of no more than five (5) pages in length (excluding exhibits and declarations). Neither Party will be allowed to conduct any discovery. Neither Party may have any communications (either written or oral) with the other Party's Representative Experts or the Neutral Expert other than for the sole purpose of engaging the expert panel or as expressly permitted in this Section 16.3; provided, that oral presentations and follow-up written submissions may be made to the Neutral Expert at such Neutral Expert's request. The Neutral Expert may consult in writing with the Representative Experts regarding the submissions made by either Party; provided that both Representative Experts are aware of such consultation and provided an opportunity to respond. Evaluating each Party's written submissions, the Neutral Expert shall, within ten (10) Business Days of receipt of the written opposition statement, select in total, either Takeda's submission or Ultragenyx's submission. Such decision shall be final, binding and not appealable.
- (d) The Party whose submission is not selected shall be solely responsible for the expenses and fees of the Neutral Expert and the reasonable costs and fees of the other Party's Representative Expert.

88

CONFIDENTIAL TREATMENT REQUESTED

- 16.4 **Litigation.** Any unresolved Dispute that was subject to Section 16.2, shall be brought exclusively in a court of competent jurisdiction, federal or state, located in New York, New York, and in no other jurisdiction. Each Party hereby consents to personal jurisdiction and venue in, and agrees to service of process issued or authorized by, such court.
- 16.5 **Preliminary Injunctions.** Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrator(s) on the ultimate merits of any Dispute.
- 16.6 **Patent and Trademark Disputes.** Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the scope, construction, validity, and enforceability of any Patent or trademark relating to a Product that is the subject of this Agreement shall be determined in a court or other tribunal, as the case may be, of competent jurisdiction under the applicable patent or trademark laws of the country in which such Patent or trademark rights were granted or arose.
- 16.7 **Confidentiality.** Any and all activities conducted under ARTICLE 16, including any and all proceedings and decisions under Section 16.4, shall be deemed Confidential Information of each of the Parties, and shall be subject to ARTICLE 14.
- 16.8 WAIVER OF RIGHT TO JURY TRIAL. In connection with the Parties' rights under Section 16.4, EACH PARTY, TO THE EXTENT PERMITTED BY APPLICABLE LAWS, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES. THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE.

ARTICLE 17 - INDEMNIFICATION

Indemnification by Ultragenyx. Ultragenyx hereby agrees to defend, indemnify and hold harmless Takeda and its Affiliates, and each of their respective directors, officers, employees, agents and representatives (each, a "Takeda Indemnitee") from and against any and all claims, suits, actions, demands, liabilities, expenses and/or loss, including reasonable legal expense and attorneys' fees (collectively, the "Losses"), to which any Takeda Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (each, a "Claim") to the extent such Losses arise directly or indirectly out of: (i) the practice by Ultragenyx or its Affiliate of any license granted to it under ARTICLE 3; (ii) the Exploitation of a Compound or a Product by Ultragenyx, its Affiliates or its sublicensees on or after the Effective Date, including, for the avoidance of doubt, any Product Liabilities arising from the use of a Product in the Licensed Field in the Territory on or after the Effective Date and any Losses that may arise due to Ultragenyx, its Affiliates or its sublicensees continuing to Exploit a Compound or Product in its territory or field that is the subject matter of a termination by Takeda pursuant to Section 15.3; (iii) the Exploitation of any Ultragenyx Pipeline Product by Ultragenyx, its Affiliates or its licensees before the Effective Date, including, for the avoidance

89

CONFIDENTIAL TREATMENT REQUESTED

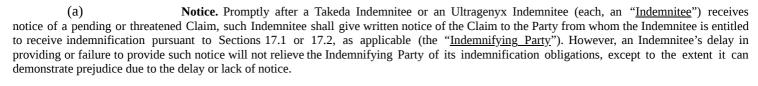
of doubt, any Product Liabilities arising from the use of a Ultragenyx Pipeline Product; (iv) the breach by Ultragenyx of any warranty, representation, covenant or agreement made by Ultragenyx in this Agreement; (v) the negligence, gross negligence or willful misconduct (including to the extent such negligence, gross negligence or willful misconduct gives rise to Product Liabilities under any legal theory) of Ultragenyx, its Affiliate or its sublicensee, or any officer, director, employee, agent or representative thereof; except, with respect to each of subsections (i) through (v) above, to the extent such Losses arise directly or indirectly from the negligence, gross negligence or willful misconduct of any Takeda Indemnitee or the breach by Takeda of any warranty, representation, covenant or agreement made by Takeda in this Agreement. Notwithstanding the foregoing, following the execution of an Exercised Product License Agreement or Option Product License Agreement, the terms of such license agreement shall govern the indemnification terms with respect to such Product(s) that are the subject of such license agreement.

17.2 Indemnification by Takeda. Takeda hereby agrees to defend, indemnify and hold harmless Ultragenyx and its Affiliates and each of their respective directors, officers, employees, agents and representatives (each, an "Ultragenyx Indemnitee") from and against any and all Losses to which any Ultragenyx Indemnitee may become subject as a result of any Claim to the extent such Losses arise directly or indirectly out of: (i) the practice by Takeda or its Affiliate of any license granted to it under ARTICLE 3; (ii) the Exploitation of a Product by Takeda, its Affiliates or its sublicensees on or after the Effective Date, including, for the avoidance of doubt, any Product Liabilities arising from the use on or after the Effective Date of a Licensed [***] Product in the Takeda Field in the Territory and any Losses that may arise due to Takeda, its Affiliates or its sublicensees continuing to Exploit a Compound or Product in its territory or field that is the subject matter of a termination by Ultragenyx pursuant to Section 15.3; (iii) the Exploitation of any Licensed [***] Product, [***] Product or Candidate Product by Takeda, its Affiliates or its licensees before the Effective Date, including, for the avoidance of doubt, any Product Liabilities arising from the use of a Licensed [***] Product, [***] Product or Candidate Product by Takeda, its Affiliates or its licensees before the Effective Date, (iv) the breach by Takeda of any warranty, representation, covenant or agreement made by Takeda in this Agreement; (iv) the negligence, gross negligence or willful misconduct (including to the extent such negligence, gross negligence or willful misconduct gives rise to product liability Claims under any legal theory) of Takeda or its Affiliate or its licensee (other than Ultragenyx or its Affiliate or sublicensee), or any officer, director, employee, agent or representative thereof; except, with respect to each of subsections (i) through (iv) above, to the extent such Losses arise directly or indirectly from the negligence, gross negligence or willful misconduct of any Ultragenyx Indemnitee or the breach by Ultragenyx of any warranty, representation, covenant or agreement made by Ultragenyx in this Agreement. Notwithstanding the foregoing, following the execution of an Exercised Product License Agreement or Option Product License Agreement, the terms of such license agreement shall govern the indemnification terms with respect to such Product(s) that are the subject of such license agreement.

17.3 **Indemnification Procedures**.

90

CONFIDENTIAL TREATMENT REQUESTED



- (b) **Defense.** Upon receipt of notice under Section 17.3(a) from the Indemnitee, the Indemnifying Party will have the duty to either compromise or defend, at its own expense and by counsel (reasonably satisfactory to Indemnitee), such Claim. The Indemnifying Party will promptly (and in any event not more than twenty (20) days after receipt of the Indemnitee's original notice) notify the Indemnitee in writing that it acknowledges its obligation to indemnify the Indemnitee with respect to the Claim pursuant to this ARTICLE 17 and of its intention either to compromise or defend such Claim. Once the Indemnifying Party gives such notice to the Indemnitee, the Indemnifying Party is not liable to the Indemnitee for the fees of other counsel or any other expenses subsequently incurred by the Indemnitee in connection with such defense, other than the Indemnitee's reasonable costs of investigation and cooperation. However, the Indemnitee will have the right to employ separate counsel and to control the defense of a Claim at its own expense.
- (c) Cooperation. The Indemnitee will cooperate fully with the Indemnifying Party and its legal representatives in the investigation and defense of any Claim. The Indemnifying Party will keep the Indemnitee informed on a reasonable and timely basis as to the status of such Claim (to the extent the Indemnitee is not participating in the defense of such Claim) and conduct the defense of such Claim in a prudent manner.
- (d) **Settlement.** If an Indemnifying Party assumes the defense of a Claim, no compromise or settlement of such Claim may be effected by the Indemnifying Party without the Indemnitee's written consent (which consent will not be unreasonably withheld, conditioned or delayed), unless: (i) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnitee; (ii) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party; and (iii) the Indemnitee's rights under this Agreement are not adversely affected. If the Indemnifying Party fails to assume defense of a Claim within a reasonable time, the Indemnitee may settle such Claim on such terms as it deems appropriate with the consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed), and the Indemnifying Party will be obligated to indemnify the Indemnitee for such settlement as provided in this ARTICLE 17.
- 17.4 **Insurance.** Each Party shall, at its own expense, procure and maintain during the Term and for a period of five (5) years thereafter, insurance policy/policies, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such insurance shall not be construed to create a limit of a Party's liability with respect to its indemnification obligations

CONFIDENTIAL TREATMENT REQUESTED

under this ARTICLE 17. Each Party shall provide the other Party with written evidence of such insurance or self-insurance upon request. Each Party shall provide the other Party with prompt written notice of cancellation, non-renewal or material change in such insurance or self- insurance that could materially adversely affect the rights of such other Party hereunder, and shall provide such notice within thirty (30) days after any such cancellation, non-renewal or material change.

17.5 Limitation of Liability. EXCEPT FOR A PARTY'S OBLIGATIONS SET FORTH IN THIS ARTICLE 17, AND ANY BREACH OF ARTICLE 14 (CONFIDENTIALITY), IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES OR SUBLICENSES) IN CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 18 - MISCELLANEOUS

18.1 HSR Act.

Each of Ultragenyx and Takeda shall, within ten (10) Business Days after Execution Date, file with the United (a) States Federal Trade Commission and the Antitrust Division of the United States Department of Justice, any HSR Filing required of it under the HSR Act with respect to the subject matter of this Agreement, which forms shall specifically request early termination of the initial HSR Act waiting period. The Parties will cooperate with one another to the extent necessary in the preparation of any such HSR Filing. The Parties hereto commit to instruct their respective counsel to cooperate with each other and use good faith, diligent efforts to facilitate and expedite the identification and resolution of any such issues and, consequently, the expiration of the applicable HSR Act waiting period, such good faith diligent efforts to include counsel's undertaking: (i) to keep each other appropriately informed of communications received from and submitted to personnel of the reviewing antitrust authority; and (ii) to confer with each other regarding appropriate contacts with and response to personnel of the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice. Each Party will be responsible for its own costs and expenses and Ultragenyx will be responsible for all filing fees associated with any HSR Filing. In respect of any HSR Filing, each of Ultragenyx and Takeda will use its good faith, diligent efforts to eliminate any concern on the part of any court or governmental authority regarding the legality of the proposed transaction, including cooperating in good faith with any government investigation and the prompt production of documents, information, and witnesses requested in the course of such of any such investigation, including those contained in a Request for Additional Information and Documentary Materials (as that term is defined in the HSR Act), and to cause the Effective Date of this Agreement to occur as soon as practical, as provided in Section 18.1(b). Nothing in this Section shall require either Party to consent to the divestiture or other disposition of any of its or its Affiliates' assets or to consent to any other structural or conduct remedy, and each Party and

92

CONFIDENTIAL TREATMENT REQUESTED

its Affiliates shall hav	e no obligati	ion to cont	est, admin	stratively	or in court,	any ruling,	order or	other a	action o	of the 1	United	States	Federal	Trade
Commission and the	Antitrust Di	ivision of	the United	States De	epartment o	f Justice or	any Thir	d Party	respec	cting th	ne trans	actions	contem	plated
by this Agreement.														

- (b) Except for the specific provisions expressly identified in Section 18.1(c), this Agreement shall not be effective until the (i) the HSR Conditions are met and (ii) the earlier of (A) the date on which the Tax Conditions are met, or (B) July 18, 2016, at which time this Agreement shall be effective automatically in its entirety (such date the "Effective Date").
- (c) Notwithstanding Section 18.1(b) and anything in this Agreement to the contrary, the following provisions of this Agreement shall be in full force and effect as of the Execution Date: Sections 14.5 (Publicity) and 14.6 (Securities Filings), ARTICLE 1 (Definitions) and ARTICLE 18 (other than Sections 18.2, 18.5 and 18.6) (Miscellaneous).
- (d) If the Effective Date has not occurred within one hundred eighty (180) days following the Execution Date, or such date as the Parties may mutually agree, this Agreement may be terminated by either Party on written notice to the other.

18.2 Exports and Restrictions on Competition.

- (a) **Exports.** Except as provided in this Agreement, each Party shall not, and shall cause its Affiliates and sublicensees not to, whether directly or indirectly through a Third Party, export, distribute or sell:
- (i) in the case of Ultragenyx, (A) Licensed [***] Products outside the Ultragenyx Field or outside the Territory, (B) Licensed Analog Products outside the Licensed Field or outside the Territory, (C) Research Products unless and until an Option Product License Agreement is executed for such Products and then only in accordance with such Option Product License Agreement; provided further that, if the Takeda Option has been exercised for a given Product Ultragenyx may not export, distribute or sell such Product in the Takeda Territory.

In the case of Takeda, Ultragenyx Pipeline Products outside of the Takeda

Territory.

(ii)

(b) Non-Competition Obligations. Ultragenyx shall not, and shall cause its Affiliates not to, whether directly or indirectly through a Third Party (including any sublicensee), (i) develop a Competing Product in the Territory at any time prior to the [***] of the Effective Date or (ii) commercialize a Competing Product in the Territory at any time prior to the [***] of the First Commercial Sale of a Product. Ultragenyx shall not be in breach of this Section 18.2(b) by acquiring, merging or consolidating with a Third Party which develops or commercializes a Competing Product; provided, however, that in the event Ultragenyx acquires such Competing Product, it must, unless Takeda agrees to the contrary, within [***] of such acquisition, either divest such Competing Product to a Third Party, discontinue the development or commercialization of such Competing Product, or, if applicable, terminate

93

CONFIDENTIAL TREATMENT REQUESTED

this Agreement with respect to the Licensed Product that is the subject of competition in accordance with Section 15.4.

18.3 **Notice.** Any notice, request, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be hand delivered or sent by a recognized overnight delivery service, costs prepaid, or by facsimile (with transmission confirmed), to the following addresses or to such other addresses as a Party may designate by written notice in accordance with this Section 18.3:

If to Takeda:

Takeda Pharmaceutical Company Limited 1-1, Doshomachi 4-

chome,

Chuo-ku, Osaka 540-8645

Attention: Head of Global Business Development Facsimile: (+81) 3-3278-2323

Copy to:

Takeda Pharmaceuticals U.S.A., Inc. One Takeda Parkway

Deerfield, IL 60015

Attention: General Counsel, Legal Department Facsimile: 224-554-7831

If to Ultragenvx:

Ultragenyx Pharmaceutical Inc. 60 Leveroni Court

Novato, CA 94949

Attention: Chief Business Officer

Copy to:

Cooley LLP

3175 Hanover Street Palo Alto, CA 94304 Attention: Glen Sato

Fax: 650-849-7400

Designation of Affiliates. Each Party may discharge any obligations and exercise any rights hereunder through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party

94

CONFIDENTIAL TREATMENT REQUESTED

may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

18.5 Change of Control of Ultragenyx.

- (a) **Notice**. Ultragenyx (or its successor) shall provide notice to Takeda of any Change of Control of Ultragenyx within [***] Business Days after the date upon which the Ultragenyx Change of Control closes or otherwise becomes effective.
- (b) **Effects of Change of Control of Ultragenyx**. In the event of a Change of Control of Ultragenyx, the following shall apply:
- (i) The Takeda Option Term applicable in the event of a Change of Control of Ultragenyx shall apply.
- (ii) On or before the date that is one hundred eighty (180) days after the date upon which a Change of Control of Ultragenyx closes or otherwise becomes effective, Takeda may take or require that Ultragenyx, or its successor, take or perform, as applicable, any one or more of the following actions: (A) Ultragenyx and its successor shall adopt reasonable written procedures, approved by Takeda, to prevent disclosure of Takeda's Confidential Information, (B) the definition of Licensed Analog Compounds shall be amended to be limited to those Compounds listed on Exhibit 1.99 as of the effective date of the Ultragenyx Change of Control, provided that if Ultragenyx has paid costs in connection with the Development of a Licensed Analog Compound, such Licensed Analog Compound shall be listed on Exhibit 1.99, as amended, (C) Section 5.1 shall be amended to require Takeda's written consent in order for Ultragenyx and its successor to exercise its rights to co-Commercialize and Co-Develop thereunder to the extent Ultragenyx has not previously exercised such right(s), and (D) Takeda may terminate, in its sole discretion, one or more of the ongoing Validation Research Plans and Research Plans, in which case any associated licenses to Ultragenyx and its successor under Section 6.5 shall terminate, and any Research Products designated by Takeda shall be deemed Terminated Products; provided that to the extent that Ultragenyx has paid costs in connection with the Development of a Research Product on or before such date, such Validation Research Plan or Research Plan, as applicable, and associated licenses to Ultragenyx or its successor shall continue in full force and effect and such Research Products shall not be deemed Terminated Products under this Section 18.5(b)(ii). For clarity, termination pursuant to this Section 18.5(b)(ii) shall not terminate the Collaboration Term for any purposes under this Agreement other than the foregoing clause (D).
- 18.6 **Force Majeure.** Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a Force Majeure affecting such Party. If a Force Majeure persists for more than ninety (90) days,

95

CONFIDENTIAL TREATMENT REQUESTED

then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such Force Majeure.

- Assignment. Prior to the Effective Date, neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other. On or after the Effective Date, neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other; provided that no such consent is required for (a) assignment to Affiliates or (b) in connection with the sale of all or substantially all of the assets to which this Agreement relates, whether in a merger, sale of stock, sale of assets or any other transaction (subject, in the case of Ultragenyx, to Section 18.5). Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section shall be null, void and of no legal effect.
- **Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.
- 18.9 **English Language.** This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement, shall be in the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.
- 18.10 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Laws or otherwise available except as expressly set forth herein.
- **Further Assurance.** Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof.

96

CONFIDENTIAL TREATMENT REQUESTED

- Relationship of the Parties. It is expressly agreed that Takeda, on the one hand, and Ultragenyx, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Takeda nor Ultragenyx shall have the authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other, without the prior written consent of the other Party to do so. All persons 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. For clarity, (a) if Takeda provides Research Support for an Ultragenyx Pipeline Product (other than Exercised Products) or Licensed Option Product (in connection with an Option Product License Agreement), Takeda shall be deemed an independent contractor in the performance of such Research Support and (b) in no case shall Takeda provide Research Support with respect to a Licensed Product.
- 18.13 **Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile, .pdf or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were the original signatures.
- Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, and the use of any gender shall be applicable to all genders. Whenever this Agreement refers to a number of days, such number refers to calendar days. The terms "including," "include," or "includes" as used herein shall mean "including, but not limited to," and shall not limit the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. 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 apply against the Party which drafted such terms and provision.
- **Governing Laws.** This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.
- 18.16 Entire Agreement. This Agreement, including the Exhibits hereto, and the Common Stock Purchase Agreement set forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Execution Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof; provided, that, until the Effective Date, the Confidentiality Agreement shall continue in full force and effect in accordance with its terms.

CONFIDENTIAL TREATMENT REQUESTED

Except as provided in the Common Stock Purchase Agreement, there are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. In the event of any inconsistency between the body of this Agreement and the Exhibits to this Agreement, the Common Stock Purchase Agreement, or any subsequent agreements ancillary to this Agreement, unless otherwise expressly stated to the contrary in such Exhibit, Common Stock Purchase Agreement or subsequent ancillary agreement, the terms contained in this Agreement shall control.

18.17 **Headings.** The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

SIGNATURE PAGE FOLLOWS

98

CONFIDENTIAL TREATMENT REQUESTED

THIS AGREEMENT is executed by the authorized representatives of the Parties as of the Execution Date.

ULTRAGENYX PHARMACEUTICAL INC. TAKEDA PHARMACEUTICALCOMPANY LIMITED

By /s/ Misako Hamamura

By /s/ Emil Kakkis Name: Emil Kakkis Name: Misako Hamamura Title: CEO Title: Head of JP Strategy & BD

{Signature Page to License and Collaboration Agreement}

Exhibit 1.6(i)

[***]

Chemical Name: [***]

Molecular Formula: [***] Molecular Weight: [***]

Exhibit 1.6(iii)

[***]

Exhibit 1.82

Initial [***] Development Plan

<u>Initial Development Plan Framework</u>
[***]
<u>Estimated Timeline</u>
[***]
Development Activities and Budget
[***]

Exhibit 1.91 **Knowledge Group**

<u>Ultragenyx Position Titles</u>

Tom Kassberg, SVP and Chief Business Officer Shalini Sharp, SVP and Chief Financial Officer Sunil Agarwal, SVP and Chief Medical Officer Cori Leonard, VP, Yael Weiss, Executive Director, Search and Evaluation, Business Development Rob Anstey, Senior Director, Business Development

Takeda Position Titles

[***]

Exhibit 1.94

[***]

Chemical Name: [***]

2 Molecular Formula: [***]

2 Molecular Weight: [***]

Exhibit 1.99 Licensed Analog Compounds [***]

Exhibit 1.137 **Preexisting Third Party IP**

[***]

[3 pages omitted]

Exhibit 1.141 **Product INDs** [***]

Exhibit 1.168 **Takeda Patents**

Licensed [***] Patent

Patent / Publication	Priority / Application	Inventor(s) / Assignee(s)	<u>Title / Claims</u>	<u>Status</u>
[***]	[***]	[***]	[***]	[***]

[2 pages omitted]

Exhibit 1.188 Ultragenyx Patents

Ultragenyx [***] Patents		
[***]		
Ultragenyx [***] Patents		
[***]		
[3 pages omitted]		

Exhibit 1.195

[***]

Exhibit 6.1 **Listed Compounds** [***]

Exhibit 6.3(a) [***] Research Plan [***]



Exhibit 13.2(b)	
[***]	
[4 pages omitted]	

Exhibit 14.5 Form of Press Release





Contact Ultragenyx Pharmaceutical Inc. Investors & Media Ryan Martins 844-758-7273

<u>For Takeda Pharmaceutical Company Limited:</u> Tsuyoshi Tada – Japan <u>tsuyoshi.tada@takeda.com</u> +81332782417

Julia Ellwanger — USA <u>julia.ellwanger@takeda.com</u> +1-224-554-7681

Ultragenyx and Takeda enter into a Collaboration to Develop and Commercialize Therapies for Rare Genetic Diseases

Ultragenyx to license and develop one or more product candidates from Takeda Takeda to make equity investment in Ultragenyx to fund development

NOVATO, CA, June 7, 2016 and OSAKA, JAPAN, June 8, 2016 – Ultragenyx Pharmaceutical Inc. (NASDAQ: RARE), a biopharmaceutical company focused on the development of novel products for rare and ultra- rare genetic diseases, and Takeda Pharmaceutical Company Limited (TSE: 4502), today announced a strategic partnership to develop and commercialize therapies to treat rare genetic diseases.

Ultragenyx will initially receive an exclusive license to one preclinical Takeda product candidate in a pre- determined field of use, and will have an exclusive option to co-develop and co-commercialize the product candidate in additional therapeutic areas. The companies have also established a five-year research collaboration in which Ultragenyx will have the option to license up to five additional Takeda

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product candidates for rare diseases after the parties agree on and conduct initial validation activities under the purview of a Joint Research Committee.

"This broad collaboration provides Ultragenyx with a product opportunity that is approaching clinical- stage development as well as a potential continued source of new product candidates that will help us achieve our goal of bringing a new therapy into the clinic every one to two years," said Emil D. Kakkis, MD, PhD, Chief Executive Officer of Ultragenyx. "Takeda has an impressive early pipeline of therapies with potential across a number of rare genetic diseases, and we are pleased that Takeda has chosen to partner with us to bring these therapies to patients with rare diseases that have few or no treatment options."

"Ultragenyx is a rapidly emerging rare disease company, led by a highly experienced and successful management team," said Andrew Plump, M.D., Ph.D., Chief Medical and Scientific Officer of Takeda. "This partnership provides Takeda access to Ultragenyx's strong patient-centric development and regulatory capabilities in the rare disease space, and could create significant value for both companies by delivering important new therapies to patients."

Takeda will receive an exclusive option to commercialize any licensed products resulting from the collaboration in Asia, including Japan. In addition, Takeda receives an option to exclusively license one Ultragenyx pipeline product in Japan. Each company will receive potential development and sales milestone payments and royalties on net sales of licensed products by the other party.

Takeda will invest up to \$65 million in Ultragenyx in two tranches, the first of which will comprise a \$25million stock purchase along with a \$15 million cash premium at closing. This will be followed at Ultragenyx's option, within 12 months, by a second equity purchase of \$25million with no additional premium. A potential third equity investment by Takeda is contingent upon Ultragenyx achieving a specific development milestone on a second asset. No additional financial details were disclosed.

The completion of the transactions are subject to Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR) review and the satisfaction of other customary closing conditions.

About Ultragenyx

Ultragenyx is a clinical-stage biopharmaceutical company committed to bringing to market novel products for the treatment of rare and ultra-rare diseases, with a focus on serious, debilitating genetic diseases. Founded in 2010, the company has rapidly built a diverse portfolio of product candidates with the potential to address diseases for which the unmet medical need is high, the biology for treatment is clear, and for which there are no approved therapies.

The company is led by a management team experienced in the development and commercialization of rare disease therapeutics. Ultragenyx's strategy is predicated upon time and cost-efficient drug development, with the goal of delivering safe and effective therapies to patients with the utmost urgency.

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For more information on Ultragenyx, please visit the company's website at www.ultragenyx.com.

About Takeda

Takeda Pharmaceutical Company Limited (TSE: 4502) is a global, R&D-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life- changing medicines. Takeda focuses its research efforts on oncology, gastroenterology and central nervous system therapeutic areas. It also has specific development programs in specialty cardiovascular diseases as well as late-stage candidates for vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology, central nervous system and gastroenterology, as well as its presence in emerging markets, fuel the growth of Takeda. More than 30,000 Takeda employees are committed to improving quality of life for patients, working with our partners in health care in more than 70 countries. For more information, visit http://www.takeda.com/news.

Ultragenyx Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding the potential to develop the licensed product candidate in additional therapeutic areas, as well as the potential to develop additional rare disease targets pursuant to the collaboration and the ability to bring new therapies to clinic, are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve substantial risks and uncertainties that could cause our development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the satisfaction of the HSR requirements and the impact on the timing of the closing, whether any products will be successfully developed and commercialized from the collaboration, uncertainties inherent in the drug development process and other matters that could affect the potential for success of the collaboration, including the sufficiency of existing cash, cash equivalents and short-term investments to fund operations. Ultragenyx undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the company in general, see Ultragenyx's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on March 10 2016, and its subsequent periodic reports filed with the Securities and Exchange Commission.

Takeda Forward-Looking Statements

This press release contains "forward-looking statements." Forward-looking statements include all statements other than statements of historical fact, including plans, strategies and expectations for the future, statements regarding the expected timing of filings and approvals relating to the transaction, the expected timing of the completion of the transaction, the ability to complete the transaction or to satisfy the various closing conditions, future revenues and profitability from or

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growth or any assumptions underlying any of the foregoing. Statements made in the future tense, and words such as "anticipate," "expect," "project," "continue," "believe," "plan," "estimate," "pro forma," "intend," "potential," "target," "forecast," "guidance," "outlook," "seek," "assume," "will," "may," "should," and similar expressions are intended to qualify as forward-looking statements. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors and security holders are cautioned not to place undue reliance on these forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to: required regulatory approvals for the transaction may not be obtained in a timely manner, if at all; the conditions to closing of the transaction may not be satisfied; competitive pressures and developments; applicable laws and regulations; the success or failure of product development programs; actions of regulatory authorities and the timing thereof; changes in exchange rates; and claims or concerns regarding the safety or efficacy of marketed products or product candidates in development.

The forward-looking statements contained in this press release speak only as of the date of this press release, and neither Ultragenyx nor Takeda undertakes any obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If one or more of these statements is updated or corrected, investors and others should not conclude that additional updates or corrections will be made.

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COMMON STOCK PURCHASE AGREEMENT

THIS COMMON STOCK PURCHASE AGREEMENT (this "**Agreement**") is entered into as of June 6, 2016, by and among Ultragenyx Pharmaceutical Inc., a Delaware corporation (the "**Company**"), and Takeda Pharmaceutical Company Limited, a Japanese corporation ("**Purchaser**").

WHEREAS, the Company desires to issue and sell to Purchaser up to Seventy Five Million Dollars (\$75,000,000) worth of shares (the "Shares") of common stock, par value \$0.001 per share, of the Company (the "Common Stock"), which Shares shall be authorized and issued in accordance with the terms of this Agreement (the "Common Stock Financing");

WHEREAS, prior to or concurrently with the consummation of the transactions contemplated hereby, and as a condition to the willingness of, and material inducement to, Purchaser to enter into this Agreement, the Company and Purchaser shall enter into a Collaboration and License Agreement of even date herewith (the "Collaboration Agreement"); and

WHEREAS, subject to the terms and conditions set forth in this Agreement, Purchaser desires to purchase from the Company the Shares.

NOW, THEREFORE, in consideration of the mutual promises, representations, warranties, covenants and conditions set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. PURCHASE AND SALE

- **Sale and Issuance of Shares.** In consideration of the Collaboration Agreement and in express reliance upon the representations, warranties and covenants set forth herein, and subject to the terms and conditions set forth in this Agreement, the Company shall issue and sell to Purchaser, and Purchaser shall purchase from the Company, the Shares; *provided* that in no event shall the aggregate number of Shares subject to issuance pursuant to this <u>Section 1</u> exceed twenty percent (20%) of the total outstanding shares of the Company's Common Stock calculated as of the Initial Closing (as defined below).
- Initial Closing. The initial purchase and sale of the Shares shall take place remotely via the exchange of documents and signatures at 10:00 a.m. on the Effective Date, as defined in the Collaboration Agreement (the "Effective Date"), or at such other time as the Company and Purchaser shall mutually agree (which time, date and place are referred to in this Agreement as the "Initial Closing"). At the Initial Closing, the Company shall instruct American Stock Transfer & Trust Company, LLC (the "Transfer Agent") to register the issuance of the Initial Closing Shares (as defined below) via book entry, against delivery to the Company by Purchaser at the Initial Closing of Forty Million Dollars (\$40,000,000) (the "Initial Closing Consideration"), payable in immediately available funds by wire transfer to an account or accounts designated by the Company. The "Initial Closing Shares" shall mean that number of shares of Common Stock equal to Twenty Five Million (\$25,000,000) divided by the Bloomberg volume-weighted average price for a share of Common Stock on the NASDAQ Global Select Market for the 30 trading day period ending on the last day on which the NASDAQ Global Select Market is open (a "Trading Day") prior to the Execution Date, as defined in the Collaboration Agreement, rounded to the nearest whole share. For the avoidance of doubt, the Initial Closing Consideration represents Twenty Five Million Dollars (\$25,000,000) worth of Common Stock plus a Fifteen Million Dollar (\$15,000,000) premium, which premium represents the consideration paid in return for certain rights under the Collaboration Agreement, including rights under Sections 8.1 and 8.3 of the Collaboration Agreement.

CONFIDENTIAL TREATMENT REQUESTED

- **1.3** Second Tranche Closing. During the period beginning on the three-month anniversary of the Effective Date and ending on the one-year anniversary thereof, the Company shall have the right, but not the obligation, to direct Purchaser, by its delivery to Purchaser of a Second Tranche Notice (as defined below), to purchase the Second Tranche Shares (as defined below) pursuant to this Section 1.3, and Purchaser thereupon shall have the obligation to purchase the Second Tranche Shares, subject to the conditions set forth in this Agreement, provided that the Collaboration Agreement has not been suspended or terminated in accordance with Section 15.7(d) of the Collaboration Agreement. A "Second Tranche Notice" shall mean an irrevocable written notice specifying a closing date for the purchase of the Second Tranche Shares pursuant to this Section 1.3 (the "Second Tranche Closing"), which notice shall be delivered no less than ten (10) Trading Days prior to the date of the Second Tranche Closing. At the Second Tranche Closing, the Company shall instruct the Transfer Agent to register the Second Tranche Shares (as defined below) via book entry against delivery to the Company by Purchaser at or before the Second Tranche Closing of Twenty Five Million Dollars (\$25,000,000) (the "Second Tranche Consideration"), payable in immediately available funds by wire transfer to an account or accounts designated by the Company. The "Second Tranche Shares" shall mean that number of shares of Common Stock equal to Twenty Five Million Dollars (\$25,000,000) divided by the Bloomberg volume-weighted average price for a share of Common Stock on the NASDAQ Global Select Market for the 30 Trading Day period ending on the last Trading Day prior to the Second Tranche Notice, rounded to the nearest whole share.
- Third Tranche Closing. During the 30 calendar day period following the [***] (as defined in the Collaboration Agreement), the Company shall have the right, but not the obligation, to direct Purchaser, by its delivery to Purchaser of a Third Tranche Notice (as defined below), to purchase the Third Tranche Shares (as defined below) pursuant to this Section 1.4, and Purchaser thereupon shall have the obligation to purchase the Third Tranche Shares, subject to the conditions set forth in this Agreement, provided that the Collaboration Agreement has not been suspended or terminated in accordance with Section 15.7(d) of the Collaboration Agreement. The Company shall notify Purchaser in writing within 5 business days after [***]. A "Third Tranche Notice" shall mean an irrevocable written notice specifying a closing date for the purchase of the Third Tranche Shares pursuant to this Section 1.4 (the "Third Tranche Closing"), which notice shall be delivered no less than ten (10) Trading Days prior to the date of the Third Tranche Closing. At the Third Tranche Closing, the Company shall instruct the Transfer Agent to register such issuance via book entry the Third Tranche Shares (as defined below) against delivery to the Company by Purchaser at or before the Third Tranche Closing of Ten Million Dollars (\$10,000,000) (the "Third Tranche Consideration"), payable in immediately available funds by wire transfer to an account or accounts designated by the Company. The "Third Tranche Shares" shall mean that number of shares of Common Stock equal to Ten Million Dollars (\$10,000,000) divided by the Bloomberg volume-weighted average price for a share of Common Stock on the NASDAQ Global Select Market for the 30 Trading Day period ending on the last Trading Day prior to the Third Tranche Notice, rounded to the nearest whole share. For clarity, each of the Initial Closing, Second Tranche Closing and Third Tranche Closing shall be referred to as a "Closing."
- **Capital Adjustments.** If after the date hereof (A) the Company shall pay a dividend in securities of the Company (other than in Common Stock) or of other property (including cash) on the Common Stock, or (B) there shall occur any merger, consolidation, capital reorganization or reclassification in which the Common Stock is converted or exchanged for securities, cash or other property, the class or series of stock constituting the Common Stock for purposes of this Agreement, shall be appropriately adjusted to reflect such other dividend, merger, consolidation, capital reorganization or reclassification. After any event referenced in clauses (A) and (B) of the preceding sentence is consummated, all references herein to the Common Stock shall be deemed to refer to the capital stock or

CONFIDENTIAL TREATMENT REQUESTED

property (including cash) into or for which the Common Stock was converted or exchanged, with the necessary changes in detail.

2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

As of the date of each Closing, the Company represents and warrants to Purchaser that, subject to exceptions and disclosures set forth in any part or subpart of the Company Disclosure Schedule corresponding to the particular Section or subsection of this Section 2, or any exceptions or disclosures set forth in any other part or subpart of the Company Disclosure Schedule to the extent it is reasonably apparent from the wording or any such exception or disclosure that such exception or disclosure is applicable to qualify such representation or warranty, and (i) in the case of the Initial Closing, only to the extent specifically referenced in the applicable representation or warranty, disclosures in the SEC Filings (as defined below) and (ii) in the case of the Second Tranche Closing and Third Tranche Closing, disclosures in the SEC Filings, provided that in cases (i) or (ii), in any event excluding any disclosure of risks included in any "risk factors," "forward-looking statements" disclaimer or other statements that are similarly predictive or forward-looking in nature, the statements contained in this Section 2 are true, complete and correct (except that those statements which address matters only as of a particular date are true, correct and complete as of such date). The Company shall deliver an updated and current Company Disclosure Schedule prior to each Closing.

- 2.1 **Organization and Qualification.** The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as now conducted and as it is described in the SEC Filings. The Company is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify would or would be reasonably expected to have, individually or in the aggregate, a material adverse effect on (i) the business, properties or financial condition of the Company, (ii) the Shares or (iii) the enforceability of this Agreement (a "Material Adverse Effect"); provided that none of the following shall be taken into account in determining whether there is a Material Adverse Effect: (a) any change in the market price or trading volume of the Company's stock; (b) any event, circumstance, change or effect in the industries in which the Company or its subsidiaries operates generally or the United States or European economy generally, financial markets or political conditions generally; (c) any act of terrorism, military action or war (whether or not declared), national or international calamity or similar event or any escalation or worsening thereof; (d) any event, circumstance, change or effect arising from or relating to any change in legal requirements or generally accepted accounting principles ("GAAP") (or interpretations of any legal requirements or GAAP); or (e) any change or effect attributable to the consummation of the transactions contemplated hereby, or the public announcement of the execution of, this Agreement (provided any such public announcement is not in breach of this Agreement); provided, in each case, that such effects do not, individually or in the aggregate, have a materially disproportionate adverse impact on the Company, taken as a whole, relative to any other "person" as such term is defined under Section 3(a)(9) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and as used in Sections 13(d)(3) and 14(d) (2) of the Exchange Act ("**Person**") in the industries or markets in which the Company operates.
- **2.2** Certificate of Incorporation and Bylaws. The certificate of incorporation, bylaws and documents of similar substance (the "Governing Documents") of the Company and its subsidiaries that are on file with the United States Securities and Exchange Commission (the "SEC") are current, complete and correct copies thereof as in effect on the date hereof. The Governing Documents of the Company and its subsidiaries are in full force and effect. The Company and each subsidiary of the Company are in compliance with the terms of their respective Governing Documents.

2.3 <u>Capitalization</u>.

CONFIDENTIAL TREATMENT REQUESTED

(a)	The authorized capital sto	ock of the Company	consists of 275,000,000	shares of capital
stock, of which 250,000,000 are designated a	s Common Stock and 25,000	,000 are designated as	preferred stock, \$0.001 pa	ar value per share
("Preferred Stock"). As of the close of busing	ness on the date that is two Ti	rading Days prior to t	the date of this Agreemer	nt, (i) 39,039,083
shares of Common Stock were issued and ou	tstanding, all of which were v	alidly issued and fully	paid, nonassessable and f	ree of preemptive
rights; (ii) 5,128,090 shares of Common Stock	were issuable (and such numb	er was reserved for iss	uance) upon exercise of op	ptions to purchase
Common Stock or as restricted stock units p	payable in Common Stock (the	e " Options ") outstand	ing as of such date; (iii) 1	149,700 shares of
Common Stock were issuable (and such nur	nber was reserved for issuan	ce) upon exercise of	warrants to purchase Con	mmon Stock (the
"Warrants") outstanding as of such date; and	d (iv) no shares of Preferred S	Stock were issued and o	outstanding.	

As of the close of business on the last Trading Day immediately preceding the date of this Agreement, except for (i) the Options and (ii) the Warrants, there were no options, warrants or other rights to acquire capital stock or other equity interests from the Company, or securities convertible into or exchangeable for such capital stock or other equity interests. Other than (A) shares of capital stock reserved for issuance as provided in this Section 2.3 and (B) options to purchase Common Stock or other equity awards issued in accordance with the Company's 2011 Equity Incentive Plan or 2014 Incentive Plan and shares subject to purchase under the 2014 Employee Stock Purchase Plan (collectively, the "Awards"), the Company has not issued any shares of its capital stock or other equity interests, or securities convertible into or exchangeable for such capital stock or other equity interests except as set forth in its filings under the Securities Act of 1933, as amended ("Securities Act") and the Exchange Act. All outstanding shares of Common Stock and all shares of Common Stock subject to issuance upon exercise of the Options, the Awards and the Warrants, upon issuance prior to the Closing on the terms and conditions specified in the instruments pursuant to which they are issuable, will be duly authorized, validly issued, fully paid, nonassessable and free of preemptive rights. The Shares to be issued in connection with the Agreement, when issued as contemplated herein, will be duly authorized, validly issued, fully paid and nonassessable, will not be in violation of any preemptive rights and will be free and clear of all liens, charges, restrictions, claims, rights of first refusal and encumbrances except as set forth in this Agreement and the Company's Governing Documents. The issuance and sale of the Shares will not obligate the Company to issue shares of Common Stock or other securities to any Person (other than the Purchaser) and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities.

2.4 <u>Authorization; Enforceability.</u>

(a) The Company has all requisite corporate power and authority to execute, deliver and perform, as applicable, this Agreement and to issue and sell the Shares in accordance with the terms hereof.

(b) All corporate action on the part of the Company and its officers and directors necessary for (i) the authorization, execution, delivery and performance of all obligations of the Company under this Agreement has been taken and (ii) the issuance and sale by the Company of the Shares hereunder has been taken. This Agreement constitutes a valid and legally binding obligation of the Company, enforceable in accordance with its terms, except (A) as limited by applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally or by equitable principles and (B) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies (the "Equitable Exceptions"). No action on the part of the Company's stockholders is necessary for the authorization, execution, delivery or performance of the Company's obligations hereunder.

CONFIDENTIAL TREATMENT REQUESTED

2.5 <u>SEC Filings; Financial Statements.</u>

- (a) The Company has timely filed with or furnished to the SEC all registration statements, prospectuses, forms, reports, definitive proxy statements, schedules and documents required to be filed by it under the Securities Act or the Exchange Act, as the case may be (collectively, the "SEC Filings"). Each SEC Filing, as amended or supplemented, if applicable, (i) as of its date, or, if amended, as of the date of the last such amendment, complied in all material respects with the applicable requirements of the Securities Act, the Exchange Act and the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), as the case may be, and the rules and regulations of the SEC thereunder, applicable to such SEC Filing, and (ii) did not, at the time it was filed (or at the time it became effective in the case of registration statements), or, if amended, as of the date of the last such amendment, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading. The Company has never been an issuer subject to Rule 144(i) under the Securities Act. As of the Initial Closing, the Company meets the "Registrant Requirements" for eligibility to use Form S-3 set forth in General Instruction I.A to Form S-3. As of the date of this Agreement, there are no outstanding or unresolved comments in comment letters received from the SEC staff with respect to the SEC Filings and, to the Company's knowledge, none of the SEC Filings is the subject of ongoing SEC review, outstanding SEC comment or outstanding SEC investigation.
- (b) Each of the consolidated financial statements (including, in each case, any notes thereto) contained in the SEC Filings, as amended, supplemented or restated, if applicable, was prepared in accordance with GAAP applied (except as may be indicated in the notes thereto and, in the case of unaudited quarterly financial statements, as permitted by the Form 10-Q under the Exchange Act) on a consistent basis throughout the periods indicated (except as may be indicated in the notes thereto), and each presented fairly, in all material respects, the consolidated financial position, results of operations and cash flows of the Company and the consolidated subsidiaries of the Company as of the respective dates thereof and for the respective periods indicated therein (subject, in the case of unaudited quarterly financial statements, to normal year-end adjustments).
- (c) The Company and its subsidiaries have implemented and maintain a system of internal control over financial reporting (as required by Rule 13a-15(a) under the Exchange Act) that is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with GAAP for external purposes and includes policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP and to maintain accountability of assets, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company, and (iii) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on its financial statements, and such system of internal control over financial reporting is reasonably effective.
- (d) The Company has implemented and maintains disclosure controls and procedures (as defined in Rule 13a-15(d) of the Exchange Act) that are designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time frames specified by the SEC's rules and forms (and such disclosure controls and procedures are reasonably effective), and has disclosed, based on its most recent evaluation of its system of internal control over financial reporting prior to the date of this Agreement, to the Company's independent registered accountant and the audit committee of the Board of

CONFIDENTIAL TREATMENT REQUESTED

Directors (A) any significant deficiencies and material weaknesses to the Company's Knowledge in the design or operation of its internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) and (B) to the Company's Knowledge any fraud that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

2.6 <u>No Conflict; Required Filings and Consents.</u>

- (a) The execution and delivery of this Agreement by the Company does not, and the performance of this Agreement by the Company will not, (i) conflict with or violate any provision of the Governing Documents of the Company or its subsidiaries, (ii) assuming that all consents, approvals, authorizations and permits described in the Collaboration Agreement have been obtained, conflict with or violate any law applicable to the Company or by which any property or asset of the Company is bound or affected or (iii) conflict with, or constitute a default (or an event which, with notice or lapse of time or both, would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any Material Contract (as defined below).
- (b) The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any federal, national, supranational, state, provincial, municipal, local or other government, governmental, regulatory or administrative authority, agency or commission or any court, tribunal, or judicial or arbitral body of competent jurisdiction ("Governmental Authority") or other Person in connection with the execution, delivery and performance by the Company of the issuance of the Shares, other than (i) (A) the filing of a prospectus (and potentially the filing of a registration statement) with the SEC in accordance with the requirements of Section 7.2 below, (B) filings required by applicable Blue Sky Laws, (C) the filing of a Notice of Sale of Securities on Form D with the SEC under Regulation D of the Securities Act, (D) the filing of any requisite notices and/or application(s) to the NASDAQ Global Select Market for the issuance and sale of the Shares and the listing of the Shares thereon in the time and manner required thereby, (E) any filing required by the Collaboration Agreement, and (F) those that have been made or obtained prior to the date of this Agreement, or (ii) where failure to obtain such consents, approvals, authorizations or permits, or to make such filings or notifications, would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.
- 2.7 Employees and Employee Matters. Except as would not reasonably be expected to have a Material Adverse Effect, the Company has complied with all federal, state and local laws relating to the hiring of employees, consultants and advisors and the employment of labor, including provisions thereof relating to wages, hours, equal opportunity, collective bargaining and the payment of social security and other taxes. The Company is not delinquent in material payments to any of its employees for any wages, salaries, commissions, bonuses or other direct compensation for any services performed by them to date or amounts required to be reimbursed to such employees or upon any termination of the employment of any such employees.
- **Material Contracts.** Except as disclosed in the SEC Filings, neither the Company nor any of its assets, properties, businesses or operations is a party to, bound or affected by, or receives benefits under any contract which is a "material contract" (as such term is defined in Item 601(b)(10) of Regulation S-K of the SEC) (a "**Material Contract**"). Except as would not, individually or in the aggregate, be reasonably expected to have a Material Adverse Effect, (i) each Material Contract is enforceable against the Company's knowledge, each other party thereto, and in full force and effect, (ii) each Material Contract is enforceable against the Company and, to the Company's knowledge, the other parties thereto in accordance with the terms thereof, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium and other similar laws of general applicability relating to or affecting creditor's rights generally and by the application of general principles

CONFIDENTIAL TREATMENT REQUESTED

of equity and (iii) the Company has not received written notice of any violation or default under (or any condition which with the passage of time or the giving of notice would cause such a violation of or default under) any Material Contract.

- **2.9** Litigation. There is no material action, suit or proceeding pending or, to the Company's knowledge, currently threatened against the Company or against any director, officer or employee of the Company. The Company is not a party to, or subject to the provisions of, any order, writ, injunction, judgment or decree of any court or government agency or instrumentality. There is no material action, suit, proceeding or investigation by the Company currently pending or that the Company intends to initiate.
- **2.10** Taxes. Except as would not reasonably be expected to have a Material Adverse Effect, (i) all federal, state and local tax returns, reports and declarations of the Company required by law to be filed have been duly filed, (ii) all taxes and other fees due thereon have been paid and (iii) the Company has set aside on its books provisions reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There is no tax lien, whether imposed by any federal, state, county or local taxing authority, outstanding against the assets, properties or business of the Company. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company know of no basis for any such claim.
- **Listing and Maintenance Requirements.** The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. The Company is in compliance with the requirements of the NASDAQ Global Select Market for continued listing of the Common Stock thereon and has not received any notification that the NASDAQ Global Select Market is contemplating terminating such listing. The Company has no reason to believe that it will not upon issuance of the Shares continue to be in compliance with all such listing and maintenance requirements. The issuance of the Shares hereunder does not contravene the rules of the NASDAQ Global Select Market.
- Offering Exemption. Based in part on the representations of Purchaser set forth in Section 4.2 below, the offer, sale and issuance of the Shares in conformity with the terms of this Agreement are exempt from the registration requirements of the Securities Act and are exempt from the qualification or registration requirements of applicable state securities laws. Neither the Company nor its affiliates, nor any agent on its or their behalf, (i) has engaged in any form of general solicitation or general advertising (within the meaning of Regulation D under the Securities Act) in connection with the Common Stock Financing, (ii) has solicited or will solicit any offers to sell or has offered to sell or will offer to sell all or any part of the Shares to any Person or Persons so as to bring the sale of the Shares by the Company within the registration provisions of the Securities Act or any state securities laws or (iii) has issued any shares of Common Stock or shares of any series of Preferred Stock or other securities or instruments convertible into, exchangeable for or otherwise entitling the holder thereof to acquire shares of Common Stock which would be integrated with the sale of the Shares to Purchaser for purposes of the Securities Act or of any applicable shareholder approval provisions, including, without limitation, under the rules and regulations of any exchange or automated quotation system on which any of the securities of the Company are listed or designated, nor will the Company or any of its subsidiaries or affiliates take any action or steps that would require registration of any of the Shares under the Securities Act.
- **2.13 Affiliate Transactions.** No employee, officer, director or 10% or greater shareholder of the Company or member of his or her immediate family (each a "**Covered Person**") is currently indebted

CONFIDENTIAL TREATMENT REQUESTED

to the Company, nor is the Company indebted (or committed to make loans or extend or guarantee credit) to any Covered Person. Except as disclosed in the SEC Filings, as of the date hereof, no Covered Person has any direct or indirect ownership interest in any firm or corporation with which the Company is affiliated or with which the Company has a business relationship, or any firm or corporation that competes with the Company (except for ownership of stock not to exceed 1% of the outstanding capital stock of any publicly traded company that may compete with the Company).

- **2.14** Investment Company Act. The Company is not, and is not an Affiliate (as defined below) of, and after giving effect to the Common Stock Financing, will not be and will not be an Affiliate of, an "investment company" or an entity "controlled" by an "investment company," as such terms are defined in the Investment Company Act of 1940. For purposes of this Agreement, "Affiliate" shall mean any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.
- **2.15 Brokers or Finders.** The Company has not retained any brokers, consultants or advisors in connection with this Agreement, and has no agreements to pay any commission or compensation in the nature of a finder's or broker's fee arising out of this Agreement or the transactions contemplated hereby.
- **Compliance with Rule 506.** None of the Company, any of its predecessors, any affiliated issuer, any director, 2.16 executive officer, other officer of the Company participating in the offering contemplated hereby, any beneficial owner of 20% or more of the Company's outstanding voting equity securities, calculated on the basis of voting power, nor any promoter (as that term is defined in Rule 405 under the Securities Act) connected with the Company in any capacity at the time of sale is disqualified from relying on Rule 506 of Regulation D under the Securities Act ("Rule 506") for any of the reasons stated in Rule 506(d) in connection with the issuance and sale of the Shares to Purchaser pursuant to this Agreement. The Company has exercised reasonable care, including without limitation, conducting a factual inquiry that is appropriate in light of the circumstances, into whether any such disqualification under Rule 506(d) exists, but has assumed the accuracy of the Purchaser's representations and warranties. The Company has furnished to Purchaser, a reasonable time prior to the date hereof, a description in writing of any matters that would have triggered disqualification under Rule 506(d) but which occurred before September 23, 2013, in each case, in compliance with the disclosure requirements of Rule 506(e). The Company has exercised reasonable care, including without limitation, conducting a factual inquiry that is appropriate in light of the circumstances, into whether any such disqualification under Rule 506(d) would have existed and whether any disclosure is required to be made to Purchaser under Rule 506(e). Any outstanding securities of the Company (of any kind or nature) that were issued in reliance on Rule 506 at any time on or after September 23, 2013 have been issued in compliance with Rules 506(d) and (e) and no party has any reasonable basis for challenging any such reliance on Rule 506 in connection therewith.

3. ADDITIONAL REPRESENTATIONS AND WARRANTIES OF THE COMPANY AS OF THE INITIAL CLOSING

As of the date of the Initial Closing only, the Company represents and warrants to Purchaser that, subject to exceptions and disclosures set forth in any part or subpart of the Company Disclosure Schedule corresponding to the particular Section or subsection of this Section 3, or any exceptions or disclosures set forth in any other part or subpart of the Company Disclosure Schedule to the extent it is reasonably apparent from the wording or any such exception or disclosure that such exception or disclosure is applicable to qualify such representation or warranty, and disclosures in the SEC Filings, excluding any disclosure of risks included in any "risk factors," "forward-looking statements" disclaimer or other statements that are similarly predictive or forward-looking in nature, the statements contained in this

CONFIDENTIAL TREATMENT REQUESTED

<u>Section 3</u> are true, complete and correct (except that those statements which address matters only as of a particular date are true, correct and complete as of such date).

- 3.1 Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Filings, except as specifically set forth in a subsequent SEC Filing filed at least one (1) Trading Day prior to the date hereof: (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (a) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (b) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to the holders of its Common Stock or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans. The Company does not have pending before the SEC any request for confidential treatment of information. Except for the issuance of the Shares contemplated by this Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its business, properties, operations, assets or financial condition, that would be required to be disclosed by the Company under applicable securities laws if the Company were publicly offering securities pursuant to an effective registration statement under the Securities Act at the time this representation is made or deemed made that has not been publicly disclosed at least one (1) Trading Day prior to the date that this representation is made.
- 3.2 <u>Labor Relations</u>. No material labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's employees is a member of a union that relates to such employee's relationship with the Company, the Company is not a party to any collective bargaining agreement, and the Company believes that its relationships with its employees are good. The Company is in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.
- Environmental Matters. The Company is in compliance with and has not received notice of any actual or potential liability under or relating to, or actual or potential violation of, applicable federal, state and local laws, rules and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to its business (the "Environmental Laws"). The Company has not received notice of any actual or potential liability under or relating to, or actual or potential violation of, any Environmental Laws, including for the investigation or remediation of any release or threat of release of hazardous materials, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice. The Company is not conducting or paying for, in whole or in part, any investigation, remediation or other corrective action pursuant to any Environmental Law at any location, and is not a party to any order, decree or agreement that imposes any obligation or liability under any Environmental Law. There are no costs or liabilities associated with Environmental Laws of or relating to the Company, except for any such matter, as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company is not aware of any facts or issues regarding its compliance with Environmental Laws, or liabilities or other obligations under Environmental Laws, that, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect, and the Company does not anticipate material capital expenditures relating to any Environmental Laws.

CONFIDENTIAL TREATMENT REQUESTED

3.4	Title to Assets. Except as set forth in the SEC Filings, the Company has good and marketable title in all
personal property owned	by the Company that is material to the business of the Company, in each case free and clear of all liens, except for
liens as do not materially a	affect the value of such property and do not materially interfere with the use made and proposed to be made of such
	and liens for the payment of federal, state or other taxes, the payment of which is neither delinquent nor subject to
penalties. Any real proper	ty and facilities held under lease by the Company are held by it under valid, subsisting and enforceable leases with
which the Company are in	compliance.

- 3.5 Insurance. The Company is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the business in which the Company is engaged, including, but not limited to, directors and officers insurance. The Company does not have any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.
- **3.6** Registration Rights. Except as provided for in this Agreement or as set forth in the SEC Filings, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company.
- **3.7 Application of Takeover Protections.** The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti- takeover provision under the Company's certificate of incorporation or the laws of its state of incorporation that is or could become applicable to Purchaser as a result of Purchaser and the Company fulfilling their obligations or exercising their rights under this Agreement, including without limitation as a result of the Company's issuance of the Shares and the Purchaser's ownership of the Shares.
- 3.8 Foreign Corrupt Practices. Neither the Company, nor to the knowledge of the Company, any agent or other person acting on behalf of the Company, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company (or made by any person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended.
- **Accountants.** The Company's independent registered public accounting firm is Ernst & Young LLP. To the knowledge and belief of the Company, such accounting firm: (i) is a registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in the Company's Annual Report for the fiscal year ending December 31, 2016.
- **3.10** Office of Foreign Assets Control. Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee or Person acting on behalf of the Company, is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.
- **Money Laundering.** The operations of the Company are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "**Money Laundering Laws**"), and no

CONFIDENTIAL TREATMENT REQUESTED

action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

Acknowledgement. The Company acknowledges and agrees that Purchaser is acting solely in the capacity of an arm's length purchaser with respect to this Agreement and the transactions contemplated hereby. The Company further acknowledges that Purchaser is not acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to this Agreement and the transactions contemplated hereby and any advice given by Purchaser or any of their respective representatives or agents in connection with this Agreement and the transactions contemplated hereby is merely incidental to Purchaser's purchase of the Shares. The Company further represents to Purchaser that the Company's decision to enter into this Agreement has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

4. REPRESENTATIONS AND WARRANTIES OF PURCHASER

As a material inducement to the Company to enter into and perform its obligations under this Agreement, Purchaser represents and warrants to the Company as follows:

4.1 Authorization; Enforceability. Purchaser has all requisite power and authority to execute, deliver and perform this Agreement. All action on the part of Purchaser and, as applicable, its directors, officers, members, partners and shareholders, necessary for the authorization, execution, delivery and performance of all obligations of Purchaser under this Agreement has been taken. This Agreement constitutes the valid and legally binding obligations of Purchaser, enforceable in accordance with their terms, except as limited by the Equitable Exceptions.

4.2 <u>Investor Representations</u>.

satisfaction of certain conditions.

- (a) The Shares acquired by Purchaser hereunder will be acquired by Purchaser for its own account for investment purposes and not with a view to distribution in violation of the Securities Act. Purchaser does not presently have any contract, undertaking or agreement with any Person to sell, transfer or grant participation rights to such Person or to any other Person with respect to any of the Shares acquired by Purchaser hereunder.
- (b) Purchaser is an "accredited investor" within the meaning of Rule 501(a) promulgated under the Securities Act.

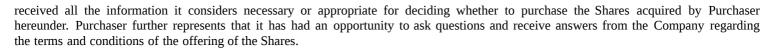
(c) Purchaser understands that the Shares are characterized as "restricted securities" under the federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances. Purchaser acknowledges and agrees that the Shares must be held indefinitely unless they are subsequently registered under the Securities Act or an exemption from such registration is available or the Company receives an opinion of counsel reasonably satisfactory to the Company that such registration is not required. Purchaser has been advised or is aware of the provisions of Rule 144 promulgated under the

Securities Act as in effect from time to time ("Rule 144"), which permit limited resale of shares purchased in a private placement subject to the

(d) Purchaser acknowledges and agrees that it can bear the economic risk of its investment in the

Shares and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares. Purchaser believes that it has

CONFIDENTIAL TREATMENT REQUESTED



- (e) Purchaser has not agreed to incur, directly or indirectly, any liability for brokerage or finders' fees, agents' commissions or other similar charges in connection with this Agreement or any of the transactions contemplated hereby.
- (f) Purchaser is not relying and has not relied on any representations or warranties whatsoever regarding the subject matter of this Agreement, express or implied, except for the representations and warranties in Section 2 and Section 3, including the Company Disclosure Schedule. Such representations and warranties by the Company constitute the sole and exclusive representations and warranties of the Company in connection with the transactions contemplated by this Agreement and Purchaser understands, acknowledges and agrees that all other representations and warranties of any kind or nature whether express, implied or statutory are specifically disclaimed by the Company.
- In connection with the due diligence investigation of the Company by Purchaser and its affiliates, stockholders, directors, officers, employees, agents, representatives or advisors, Purchaser and its affiliates, stockholders, directors, officers, employees, agents, representatives and advisors have received and may continue to receive after the date hereof from the Company and its affiliates, stockholders, directors, officers, employees, consultants, agents, representatives and advisors certain estimates, projections, forecasts and other forward-looking information, as well as certain business plan information, regarding the Company and its business and operations. Purchaser hereby acknowledges that there are uncertainties inherent in attempting to make such estimates, projections, forecasts and other forward-looking statements, as well as in such business plans, and that Purchaser will have no claim against the Company, or any of its affiliates, stockholders, directors, officers, employees, consultants, agents, representatives or advisors, or any other Person with respect thereto unless any such information is expressly addressed or included in a representation or warranty contained in this Agreement. Accordingly, Purchaser hereby acknowledges and agrees that neither the Company nor any of its respective affiliates, stockholders, directors, officers, employees, consultants, agents, representatives or advisors, nor any other Person, has made or is making any express or implied representation or warranty with respect to such estimates, projections, forecasts, forward-looking statements or business plans unless any such information is expressly addressed or included in a representation or warranty contained in this Agreement.
- 4.3 Compliance with Laws. Neither Purchaser nor, to Purchaser's knowledge, any director, officer, agent, employee or Person acting on behalf of Purchaser, is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department. Purchaser represents and warrants to the Company as of each Closing as follows: if Purchaser is not a United States person (as defined by Section 7701(a)(30) of the Code), Purchaser has satisfied itself as to the full observance of the laws of its jurisdiction in connection with any invitation to subscribe for the Shares or any use of this Agreement, including (i) the legal requirements within its jurisdiction for the purchase of the Shares, (ii) any foreign exchange restrictions applicable to such purchase, (iii) any governmental or other consents that may need to be obtained and (iv) the income tax and other tax consequences, if any, that may be relevant to the purchase, holding, redemption, sale or transfer of the Shares. Purchaser's subscription and payment for and continued beneficial ownership of the Shares will not violate any applicable securities or other laws of Purchaser's jurisdiction.

5. CONDITIONS TO PURCHASER'S OBLIGATIONS AT CLOSING

CONFIDENTIAL TREATMENT REQUESTED

The obligations of Purchaser	under this Agreemen	t to purchase and pay for	the Shares being purchased	by Purchaser at each
Closing are subject to the satisfaction	or waiver, at or prior	to the applicable Closing	, of the following conditions:	

- 8.1 Representations and Warranties. The representations and warranties of the Company contained in Section 2 and Section 3 of this Agreement and in Section 13.1 and Section 13.3 of the Collaboration Agreement shall be true, correct and complete on and as of the Initial Closing and the representations and warranties contained in Section 2 shall be true, correct and complete as of the Second Tranche Closing and Third Tranche Closing (except that those representations and warranties which address matters only as of a particular date need only be measured as of the specific date) except that any inaccuracies in such representations and warranties will be disregarded if they collectively do not constitute and would not reasonably be expected to have a Material Adverse Effect on the Company (it being understood that for purposes of determining the accuracy of any representation or warranties all Material Adverse Effect and other materiality qualifications contained in such representations and warranties will be disregarded).
- **5.2 Performance.** The Company shall have performed and complied in all material respects with all other conditions, covenants and agreements contained in this Agreement required to be performed or complied with by it on or before the applicable Closing.
- **5.3 Legal Investment.** On the date of the applicable Closing, the sale and issuance of the Shares shall be legally permitted by all laws and regulations to which Purchaser and the Company are subject.
- **5.4** No Suspension. Trading in the Common Stock shall not have been suspended by the SEC or the NASDAQ Global Select Market.
- 5.5 <u>Consents and Approvals.</u> Any consent required for the consummation of the transactions contemplated by this Agreement, including without limitation, the issuance of the Shares, shall have been obtained (collectively, "Consents"). If applicable, the waiting period (or any extension thereof) under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, required in order for the Collaboration Agreement to become effective shall have expired or been terminated.
- **5.6 Qualifications.** All authorizations, approvals or permits, if any, of any Governmental Authority that are required in connection with the lawful issuance and sale of the Shares pursuant to this Agreement shall have been duly obtained and shall be effective on and as of the applicable Closing.
- **5.7 No Injunction.** No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any Governmental Authority of competent jurisdiction which prohibits the consummation of any of the transactions contemplated by this Agreement.
- **5.8** Collaboration Agreement. The Company shall have executed the Collaboration Agreement and the Effective Date of the Collaboration Agreement shall have occurred.
- **5.9 Legal Opinion.** Purchaser shall have received from Cooley LLP, counsel for the Company, an opinion, dated as of the Initial Closing, in form and substance reasonably satisfactory to counsel for Purchaser.

CONFIDENTIAL TREATMENT REQUESTED

5.10	Compliance Certificate	 Purchaser 	shall ha	ave received	a compliance	certificate,	executed b	y the	Chie
Executive Officer and Chief Fi	inancial Officer of the Com	ipany, dated	as of the	date of the C	Closing, to the	effect that th	e conditions	s speci	fied ir
Sections 5.1 and 5.2 have been	satisfied.								

5.11 Secretary's Certificate. Purchaser shall have received a certificate of the Company's Secretary certifying as to (A) the Company's certificate of incorporation and bylaws, (B) the resolutions of the Board of Directors approving this Agreement and the transactions contemplated hereby, and (C) good standing certificates with respect to the Company from the applicable authority(ies) in Delaware and any other jurisdiction in which the Company is qualified to do business, dated a recent date before the Closing.

6. CONDITIONS TO THE COMPANY'S OBLIGATIONS AT CLOSING

The obligations of the Company under this Agreement to sell and issue to Purchaser the Shares to be purchased by Purchaser at each Closing are subject to the satisfaction or waiver, at or prior to the applicable Closing, of the following conditions:

- **Representations and Warranties.** The representations and warranties of Purchaser contained in <u>Section 4</u> shall be true, correct and complete in all respects on and as of the applicable Closing with the same force and effect as if they had been made at such time (except that those representations and warranties which address matters only as of a particular date need only be true, correct and complete in all material respects as of such date).
- **6.2 Performance.** Purchaser shall have performed and complied with all other conditions, covenants and agreements contained in this Agreement required to be performed or complied with by Purchaser on or before the applicable Closing.
- **Qualifications.** All authorizations, approvals or permits, if any, of any Governmental Authority that are required in connection with the lawful issuance and sale of the Shares pursuant to this Agreement shall have been duly obtained and shall be effective on and as of the applicable Closing.
- **6.4 No Injunction.** No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any Governmental Authority of competent jurisdiction which prohibits the consummation of any of the transactions contemplated by this Agreement.
- **6.5 Consents and Approvals.** Any Consent required for the consummation of the transactions contemplated by this Agreement, including without limitation, the issuance of the Shares, shall have been obtained. If applicable, the waiting period (or any extension thereof) under the Hart- Scott-Rodino Antitrust Improvements Act of 1976, as amended, required in order for the Collaboration Agreement to become effective shall have expired or been terminated.
- **6.6** Collaboration Agreement. The Company shall have executed the Collaboration Agreement and the Effective Date of the Collaboration Agreement shall have occurred.

7. COVENANTS

- 7.1 <u>Purchaser Lock-Up.</u> Purchaser covenants and agrees as follows:
- (a) Purchaser will not, without the prior written consent of the Company, during the period commencing on the date of each Closing and, subject to the terms set forth herein, ending (i) 180

CONFIDENTIAL TREATMENT REQUESTED

days after the Initial Closing with respect to the Shares purchased in the Initial Closing, or (ii) 90 days after the Second Tranche Closing or Third Tranche Closing, as applicable with respect to the Shares purchased in such Closing (each, a "Lock-Up Period"), (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any Shares purchased in such Closing or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Shares, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of the Shares purchased in such Closing, in cash or otherwise. Notwithstanding the foregoing, Purchaser may transfer the Shares to any of its shareholders or Affiliates; *provided* that in the case of any transfer or distribution pursuant to this subparagraph during the Lock-Up Period, each done or transferee shall sign and deliver a lock-up letter with terms substantially similar to the terms of this Section 7.1.

- (b) Notwithstanding anything to the contrary contained herein, Purchaser agrees that Purchaser shall not effect any sale, transfer or other disposition of any Shares unless: (a) such sale, transfer or other disposition is effected pursuant to an effective registration statement under the Securities Act; (b) such sale, transfer or other disposition is made in conformity with the requirements of Rule 144, as evidenced by a broker's letter and a representation letter executed by Purchaser (reasonably satisfactory in form and content to the Company) stating that such requirements have been met; or (c) counsel reasonably satisfactory to the Company (which may be counsel to the Company) shall have advised the Company in a written opinion letter (reasonably satisfactory in form and content to the Company), upon which the Company may rely, that such sale, transfer or other disposition will be exempt from the registration requirements of the Securities Act.
- (c) Notwithstanding any other provision of this Section 7.1, this Section 7.1 shall not prohibit or restrict any disposition of Common Stock by Purchaser in connection with (i) a bona fide tender offer by a Person other than Purchaser or the Company that is not opposed by the Board of Directors and involving a Change of Control of the Company (as defined below); or (ii) an issuer tender offer by the Company; *provided*, that in the event that the tender offer is not completed, the Shares shall remain subject to the restrictions contained in this Section 7.1. For the purposes of this Agreement, a "Change of Control" means the transfer, in one transaction or a series of related transactions, to a person or group of affiliated persons, of shares of capital stock of the Company if, after such transfer, the stockholders of the Company immediately prior to such transfer do not own at least twenty percent (20%) of the outstanding voting securities of the Company (or the surviving entity).
- (d) Purchaser acknowledges and agrees that stop transfer instructions will be given to the Company's transfer agent with respect to the Shares until the expiration of the Lock-Up Period.

Registration Rights. The Company covenants and agrees as follows:

(a) As soon as practicable, and in any event within thirty (30) days following the Initial Closing, the Company shall register the Shares purchased at the Initial Closing on an active Form S-3 or file a new Form S-3 registration statement (or such other form appropriate for such purpose) under the Securities Act. For each Additional Closing, if at any time when it is eligible to use a Form S-3 registration statement, the Company shall as soon as practicable, and in any event within thirty (30) days after the date of purchase by Purchaser, either register on an active Form S-3 or file a new Form S-3 registration statement (or such other form appropriate for such purpose) under the Securities Act covering all Registrable Shares (as defined below) then purchased by Purchaser (and, at the discretion of the Company, other registrable shares held by other shareholders), subject to the limitations of Sections 7.2(b) and 7.2(c). The Company shall maintain the effectiveness of any registration statements with respect to the Registrable Shares in accordance with the terms hereof for a period ending on the date on

CONFIDENTIAL TREATMENT REQUESTED

which all Registrable Shares covered by such registration statement have been sold pursuant to such registration statement or have otherwise ceased to be Registrable Shares. The Company and the Purchaser agree that the Purchaser will suffer damages if the Company fails to fulfill its obligations under this Section 7.2(a) and that it would not be feasible to ascertain the extent of such damages with precision. Accordingly, if: (i) a registration statement is not filed with the Commission within the time period contemplated hereby; or (ii) a registration statement is not declared effective by the Commission within the time period contemplated hereby (each such event referred to in the foregoing clauses (i) and (ii), a "Registration Default"), then in such event as relief for the damages to Purchaser for the Registration Default, and not as a penalty, the Company hereby agrees to pay to Purchaser, an amount in cash equal to 1.0% of the aggregate purchase price of the unregistered Registrable Shares held by Purchaser for each 30-day period (prorated for periods totaling less than 30 days) following the Registration Default until the earlier to occur of: (1) such time as when the Company cures the Registration Default; and (2) the six (6) month anniversary of the applicable Closing Date. The payments to which a Holder shall be entitled pursuant to this Section 7.2(a) are referred to herein as "Additional Payment Amounts". The Company shall pay Additional Payment Amounts, if any, to Holders on the earlier of: (1) the last day of the calendar month during which such Additional Payment Amounts are incurred; and (2) the third Business Day following the date on which the Registration Default giving rise to the Additional Payment Amounts is cured.

- (b) Notwithstanding the foregoing obligations, if the Company furnishes to Purchaser a certificate signed by the Company's Chief Executive Officer stating that in the good faith judgment of the Board of Directors it would be materially detrimental to the Company and its shareholders for a registration statement with respect to Registrable Shares to either become effective or remain effective for as long as such registration statement otherwise would be required to remain effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization or other similar transaction involving the Company; (ii) require premature disclosure of material information that the Company has a *bona fide* business purpose for preserving as confidential; or (iii) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period not to exceed 60 days after the applicable Closing Date for the purchase of such Registrable Shares; *provided*, that the Company may not invoke this right more than once in any twelve (12) month period.
- (c) The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Section 7.2(a) during the period that is 30 days before the Company's good faith estimate of the date of filing with the SEC of, and ending on a date that is 90 days after the effective date of, a Company-initiated registration statement pertaining to an underwritten public offering for the Company's account, *provided* that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; *provided*, *however*, that a "Company-initiated registration statement" shall not include a registration statement on Forms S-4 or S-8 (or any similar or successor form providing for the registration of securities in connection with mergers, acquisitions, exchange offers, subscription offers, dividend reinvestment plans or stock option or other executive or employee benefit or compensation plans). A registration shall not be counted as "effected" for purposes of this Section 7.2(c) until such time as the applicable registration statement has been declared effective by the SEC, unless Purchaser withdraws its request for such registration, in which case such withdrawn registration statement shall be counted as "effected" for purposes of this Section 7.2(c).
- (d) All expenses, other than Selling Expenses (as defined below), incurred in connection with registrations, filings or qualifications pursuant to this <u>Section 7.2</u>, including all registration, filing and qualification fees; printers' and accounting fees; fees and disbursements of counsel for the Company; and the reasonable fees and disbursements, shall be borne and paid by the Company.

CONFIDENTIAL TREATMENT REQUESTED

All Selling Expenses shall be borne by the Purchaser; or if there are other selling shareholders with shares being registered pursuant to such registration statement, then *pro rata* by the selling shareholders based on the number of shares sold by such selling shareholder in the offering.

(e) For the purposes of this Section 7.2,

(i) "Losses" means any loss, damage, claim or liability (joint or several) to which a party hereto may become subject under the Securities Act, the Exchange Act, or other federal or state law, insofar as such loss, damage, claim or liability (or any action in respect thereof) arises out of or is based upon: (i) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto; (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or (iii) any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law.

(ii) "Registrable Shares" means the Shares held by Purchaser including, without limitation, any shares of Common Stock paid, issued or distributed in respect of any such Shares by way of stock dividend, stock split or distribution, or in connection with a combination of shares, recapitalization, reorganization, merger or consolidation, or otherwise, but excluding shares of Common Stock acquired in the open market before or after the date hereof, *provided*, *however*, that the Shares will cease to be "Registrable Shares" when (A) the Shares have been sold pursuant to an effective registration statement or (B) the Shares proposed to be sold by Purchaser, in the opinion of counsel satisfactory to the Company, may be distributed to the public without any limitation pursuant to Rule 144 (or any successor provision then in effect).

"Selling Expenses" means the fees and disbursements of counsel for

Purchaser.

(iii)

(f) With a view to making available to Purchaser the benefits of Rule 144, for a period of one year following the date of the latest Closing pursuant to this Agreement, the Company covenants that it will (i) use its commercially reasonable efforts to file in a timely manner all reports and other documents required, if any, to be filed by it under the Securities Act and the Exchange Act and the rules and regulations adopted thereunder and (ii) make available information necessary to comply with Rule 144 with respect to resales of the Registrable Shares under the Securities Act, at all times, all to the extent required from time to time to enable Purchaser to sell Registrable Shares without registration under the Securities Act within the limitation of the exemptions provided by (A) Rule 144 (if available with respect to resales of the Registrable Shares), as such rule may be amended from time to time or (B) any other rules or regulations now existing or hereafter adopted by the SEC.

(g) To the extent permitted by law, the Company will indemnify and hold harmless Purchaser, and the partners, members, officers, directors, and stockholders of Purchaser; legal counsel and accountants for Purchaser; any underwriter (as defined in the Securities Act) for Purchaser; and each Person, if any, who controls Purchaser or underwriter within the meaning of the Securities Act or the Exchange Act, against any Losses, and the Company will pay to Purchaser, underwriter, controlling Person, or other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Losses may result, as such expenses are incurred; *provided*, *however*, that the indemnity agreement contained in this Section 7.2(g) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, nor shall

CONFIDENTIAL TREATMENT REQUESTED

the Company be liable for any Losses to the extent that they arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any the Purchaser, underwriter, controlling Person, or other aforementioned Person expressly for use in connection with such registration.

- (h) To the extent permitted by law, Purchaser agrees to indemnify and hold harmless the Company, each of the directors of the Company, each of the officers of the Company who shall have signed a registration statement, and each other Person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act, against any Losses to which they or any of them may become subject under the Securities Act, the Exchange Act or otherwise, insofar as such Losses (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in a registration statement or any document incorporated by reference in such document, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, in each case to the extent, but only to the extent, that any such Loss arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon and in strict conformity with written information furnished to the Company by or on behalf of Purchaser for use therein; provided, however, that the indemnity agreement contained in this Section 7.2(h) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Purchaser, which consent shall not be unreasonably withheld;. The maximum aggregate amount of indemnifiable Losses that may be recovered from the Purchaser under the provisions of this Section 7.2(h) shall be the aggregate value of the consideration received for the Shares.
- (i) Promptly after receipt by an indemnified party under this <u>Section 7.2</u> of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this <u>Section 7.2</u>, give the indemnifying party notice of the commencement thereof. The indemnifying party shall have the right to participate in such action and, to the extent the indemnifying party so desires, participate jointly with any other indemnifying party to which notice has been given, and to assume the defense thereof with counsel mutually satisfactory to the parties; *provided*, *however*, that an indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such action. The failure to give notice to the indemnifying party within a reasonable time of the commencement of any such action shall relieve such indemnifying party's ability to the indemnified party under this <u>Section 7.2</u>, to the extent that such failure materially prejudices the indemnifying party's ability to defend such action. The failure to give notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this <u>Section 7.2</u>.
- (j) To provide for just and equitable contribution to joint liability under the Securities Act in any case in which either: (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this <u>Section 7.2</u> but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case, notwithstanding the fact that this <u>Section 7.2</u> provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any party hereto for which indemnification is provided under this <u>Section 7.2</u>, then, and in each such case, such parties will contribute to the aggregate losses, claims, damages, liabilities, or expenses to which they may be subject

CONFIDENTIAL TREATMENT REQUESTED

(after contribution from others) in such proportion as is appropriate to reflect the relative fault of each of the indemnifying party and the indemnified party in connection with the statements, omissions, or other actions that resulted in such loss, claim, damage, liability, or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission; provided, however, that, in any such case (x) Purchaser will not be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered and sold by Purchaser pursuant to such registration statement, and (y) no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation.

7.3 **Notifications.**

- (a) Prior to each Closing, the Company will promptly advise Purchaser in writing of any notice or other communication from any third Person alleging that the consent of a third Person is required in connection with the transactions contemplated by this Agreement.
- (b) Prior to each Closing, each party shall promptly notify the other of any action, suit or proceeding that is instituted or specifically threatened in writing against such party to restrain, prohibit or otherwise challenge the legality of any transaction contemplated by this Agreement.
- **7.4** Standstill. During the period commencing on the Effective Date and ending on the earliest of (i) five (5) years following the Effective Date, [***] neither the Purchaser nor any of Purchaser's representatives or affiliates will, in any manner, directly or indirectly:
- (a) make, effect, initiate or cause (i) any [***] to the extent that [***] would result in [***], (ii) any [***] of any [***] or any [***] or any [***] or (iv) any [***] provided, however, that notwithstanding the provisions of this Section 7.4(a)(i), [***] as a result of a [***] shall not be required to [***] even though such action [***];
 - (b) [***] with respect to the [***];

CONFIDENTIAL TREATMENT REQUESTED

(c)	[***];
(d)	[***] of this <u>Section 7.4</u> ;
(e)	[***] of this sentence;
(f)	[***] of this sentence;
(g)	[***]; or
(h)	[***] in this <u>Section 7.4</u> .

Notwithstanding the foregoing, it is understood and agreed that [***] by this <u>Section 7.4</u>, and [***] by this <u>Section 7.4</u>; [***].

- **7.5 Commercial Reasonable Efforts.** Each Party will use its commercially reasonable efforts to satisfy in a timely fashion each of the conditions to be satisfied by it under <u>Section 5</u> and <u>Section 6</u> of this Agreement.
- 7.6 Securities Laws Disclosure; Publicity. The Company shall, by 9:00 a.m. (New York City time) on the Trading Day immediately following the date hereof, issue a press release disclosing the material terms of the transactions contemplated hereby, and shall, within four (4) Trading Days following the date hereof, file a Current Report on Form 8-K disclosing the material terms of the transactions contemplated hereby and including this Agreement as an exhibit thereto. The Company and Purchaser shall consult with each other regarding the substance of any public disclosure by either party regarding this Agreement or the Collaboration Agreement (including the filing of either agreement as an exhibit to a periodic filing with the SEC) and regarding the issuance of any other press releases with respect to the transactions contemplated hereby, and neither the Company nor Purchaser shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of Purchaser, or without the prior consent of Purchaser, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication.
- 7.7 <u>Shareholder Rights Plan.</u> No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that Purchaser is an "Acquiring Person" under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that Purchaser could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Shares under this Agreement or under any other agreement among the Company and Purchaser.

CONFIDENTIAL TREATMENT REQUESTED

Indemnification of Purchaser. Subject to the provisions of this Section 7.8, the Company will indemnify and hold Purchaser and its directors, officers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a "Purchaser Party") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such Purchaser Party may suffer or incur due to a claim by a third party as a result of or relating to any action instituted against the Purchaser Parties in any capacity, or any of them or their respective Affiliates, by any stockholder of the Company who is not an Affiliate of such Purchaser Parties, with respect to any of the transactions contemplated by this Agreement (unless such action is based upon a breach of such Purchaser Party's representations, warranties or covenants under this Agreement or any agreements or understandings such Purchaser Parties may have with any such stockholder or any violations by such Purchaser Parties of state or federal securities laws or any conduct by such Purchaser Parties which constitutes fraud, gross negligence, willful misconduct or malfeasance). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, such Purchaser Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of the Company and the position of such Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel for all Purchaser Parties entitled to indemnification hereunder. The Company will not be liable to any Purchaser Party under this Agreement (y) for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed; or (z) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by such Purchaser Party in this Agreement. The indemnity agreements contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company and any liabilities that the Company may be subject to pursuant to law. The Company will have the exclusive right to settle any claim or proceeding, provided that the Company will not settle any such claim, action or proceeding without the prior written consent of the Purchaser Party, which will not be unreasonably withheld or delayed; provided, however, that such consent shall not be required if the settlement includes a full and unconditional release satisfactory to the Purchaser Party from all liability arising or that may arise out of such claim or proceeding and does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any Purchaser Party. Notwithstanding the foregoing, in no event will the Company's liability under this Section 7.8 exceed an aggregate of \$3,000,000.

7.9 Listing of Common Stock. The Company hereby agrees to use commercially reasonable efforts to maintain the listing or quotation of the Common Stock on the NASDAQ Global Select Market.

7.10 Form D; Blue Sky Filings. The Company agrees to timely file a Form D with respect to the Shares as required under Regulation D and to provide a copy thereof, promptly upon request of

CONFIDENTIAL TREATMENT REQUESTED

Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Shares for, sale to Purchaser at each Closing under applicable securities or "Blue Sky" laws of the states of the United States, and shall provide evidence of such actions promptly upon request of Purchaser.

7.11 Book Entry Statement. The Company hereby agrees to deliver to Purchaser a book entry statement from the Transfer Agent showing the Initial Closing Shares, Second Tranche Shares or Third Tranche Shares, as applicable, registered in the name of Purchaser within three (3) business days of the applicable Closing.

8. SURVIVAL OF REPRESENTATIONS

All representations, warranties, covenants and other agreements of the Company hereunder shall be deemed made on and as of each Closing as though such representations, warranties, covenants and other agreements were made on and as of such date. All representations and warranties made by a party to this Agreement herein or pursuant hereto shall survive each Closing and the delivery of the Shares for a period of 18 months thereafter. All covenants and other agreements made by a party to this Agreement herein or pursuant hereto shall survive until all obligations set forth therein shall have been performed or satisfied or they shall have terminated in accordance with their terms

9. TERMINATION

- **9.1 Termination.** This Agreement may be terminated at any time until the Initial Closing:
 - (a) by the mutual written consent of Purchaser and the Company;
- (b) by the Company or the Purchaser upon termination of the Collaboration Agreement in accordance with its terms;
- (c) by the Company if (i) any of the representations and warranties of Purchaser contained in <u>Section 4</u> of this Agreement shall fail to be true and correct or (ii) there shall be a breach by Purchaser of any covenant of Purchaser in this Agreement that, in either case, (A) would result in the failure of a condition set forth in <u>Section 6</u>, and (B) which is not curable or, if curable, is not cured upon the occurrence of the twentieth (20th) day after written notice thereof is given the Company to Purchaser;
- (d) by Purchaser if (i) any of the representations and warranties of the Company contained in Section 2 or Section 3 of this Agreement shall fail to be true and correct or (ii) there shall be a breach by the Company of any covenant of the Company in this Agreement that, in either case, (A) would result in the failure of a condition set forth in Section 5, and (B) which is not curable or, if curable, is not cured upon the occurrence of the twentieth (20_{th}) day after written notice thereof is given by Purchaser to the Company; or
- (e) by either Purchaser or the Company in the event that any court of competent jurisdiction or Governmental Authority shall have issued an order, decree or ruling or taken any other action restraining, enjoining or otherwise prohibiting the actions contemplated hereby and such order, decree, ruling or other action shall have become final and nonappealable.
- **9.2 Effect of Termination.** In the event of any termination of this Agreement as provided in Section 9.1, this Agreement (other than Section 10, which shall remain in full force and effect) shall forthwith become wholly void and of no further force and effect; *provided* that nothing herein shall relieve any party from liability for willful breach of this Agreement.

CONFIDENTIAL TREATMENT REQUESTED

10. GENERAL

- Successors and Assigns. Except as otherwise provided herein, the terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and permitted assigns of the parties (including any permitted transferees of any Shares). Purchaser and the Company may not assign their respective rights or obligations under this Agreement, in whole or in part, except with the consent of the other party; *provided*, *however*, the rights and obligations of Purchaser may be assigned, without the prior written consent of the Company, to one or more of Purchaser's affiliates. Any attempted assignment made in contravention of this Agreement shall be null and void and of no force or effect.
- Entire Agreement. This Agreement and the Collaboration Agreement and the documents, schedules and exhibits referred to herein or therein constitute the entire agreement between the parties and supersede all prior communications, representations, understandings and agreements of the parties with respect to the subject matter hereof and thereof. No party shall be liable or bound to any other party in any manner by any warranties, representations or covenants except as specifically set forth herein or therein. All schedules and exhibits hereto are hereby incorporated herein by reference. Nothing in this Agreement, express or implied, is intended to confer upon any third party any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.
- **General Interpretation.** The terms of this Agreement have been negotiated by the parties hereto and the language used in this Agreement shall be deemed to be the language chosen by the parties hereto to express their mutual intent. This Agreement shall be construed without regard to any presumption or rule requiring construction against the party causing such instrument or any portion thereof to be drafted, or in favor of the party receiving a particular benefit under this Agreement. No rule of strict construction will be applied against any Person.
- Injunctive Relief. Purchaser and the Company acknowledge and agree that, in view of the uniqueness of the Shares, damages at law would be insufficient for any breach by Purchaser or the Company of any of their respective covenants in this Agreement. Accordingly, each party agrees that in the event of any breach or threatened breach by the other party of any provisions of this Agreement, the non-breaching party be entitled to seek equitable relief in the form of an order to specifically perform or an injunction to prevent irreparable injury.
- **10.5 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the principles of conflicts of law thereof.
- **10.6 Jurisdiction.** The parties hereby irrevocably and unconditionally submit to the jurisdiction of the United States District Court for the Southern District of New York for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement.
- **Counterparts.** This Agreement may be executed in any number of counterparts and by the parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement, and may be delivered to the other parties hereto by facsimile.
- **10.8** Section Headings and References. The section headings contained herein are for the convenience of the parties and in no way alter, modify, amend, limit or restrict the contractual obligations of the parties. When a reference is made in this Agreement to a Section or Exhibit, such reference is to a Section or Exhibit of or to this Agreement unless otherwise indicated. The words "hereof," "herein,"

CONFIDENTIAL TREATMENT REQUESTED

"hereto" and "hereunder" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The terms defined in the singular has a comparable meaning when used in the plural, and vice versa. References to a Person are also to its successors and permitted assigns. References to an agreement are to such agreement as amended, restated, modified or otherwise supplemented, from time to time. The term "dollars" and "\$" means United States dollars. The word "including" means "including without limitation" and the words "include" and "includes" have corresponding meanings.

- 10.9 Severability. If any term of provision of this Agreement is determined to be illegal, unenforceable or invalid in whole or in part for any reason, such illegal, unenforceable or invalid provisions or party thereof shall be stricken from this Agreement, and such provision shall not affect the legality, enforceability or validity of the remainder of this Agreement. If any provision or part thereof of this Agreement is stricken in accordance with the provisions of this Section 10.9, then such stricken provision shall be replaced, to extent possible, with a legal, enforceable and valid provision that is as similar in tenor to the stricken provision as is legally possible.
- 10.10 Notices. All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when received by facsimile or email (provided that the party providing such notice promptly confirms receipt of such transmission with the other party), (c) when received after having been sent by registered or certified mail, return receipt requested and postage prepaid or (d) when received after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the Company and to Purchaser at the address as set forth below or at such other address as Purchaser or the Company may designate by 10 days advance written notice to the Company (in the case of Purchaser) or Purchaser (in the case of the Company).

if to the Company:

Ultragenyx Pharmaceutical Inc. 60 Leveroni

Ct.

Novato, CA 94949

Attn: Chief Financial Officer Facsimile:

Email:

with a copy (which shall not constitute notice) to: Cooley LLP

Attn: Glen Y Sato 3175 Hanover Street Palo Alto, CA

94304

Facsimile: (650) 849-7400 Email:

gsato@cooley.com

if to Purchaser:

Takeda Pharmaceutical Company Limited 1-1 Doshomachi 4-chome, Chuo-ku, Osaka 540-8645 Attention: Head of Global Business Development Facsimile: (+81) 3-3278-

CONFIDENTIAL TREATMENT REQUESTED

with copies (which shall not constitute notice) to:

Takeda Pharmaceuticals U.S.A., Inc. One Takeda Parkway Deer Field, IL 60015

Attention: General Counsel, Legal Department Facsimile: 224-554-7831

and

Morgan, Lewis & Bockius LLP Attn: Randall B. Sunberg Emilio Ragosa 502 Carnegie Center Princeton, NJ 08540 Facsimile: (609) 919-6701

Email: randall.sunberg@morganlewis.com emilio.ragosa@morganlewis.com

- Amendments and Waivers. Except as otherwise expressly set forth in this Agreement, any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of each party hereto (with respect to an amendment) and the written consent of each party from whom a waiver is sought (with respect to a waiver). No waiver of any provision or consent to any action shall constitute a waiver of any other provision or consent to any other action, whether or not similar. No waiver or consent shall constitute a continuing waiver or consent or commit a party to provide a waiver in the future except to the extent specifically set forth in writing.
- **10.12 Expenses.** Except with respect to the registration of the Shares pursuant to Section 7.2, each party hereto will pay its own expenses in connection with the transactions contemplated hereby.
- **10.13 Persons Entitled to Benefits of Agreement.** This Agreement is intended for the benefit of the parties hereto and their respective permitted successors and assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other person.
- **10.14 Further Assurances.** The Company and Purchaser shall use their commercially reasonable efforts, in the most expeditious manner practicable, to satisfy or cause to be satisfied the intent and purposes of this Agreement by executing and delivering such instruments, documents and other writings as may be reasonably necessary or desirable.

CONFIDENTIAL TREATMENT REQUESTED

IN WITNESS WHEREOF, the undersigned parties have duly executed this Common Stock Purchase Agreement effective as of the date first above written.

COMPANY:

ULTRAGENYX PHARMACEUTICAL INC.

By: /s/ Emil Kakkis

Name: Emil Kakkis

Title: CEO

Date: June 6, 2016

PURCHASER:

TAKEDA PHARMACEUTICAL COMPANY LIMITED

By: /s/ Misako Hamamura

Name: Misako Hamamura

Title: Head of JP Strategy & BD

Date: June 6, 2016

Exhibit 1	10.1
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Exhibit A

Collaboration and License Agreement

See attached.

LICENSE AND COLLABORATION AGREEMENT

BY AND BETWEEN

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND **ULTRAGENYX PHARMACEUTICAL INC. JUNE 6, 2016**

LICENSE AND COLLABORATIONAGREEMENT

This License and Collaboration Agreement (this "Agreement") is made as of the 6th day of June, 2016 (the "Execution Date") by and between Takeda Pharmaceutical Company Limited, a company incorporated under the laws of Japan having its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan ("Takeda"), and Ultragenyx Pharmaceutical Inc., a company incorporated under the laws of California, having its principal place of business at 60 Leveroni Court, Novato, CA 94949, United States ("<u>Ultragenyx</u>"). Ultragenyx and Takeda are sometimes referred to herein individually as a "<u>Party</u>" and collectively as the "<u>Parties</u>."

RECITALS

WHEREAS, Takeda has developed certain compounds and products potentially applicable to rare genetic disease indications;

WHEREAS, Ultragenyx is a pharmaceutical company with significant experience with the development of products for rare genetic disease indications; and

WHEREAS, Ultragenyx and Takeda desire to establish a collaboration for the further development and commercialization of certain products potentially applicable to rare genetic disease and other indications.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1 - DEFINITIONS

1.1	"[***] <u>Development Plans</u> " has the meaning set forth in Section 4.3(b).
1.2	"[***] <u>License Negotiation Period</u> " has the meaning set forth in Section 5.1(a).
1.3	"[***] Option" has the meaning set forth in Section 5.1(a).
1.4	"[***] Option Term" has the meaning set forth in Section 5.1(a).
1.5	"[***] Patent Prosecution" has the meaning set forth in Section 12.3(a).
1.6	"[<u>***] Compound</u> " means [***].

- 1.7 "[***] Product" means any pharmaceutical product that contains a [***] Compound, including all forms, presentations, strengths, doses and formulations (including any method of delivery).
- 1.8 "[***] Research Plan" has the meaning set forth in Section 6.3(a).
- 1.9 "Accounting Standards" mean GAAP in the case of Ultragenyx and IFRS in the case of Takeda.
- 1.10 "Affiliate" means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise.
- 1.11 "Agreement" has the meaning set forth in the preamble.
- 1.12 "Alliance Manager" means the person appointed by each Party from within their respective organization to coordinate and facilitate the communication, interaction and cooperation of the Parties pursuant to this Agreement.
- 1.13 "Applicable Laws" means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any Governmental Authority, including the U.S. Food, Drug and Cosmetic Act, (21 U.S.C. §301 et seq.) (the "FFDCA"), Prescription Drug Marketing Act, the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335a et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal Civil 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.
- 1.14 "<u>Bankruptcy Laws</u>" has the meaning set forth in Section 15.6(b).
- 1.15 "Bayh-Doyle Act" means the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as well as any regulations promulgated pursuant thereto, including 37 C.F.R. Part 401, and any successor statutes or regulations.
- 1.16 "[***] License Agreement" means the License Agreement by and between Ultragenyx and [***].
- 1.17 "Breaching Party" has the meaning set forth in Section 15.2(a).
- 1.18 "<u>Bulk Drug Product</u>" means a Product that has been Manufactured into a final pharmaceutical product, including drug substance (e.g., tablets or granules) for administration to humans in accordance with Applicable Laws, but has not been Packaged for use in Clinical Trials or for Commercialization.

CONFIDENTIAL TREATMENT REQUESTED

- 1.19 "Business Day" means a day other than Saturday, Sunday or any other day on which commercial banks located in the State of New York, U.S., or Japan, are authorized or obligated by Applicable Laws to close.
- 1.20 "<u>Calendar Quarter</u>" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that
- (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.
- 1.21 "<u>Calendar Year</u>" means the twelve-month period ending on December 31; provided however, that (a) the first Calendar Year of the Term, shall begin on the Effective Date and end on December 31, 2016; and (b) the last Calendar Year of the Term shall end on the date of expiration or termination of this Agreement.
- 1.22 "Candidate Product" has the meaning set forth in Section 6.2(a).
- "Change of Control" of Ultragenyx means if: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of Ultragenyx, or if the percentage ownership of such person or entity in the voting securities of Ultragenyx 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 voting securities representing more than fifty percent (50%) of the total voting power of all of the thenoutstanding voting securities of Ultragenyx; (b) the consummation of a merger, consolidation, recapitalization, or reorganization of Ultragenyx, other than any such transaction, which would result in stockholders or equity holders of Ultragenyx, or an Affiliate of Ultragenyx, immediately prior to such transaction owning at least fifty percent (50%) of the outstanding securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the stockholders or equity holders of Ultragenyx approve a plan of complete liquidation of Ultragenyx, or an agreement for the sale or disposition by Ultragenyx of all or a substantial portion of Ultragenyx's assets, other than pursuant to the transaction as described above or to an Affiliate; or (d) the sale or other transfer to a Third Party of all or substantially all of Ultragenyx's assets which relate to this Agreement.
- "Claim" has the meaning set forth in Section 17.1.
- 1.25 "Clinical Trial" means any human clinical study or trial of a pharmaceutical product in the Licensed Field in the Territory, including Phase I Trials, Phase II Trials and Phase IV Trials.
- 1.26 "Collaboration Activities" has the meaning set forth in Section 2.2(a).
- 1.27 <u>"Collaboration Term"</u> means (a) with respect to [***] Products, twenty-four (24) months from the Effective Date and (b) other than with respect to [***] Products, five (5) years from the Effective Date, unless, in case of each of the foregoing clauses (a) or (b), (i) extended by mutual agreement of the Parties, or (ii) terminated earlier in accordance with the terms of this

CONFIDENTIAL TREATMENT REQUESTED

Agreement; provided that if at the expiration of the foregoing period, an Option Negotiation Period is then ongoing, the Collaboration Term with respect to such Option Product will automatically extend until the earlier of (A) expiration of such Option Negotiation Period or (B) execution of the applicable Option Product License Agreement.

- 1.28 "Combination Product" means a Product that is comprised of or contains a Compound as an active ingredient together with one (1) or more other active ingredients and is sold by a Party, or any of its Affiliates or sublicensees, either as a fixed dose or as separate doses as one (1) product.
- 1.29 "Commercialization" means all activities undertaken in support of the promotion, marketing, sale and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering the applicable Product to customers) of the applicable Product, including Manufacturing Product for commercial sale, sales force efforts, detailing, advertising, marketing, the creation and approval of Promotional Materials, sales and distribution, pricing, customer and government contracting, and medical affairs, including medical education, medical information, clinical science liaison activities, health economics and outcomes research, publications and investigator initiated research studies. "Commercialize" means to engage in Commercialization activities.
- 1.30 "<u>Commercialization Plan</u>" means, as applicable, (a) a plan prepared by Ultragenyx pursuant to Section 5.3 containing an overview of the general strategy and a high-level budget for the promoting and marketing of the Licensed Products in the Ultragenyx Field in the Territory or (b) a plan prepared by Takeda pursuant to Section 5.3 containing an overview of the general strategy for the promoting and marketing of the Licensed [***] Product in the Takeda Field in the Territory.
- 1.31 "Commercially Reasonable Efforts" means with respect to the efforts to be expended, or considerations to be undertaken, by a Party or its Affiliates with respect to any objective, activity or decision to be undertaken under this Agreement with respect to the Compounds or Products, the commercially reasonable efforts, expertise, and resources commonly used by such Party for a product owned by it or to which it has exclusive rights in the applicable territory, which, as compared with a Product, is of similar market potential, at a similar stage in its development or product life, and involves similar risks, all as measured based upon the facts and circumstances at the time such efforts are due, taking into account issues of: efficacy and safety, the competitiveness of alternative products sold by Third Parties, the product profile (including Labeling), the proprietary protection and regulatory exclusivity, the expected and actual profitability and return on investment, and all other similar relevant factors.
- 1.32 "Committee" has the meaning set forth in Section 2.3(a).
- 1.33 "Common Stock Purchase Agreement" means the common stock purchase agreement entered into on even date hereof by and between Ultragenyx and Takeda (or one of its Affiliates) providing for Takeda's (or one of its Affiliate's) purchase of common stock of Ultragenyx.

5

CONFIDENTIAL TREATMENT REQUESTED

- 1.34 "Competing Product" means [***].
- 1.35 "Compound" means the Licensed [***] Compound, a Licensed Analog Compound, [***] Compound, Candidate Product or Ultragenyx Pipeline Compound, as applicable.
- 1.36 "Confidential Information" means all non-public or proprietary Information disclosed by a Party to the other Party under this Agreement, which may include ideas, inventions, discoveries, concepts, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, inventories, machines, techniques, development and commercialization plans and related information, designs, drawings, computer programs, skill, experience, documents, apparatus, results, clinical and regulatory strategies, regulatory documentation, information and submissions pertaining to, or made in association with, filings with any Regulatory Authority, data, including pharmacological, toxicological and clinical data, analytical and quality control data, manufacturing data and descriptions, Patent and legal data, 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, without regard as to whether any of the foregoing is marked "confidential" or "proprietary," or disclosed in oral, written, graphic, or electronic form. Confidential Information shall include: (a) the terms and conditions of this Agreement; and (b) Confidential Information disclosed by either Party pursuant to the Confidentiality Agreement.
- 1.37 "Confidentiality Agreement" means the Mutual Confidential Disclosure Agreement dated March 13, 2015 by and between Takeda Pharmaceuticals International, Inc. and Ultragenyx Pharmaceutical Inc.
- 1.38 "Control" means, with respect to any Information, Patent, trademark or other intellectual property right, ownership or possession by a Party, including its Affiliates, of the ability (without taking into account any rights granted by one Party to the other Party under the terms of this Agreement) to grant access, a license or a sublicense to such Information, Patent, trademark or other intellectual property right without violating the terms of any agreement or other arrangement with, or necessitating the consent of, any Third Party, at such time that the Party would be first required under this Agreement to grant the other Party such access, license or sublicense.
- 1.39 "<u>Cover</u>", "<u>Covering</u>" or "<u>Covered</u>" means, with respect to a product, technology, process or method, that, in the absence of ownership of or a license granted under a Valid Claim, the practice or Exploitation of such product, technology, process or method would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).
- 1.40 "Cure Period" has the meaning set forth in Section 15.2(a).
- 1.41 "<u>Data Package</u>" means the Final [***] Data Package, Final Phase II Data Package or Final Phase III Data Package, as applicable.

CONFIDENTIAL TREATMENT REQUESTED

- 1.42 "<u>Development</u>" means all non-clinical and clinical drug development activities, including toxicology, pharmacology, and other non-clinical efforts, statistical analysis, the performance of Clinical Trials, including the Manufacturing of the applicable Product for use in the Clinical Trials, or other activities necessary to obtain or maintain, Regulatory Approval of the applicable Products. "Development" shall exclude Commercialization activities. When used as a verb, "<u>Develop</u>" means to engage in Development activities.
- 1.43 "<u>Disclosing Party</u>" has the meaning set forth in Section 14.1.
- 1.44 "<u>Dispute</u>" has the meaning set forth in Section 16.1.
- 1.45 "Effective Date" means the date this Agreement becomes effective, as determined in accordance with Section 18.1.
- 1.46 "EMA" means the European Medicines Agency or any successor agency or authority having substantially the same function.
- 1.47 "<u>EU</u>" means all of the European Union member states as of the applicable time during the Term.
- 1.48 "Execution Date" has the meaning set forth in the preamble.
- 1.49 "Exercised Countries" has the meaning set forth in Section 8.2(c).
- 1.50 "Exercised Product License Agreement" has the meaning set forth in Section 8.2(d).
- 1.51 "Exercised Products" has the meaning set forth in Section 8.2(c).
- 1.52 "Expert" means a disinterested, conflict-of-interest-free individual who is neutral and independent of both Parties and all of their respective Affiliates and sublicensees and who, with respect to a dispute concerning a financial, commercial, scientific or regulatory matter, possesses appropriate expertise to resolve such dispute. Neither the Expert (nor any of the Expert's current or former employers) shall be or have been at any time, to the Knowledge of the Parties, an employee, officer, director or, during the previous five (5) years, a consultant or contractor of either Party or any of its Affiliates.
- 1.53 "Exploit" or "Exploitation" means to research, import, Manufacture, have Manufactured, export distribute, use, have used, sell, have sold, or offer for sale, including to Develop, Commercialize, register, modify, enhance, improve or otherwise dispose of.
- 1.54 "FDA" means the U.S. Food and Drug Administration, or any successor agency thereto.
- 1.55 "Final [***] Data Package" means all information the Parties agree that Ultragenyx shall provide to or give access to Takeda at the conclusion of the activities contemplated under the Initial [***] Development Plan for a given Licensed [***] Product as it relates to the Takeda Field, but which will include at a minimum (a) validated and reproducible tables, listings and graphs, (b) all adverse event listings, safety narratives, CMC data and information, and applicable

CONFIDENTIAL TREATMENT REQUESTED

Regulatory Documentation, (c) preclinical study results and final, if possible, or preliminary toxicology and pharmacology reports, and (d) a preliminary Phase I report and all Phase I clinical data.

- 1.56 "Final Phase II Data Package" means on a Product-by-Product basis, all Information the Parties agree that Ultragenyx shall provide to or give access to Takeda at the conclusion of a Phase II Clinical Trial and after database lock, but which will include at a minimum (a) validated and reproducible tables, listings and graphs, (b) all adverse event listings, safety narratives, CMC data and information, and applicable Regulatory Documentation, (c) final, if possible, or preliminary toxicology and pharmacology reports, (d) the Phase I final report and all Phase I clinical data, and (e) a preliminary Phase II report and all Phase II clinical data.
- 1.57 "Final Phase III Data Package" means, on a Product-by-Product basis, all Information the Parties agree that Ultragenyx shall provide to or give access to Takeda at the conclusion of a Phase III Clinical Trial and after database lock, but which will include at a minimum (a) validated and reproducible tables, listings and graphs, (b) all adverse event listings, material safety narratives, CMC data and information, and applicable Regulatory Documentation, (c) final, if possible, or preliminary toxicology and pharmacology reports, (d) the Phase I final report and all Phase I clinical data to the extent not previously provided to Takeda, (e) the Phase II final report and all Phase II clinical data to the extent not previously provided to Takeda, and (f) the preliminary Phase III report and all Phase III clinical data.
- 1.58 "<u>Finished Product</u>" means Bulk Drug Product that has been Packaged into a form suitable for use in Clinical Trials or for Commercial purposes (i.e., bottles or blisters), including samples, in accordance with Applicable Laws.
- 1.59 "First Commercial Sale" means, on a country-by-country basis, the first sale of a Product under this Agreement by a Party, its Affiliates or its sublicensees to an end user or prescriber for use, consumption or resale of the Product in a country in the applicable territory in the applicable field where Regulatory Approval of the Product has been obtained and where the sale results in a recordable Net Sale. Sale of a Product under this Agreement by a Party to an Affiliate or a sublicensee of such Party shall not constitute a First Commercial Sale unless such Affiliate or such sublicensee is the end user of such Product. Also, sale of a Product under this Agreement by a Party, its Affiliates or its sublicensees in a jurisdiction where Regulatory Approval for that Product has not yet been attained shall not constitute a First Commercial Sale under this Agreement.
- 1.60 <u>Force Majeure</u>" means any event beyond the reasonable control of the affected Party including: embargoes; war or acts of war, including terrorism; insurrections, riots, or civil unrest; strikes, lockouts or other labor disturbances; epidemics, fire, floods, earthquakes or other acts of nature; or acts, omissions or delays in acting by any governmental authority (including the refusal of the competent government agencies to issue required Regulatory Approvals due to reasons other than the affected Party's negligence or willful misconduct or any other cause within the reasonable control of the affected Party), and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence

8

CONFIDENTIAL TREATMENT REQUESTED

that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances).

- 1.61 "FTE" means eighteen hundred (1800) hours of work per full Calendar Year (or equivalent pro-rata portion thereof for a period less than twelve (12) months) devoted to or in support of the Development of the applicable Products in accordance with the Research Plans or the Manufacturing of a Product or the provision of Research Support (but excluding, for clarity, time spent travelling to and attending meetings under this Agreement and scientific and medical conferences), that is carried out by one or more qualified scientific or technical employees or contract personnel of Takeda or its Affiliates, as such hours are measured in accordance with Takeda's normal time allocation practices. For the avoidance of doubt, FTE only applies to employees of a Party, and does not apply to contractors of Takeda.
- 1.62 "FTE Cost" means, for any period, the FTE Rate multiplied by the number of FTEs in such period.
- 1.63 "FTE Rate" means a rate of [***] per FTE per Calendar Year (pro-rated for the period beginning on the Effective Date and ending at the end of the first Calendar Year) for personnel engaged in Development activities. Such rate shall be adjusted annually, with each annual adjustment effective as of January 1 of each calendar year (with the first such annual adjustment to be made as of January 1, 2018) to correspond with the total percentage change in the Consumer Price Index for All Urban Consumers (CPI-U) for the U.S. City Average, 1982-84 = 100, calculated by the U.S. Bureau of Labor Statistics over the twelve (12)-month period preceding each such January 1.
- 1.64 "<u>GAAP</u>" means generally accepted accounting principles current in the U.S.
- 1.65 "Generic Competition Percentage" means, with respect to any Product in a given country in the Territory or Takeda Territory (as applicable), all units of the Generic Product(s) for such Product, sold in the aggregate in such country divided by the sum of: (a) all units of the Product sold in such country, and (b) all units of the Generic Product(s) sold in the aggregate in such country, where, in each case, the number of units of a Product and each Generic Product sold shall be based on the average of the monthly IMS data (or IMS-equivalent data if IMS data are not available).
- 1.66 "Generic Product" means, on a Product-by-Product and country-by-country basis, any pharmaceutical product sold by a Third Party, other than as a sublicensee to this Agreement that:
- (a) contains the same active ingredients as the applicable Product, in the same dosage form (e.g., oral) as the applicable Product; or (b) is A/B Rated with respect to such Product or otherwise approved by the Regulatory Authority in such country as a substitutable generic for such Product; or (c) is approved in the applicable field by a Regulatory Authority pursuant to an NDA filed by a Third Party under Section 505(b)(2) or 505(j)(2) of the FFDCA (or an equivalent Regulatory Approval Application filed outside the U.S.), contains the active ingredients in the Product, and relies on the finding of safety and/or effectiveness in the Regulatory Approval of the Product. For the purposes of this definition, "A/B Rated" means, inside the U.S., "therapeutically equivalent" as determined by the FDA, applying the definition of

9

CONFIDENTIAL TREATMENT REQUESTED

"therapeutically equivalent" set forth in the preface to the then-current edition of the FDA publication "Approved Drug Products With Therapeutic Equivalence Evaluations and, outside the U.S., such equivalent determination by the applicable Regulatory Authorities as is necessary to permit pharmacists or other individuals authorized to dispense pharmaceuticals under Applicable Law to substitute one product for another product in the absence of specific instruction from a physician or other authorized prescriber under Applicable Law."

- 1.67 "Good Clinical Practices", "GCP" or "cGCP" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines adopted by the International Conference on Harmonization ("ICH"), titled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," (or any successor document) including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time.
- 1.68 "Good Laboratory Practices", "GLP", or "cGLP" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in 21 C.F.R. Part 58 (or any successor statute or regulation), including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable guidelines promulgated under the ICH.
- 1.69 "Good Manufacturing Practices", "GMP", or "cGMP" means the then-current good manufacturing practices required by the FDA, as set forth in the FFDCA, as amended, and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable Applicable Law related to the manufacture and testing of pharmaceutical materials in jurisdictions outside the U.S., including the quality guideline promulgated by the ICH designated ICH Q7A, titled "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients" and the regulations promulgated thereunder, in each case as they may be updated from time to time.
- 1.70 "Governmental Authority" means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).
- 1.71 "Hatch-Waxman Act" means the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. 355, as amended
- 1.72 "House Mark" means the trademark that a Party uses to identify its commercial operations.
- 1.73 "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules promulgated thereunder.
- 1.74 "HSR Conditions" means the following conditions, collectively: (a) the waiting period under the HSR Act shall have expired or earlier been terminated; (b) no injunction (whether

10

CONFIDENTIAL TREATMENT REQUESTED

temporary, preliminary or permanent) prohibiting consummation of the transaction contemplated by this Agreement or any material portion hereof shall be in effect; (c) no judicial or administrative proceeding opposing consummation of all or any part of this Agreement shall be pending; and (d) no requirements or conditions shall have been imposed by the United States Department of Justice or Federal Trade Commission (as applicable) in connection with the filings by the Parties under the HSR Act, other than requirements or conditions that are satisfactory to the Party on whom such requirements or conditions are imposed.

- 1.75 "HSR Filing" means filings with the United States Federal Trade Commission and the Antitrust Division of the United States 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 subject matter of this Agreement, together with all required documentary attachments thereto.
- 1.76 "<u>IFRS</u>" means the International Financial Reporting Standards as promulgated by the International Standards Accounting Board and as they may be updated for time to time.
- 1.77 "IND" means an Investigational New Drug application as defined in the FFDCA, as amended, and applicable regulations promulgated hereunder by the FDA, or a clinical trial authorization application for a product filed with a Regulatory Authority in any other regulatory jurisdiction outside the U.S., the filing of which is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.
- 1.78 "IND Date" means the date on which ownership of Product INDs is transferred or a right of reference is granted pursuant to Section 9.2(a)(i), in the case of transfers or grants to Ultragenyx, or pursuant to Section 9.2(b)(i), in the case of transfers to Takeda..
- 1.79 "Indemnifying Party" has the meaning set forth in Section 17.3(a).
- 1.80 "Indemnitee" has the meaning set forth in Section 17.3(a).
- 1.81 "<u>Information</u>" means information, Inventions, discoveries, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, trade secrets, technology, techniques, designs, drawings, correspondence, computer programs, documents, apparatus, results, strategies, regulatory documentation, information and submissions pertaining to, or made in association with, filings with any Regulatory Authority or patent office, data, including pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions, devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable.
- 1.82 "<u>Initial [***] Development Plan</u>" means the plan (including timeline and budget) covering preliminary Development activities to be completed by Ultragenyx and Takeda (to the extent expressly provided in such plan) for a Licensed [***] Product in the Licensed Field attached

11

CONFIDENTIAL TREATMENT REQUESTED

hereto as Exhibit 1.82, as such plan may be amended from time to time pursuant to Section 2.1(a)(v).

- 1.83 "Inventions" means any and all inventions, discoveries and developments, whether or not patentable, made, conceived or reduced to practice in the course of performance of this Agreement, whether made, conceived or reduced to practice solely by, or on behalf of, Takeda, Ultragenyx, the Parties jointly, or any Affiliate of the same.
- 1.84 "Joint Know-How" means all Information included in the Joint Inventions.
- 1.85 "Joint Intellectual Property" means, collectively, Joint Know-How and Joint Patents.
- 1.86 "Joint Invention" has the meaning set forth in Section 12.1(b).
- 1.87 "Joint Patents" has the meaning set forth in Section 12.3(c).
- 1.88 "Joint Research Committee" or "JRC" has the meaning set forth in Section 2.2(a).
- 1.89 "Joint Steering Committee" or "JSC" has the meaning set forth in Section 2.1(a).
- 1.90 "Knowledge" means, as applied to a Party, that such Party shall be deemed to have knowledge of a particular fact or other matter to the extent that a person within the Knowledge Group knew of such fact or other matter.
- 1.91 "Knowledge Group" means, with respect to each Party, the individuals holding the positions listed on Exhibit 1.91; provided that if one or more of the individuals listed on Exhibit
- 1.191 no longer holds the same position or title set forth opposite his/her name, (a) such person shall continue to be considered part of the Knowledge Group, and (b) his/her replacement shall also be considered part of the Knowledge Group.
- 1.92 "<u>Labeling</u>" means the healthcare professional information or patient information used in the Territory that is part of the Product Regulatory Approval including the package insert, medication guides, company core safety information (CCSI) and company core data sheet (CCDS).
- 1.93 "<u>Lead Regulatory Party</u>" has the meaning set forth in Section 9.1.
- 1.94 "Licensed [***] Compound" means [***] as further described on, and with the chemical structure set forth in, Exhibit 1.94.
- 1.95 "<u>Licensed [***] Know-How</u>" means Information related to the (a) Licensed [***] Compound, Controlled by Takeda as of the Execution Date or during the Term, and/or (b) Licensed Analog Compound specified in the Agreement Controlled by Takeda as of the Execution Date, in each case including data, reports, and materials related to preclinical studies, regulatory filings/correspondence, and chemistry, manufacturing and controls and necessary or

12

CONFIDENTIAL TREATMENT REQUESTED

reasonably useful for the Exploitation of a Licensed [***] Compound or a Licensed Analog Compound.

- 1.96 "<u>Licensed [***] Patent</u>" means the Patent that is Controlled by Takeda as of the Execution Date identified as the Licensed [***] Patent on <u>Exhibit 1.168</u>, and all Patents Controlled by Takeda during the Term that claim priority to such Patent.
- 1.97 "<u>Licensed [***] Product</u>" means any pharmaceutical product that contains the Licensed [***] Compound, including all forms, presentations, strengths, doses and formulations (including any method of delivery).
- 1.98 "Licensed [***] Technology" means the Licensed [***] Patent and Licensed [***] Know-How.
- 1.99 "<u>Licensed Analog Compounds</u>" means (a) the compounds with the chemical structures listed on <u>Exhibit 1.99</u> and (b) any structures defined by [***] where approved by the JSC pursuant to Section 2.1(a)(iii)) [***], that are disclosed in the Licensed [***] Patent and that are developed pursuant to, and as specified in, a mutually agreed research plan conducted by Ultragenyx involving modifications to such structures. <u>Exhibit 1.99</u> shall be updated from time to time to include those chemical structures described in the foregoing subclause (b).
- 1.100 "<u>Licensed Analog Product</u>" means any pharmaceutical product that contains a Licensed Analog Compound, including all forms, presentations, strengths, doses and formulations (including any method of delivery).
- 1.101 "Licensed Field" means [***].
- 1.102 "<u>Licensed Option Product</u>" means any Option Product for which the Parties have executed an Option Product License Agreement.
- 1.103 "<u>Licensed Product</u>" means the Licensed [***] Products and Licensed Analog Products, as applicable.
- 1.104 "<u>Licensed Product Improvement</u>" means any Invention related to the Licensed [***] Compound, Licensed Analog Compounds, or Licensed Products made (a) solely by, or on behalf of, Ultragenyx or its Affiliates or sublicensees under this Agreement or (b) solely by Takeda or its Affiliates under this Agreement. For clarity, (i) employees of Ultragenyx or its Affiliates or sublicensees, or their respective agents or independent contractors receiving consideration from Ultragenyx or its Affiliates or sublicensees in the course of conducting activities under this Agreement, shall be considered "solely by, or on behalf of" pursuant to this Section 1.104, and
- (ii) neither Takeda nor any of its Affiliates shall, under any circumstances under this Agreement, be considered an agent or independent contractor of Ultragenyx or any of its Affiliates or sublicensees for purposes of this Section 1.104.

13

CONFIDENTIAL TREATMENT REQUESTED

- 1.105 "<u>Licensed Product Improvement Patents</u>" means Patents that Cover Licensed Product Improvements that do not claim priority (in accordance with Section 1.129) to the Licensed [***] Patent.
- 1.106 "<u>Licensed Product Royalty Term</u>" means, on a country-by-country and Licensed Product by-Licensed Product basis, the period commencing on the First Commercial Sale of such Licensed Product in such country in the Territory and ending upon the later of (a) ten (10) years after First Commercial Sale of such Licensed Product in such country, (b) the expiration in such country of the last Valid Claim from the Licensed [***] Patent that Covers the composition, or method of making or using, such Licensed Product, or (c) the expiration of the applicable Regulatory Exclusivity of a Licensed Product.
- 1.107 "<u>Listed Compounds</u>" has the meaning set forth in Section 6.1.
- 1.108 "Loss" has the meaning set forth in Section 17.1.
- 1.109 "<u>Marketing Authorization Application</u>" or "<u>MAA</u>" means an application for Regulatory Approval (but excluding Pricing Approval) in any particular jurisdiction other than the U.S.
- 1.110 "Manufacture" means all activities related to the manufacturing of a Finished Product or Bulk Drug Product, including the manufacture of any ingredient used therein, for Development or Commercialization in the Territory, packaging, in-process and Product testing, validation, release of Product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of Product, ongoing stability tests, Packaging of Bulk Drug Product into Finished Product and regulatory activities related to any of the foregoing.
- 1.111 "NDA" means a New Drug Application or supplemental New Drug Application as contemplated by Section 505(b) of the FFDCA, as amended, and the regulations promulgated thereunder, submitted to the FDA pursuant to Part 314 of Title 21 of the U.S. Code of Federal Regulations, including any amendments thereto.
- 1.112 "Net Sales" means, with respect to any Product and calculated in accordance with Accounting Standards consistently applied across Products, the gross revenue recognized by a Party, its Affiliates and sublicensees for sales of such Product to Third Parties, less the following deductions, to the extent such deductions are paid, incurred or otherwise taken, reasonable and customary, provided to Third Parties, and actually allowed with respect to such sales:
- (a) reasonable cash, trade or quantity discounts, charge-back payments, and rebates actually granted to trade customers, managed health care organizations, pharmaceutical benefit managers, group purchasing organizations and national, state, or local government; and
- (b) credits, rebates or allowances actually allowed upon prompt payment or on account of claims, damaged goods, rejections or returns of such Product, including in connection with recalls, and the actual amount of any write-offs for bad debt (not to exceed one percent (1%)) (provided that an amount subsequently recovered will be treated as Net Sales)

CONFIDENTIAL TREATMENT REQUESTED

	inventory management fees and costs of freight, carrier insurance, and other transportation charges directly Product; and
	taxes, duties or other governmental charges (including (i) any tax such as a value added or similar tax, other and (ii) any payments made to the Pharmaceutical and Medical Device Agency (" <i>Kiko</i> ") based on Section 19 icals and Medical Devices Agency (Act No.192 of 2002)") directly levied on or measured by the billing amount rebates and refunds.
Notwithstanding the foregoing	mounts received or invoiced by a Party, its Affiliates or sublicances for the sale of such Product among a Party

Notwithstanding the foregoing, amounts received or invoiced by a Party, its Affiliates or sublicensees for the sale of such Product among a Party, its Affiliates or sublicensees for resale shall not be included in the computation of Net Sales hereunder. In any event, any amounts received or invoiced by a Party, its Affiliates and sublicensees shall be accounted for only once. For purposes of determining Net Sales, a Product shall be deemed to be sold when the revenue generated from such sale is recognized in accordance with the Accounting Standards. Each Party shall record such Net Sales as the "principal" and not the "agent" as defined under the Accounting Standards. For clarity, a particular deduction may only be accounted for once in the calculation of Net Sales and no deductions may be made for the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended). Net Sales shall exclude any samples of a Product transferred or disposed of at no cost for promotional, Development or educational purposes.

The Net Sales of any Combination Product:

- (i) for which the Product(s) and other active ingredient(s) of such Combination Product are sold separately by a Party, or any of its Affiliates or sublicensees, in such country, then Net Sales for such Combination Product in such country shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/(A+B), where A is the average Net Sales price of the Product as the only active ingredient(s), as sold separately by a Party or any of its Affiliates or sublicensees in such country, and B is the average net sales (calculated in a manner analogous to the manner in which Net Sales are calculated as set forth above) price of the other active ingredient(s) in the Combination Product as sold separately by a Party or any of its Affiliates or sublicensees in such country;
- (ii) for which the (A) Licensed Product of such Combination Product is/are sold separately by a Party or any of its Affiliates or sublicensees in such country and (B) the other active ingredient(s) in the Combination Product is/are not sold separately by a Party or any of its Affiliates or sublicensees in such country, then Net Sales for such Combination Product in such country shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/D, where A is the average Net Sales price of the Licensed Product as the only active ingredient(s), as sold separately by a Party or any of its Affiliates or sublicensees in such country, and D is the average Net Sales price of the Combination Product as sold separately by a Party or any of its Affiliates or sublicensees in such country; and
- (iii) for which neither clause (i) nor clause (ii) above is applicable, the Parties shall determine Net Sales for such Combination Product in such country by mutual agreement

15

CONFIDENTIAL TREATMENT REQUESTED

based on	the	relative	contribution	of the	Licensed	Product	and	the o	other	active	ingredient((s)	in the	Combinat	ion Prod	luct.

- 1.113 "Neutral Expert" has the meaning set forth in Section 16.3(a).
- 1.114 "Non-breaching Party" has the meaning set forth in Section 15.2(a).
- 1.115 "Notice Date" has the meaning set forth in Section 16.3(a).
- 1.116 "Option Negotiation Period" has the meaning set forth in Section 6.12(a).
- 1.117 "Option Notice" has the meaning set forth in Section 6.12(a).
- 1.118 "Option Product" means (a) a Candidate Product selected pursuant to Section 6.10 or (b) a [***] Product, as applicable.
- 1.119 "Option Product Improvements" means any Invention related to a [***] Product or another Research Product made (a) solely by, or on behalf of, Ultragenyx or its Affiliates or sublicensees under this Agreement, or (b) solely by Takeda or its Affiliates under this Agreement. For clarity,
- (i) employees of Ultragenyx or its Affiliates or sublicensees, or their respective agents or independent contractors receiving consideration from Ultragenyx or its Affiliates or sublicensees in the course of conducting activities under this Agreement, shall be considered "solely by, or on behalf of" pursuant to this Section 1.119, and (ii) neither Takeda nor any of its Affiliates shall, under any circumstances under this Agreement, be considered an agent or independent contractor of Ultragenyx or any of its Affiliates or sublicensees for purposes of this Section 1.119.
- 1.120 "Option Product Improvement Patents" means Patents Covering Option Product Improvements.
- 1.121 "Option Product Key Terms" has the meaning set forth in Section 6.10(a).
- 1.122 "Option Product Know-How" means all Information Controlled by Takeda as of the Execution Date and during the Term that is necessary or reasonably useful for, as applicable, (a) Ultragenyx to evaluate whether to exercise the Ultragenyx Option or (b) Ultragenyx to Exploit an Option Product solely in accordance with the activities to be performed by Ultragenyx or its Affiliates or sublicensees under the Option Product Research Plan.
- 1.123 "Option Product License Agreement" has the meaning set forth in Section 6.12(a).
- 1.124 "Option Product Patents" means all Patents Controlled by Takeda as of the Execution Date and during the Term that are necessary or reasonably useful for the Exploitation of the Option Product(s) in the Ultragenyx Field in the Territory.
- 1.125 "Option Product Research Plan" has the meaning set forth in Section 6.10(a).
- 1.126 "Option Product Technology" means the Option Product Patents and Option Product Know-How.

CONFIDENTIAL TREATMENT REQUESTED

- 1.127 "Packaging" means all activities related to the preparation of Bulk Drug Product into Finished Product, including application of the approved Labeling. "Packaged" means that Bulk Drug Product has been subject to complete Packaging.
- 1.128 "Party" has the meaning set forth in the preamble.
- 1.129 "Patents" means all patents, including any utility or design patent, and all applications thereof, including any provisional application, whether in the Territory or any other jurisdiction; any other patent or patent application claiming priority to (a) any such specified patent or patent application or (b) any patent or patent application from which such specified patent or patent application claim priority; and (c) all divisionals, continuations, continuations in-part, registrations, reissues, re-examinations, renewals, supplemental protection certificates, or extensions of (a) or (b).
- 1.130 "Patent Term Extension" means any term extensions, supplementary protection certificates and equivalents thereof offering Patent protection beyond the initial term with respect to any issued Patents.
- 1.131 "Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.
- 1.132 "Phase I Trial" means a clinical trial of a Product with the endpoint of determining initial tolerance, safety, pharmacokinetic or pharmacodynamic information in single dose, single ascending dose, multiple dose and/or multiple ascending dose regimens.
- 1.133 "Phase II Trial" means a clinical trial of a Product on patients, including possibly pharmacokinetic, pharmacodynamic and doseranging studies, the principal purposes of which are to make a preliminary determination that such product is safe for its intended use and to obtain sufficient information about such product's efficacy or dose-response information to permit the design of further clinical trials.
- 1.134 "Phase III Trial" means a pivotal clinical trial of a Product on a sufficient number of patients, which trial is designed to (a) establish that a product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed; and (c) pivotal to support submission of a Regulatory Approval Application for such product.
- 1.135 "Phase IV Trial" means a clinical trial of a Product, including pharmacokinetic studies, which trial (a) is not required in order to obtain Regulatory Approval of an indication; and (b) either (i) is required by the Regulatory Authority as mandatory to be conducted on or after the Regulatory Approval of an indication, or (ii) is conducted voluntarily to enhance marketing or scientific knowledge of the product (e.g., providing additional drug profile, outcomes research, safety data or marketing support information, or supporting expansion of product labeling).

CONFIDENTIAL TREATMENT REQUESTED

- 1.136 "PMDA" means Japan's Pharmaceuticals and Medical Devices Agency and any successor agency(ies) or authority having substantially the same function.
- 1.137 "<u>Preexisting Third Party IP</u>" means those intellectual property rights owned or controlled by Third Parties as of the Execution Date that are necessary or reasonably useful for the Exploitation of Licensed Products and which are set forth in <u>Exhibit 1.137</u>.
- 1.138 "Pricing Approval" means governmental approval, agreement, determination or decision establishing prices that can be charged and/or reimbursed for a Product in a jurisdiction where the applicable Governmental Authority or Regulatory Authority approves or determines the pricing of pharmaceutical products.
- 1.139 "Product" means any Licensed [***] Product, Licensed Analog Product, Licensed Option Product or Ultragenyx Pipeline Product, as applicable.
- 1.140 "<u>Product Complaint</u>" means all data, which come to the attention of either Party, its Affiliates or its sub-licensees, concerning any dissatisfaction regarding a Product of such a nature and magnitude that it is required under Applicable Laws to be collected, maintained and reported to a Regulatory Authority, including reports of actual or suspected product tampering, contamination, mislabeling or inclusion of improper ingredients.
- 1.141 "<u>Product IND</u>" means any IND filed in the Territory related to a Product, whether in existence as of the Effective Date or filed with the FDA during the Term, including any supplements or amendments thereto. The Product INDs as of the Execution Date are set forth on Exhibit 1.141.
- 1.142 "Product Liabilities" means all losses, damages, fees, costs and other liabilities incurred by a Party, its Affiliate or its sublicensee and resulting from or relating to the any use of a Compound and/or a Product in a human (including in Clinical Trials and/or pursuant to Commercialization) in the Territory, other than any losses, damages, fees, costs and other liabilities that are a result of a Party's, its Affiliates' or its sublicensee's negligence, willful misconduct or breach of such Party's representations and warranties made hereunder. For the avoidance of doubt, Product Liabilities include, reasonable attorneys' and experts' fees and costs relating to any claim or potential claim against a Party, its Affiliate, or its sublicensee and all losses, damages, fees, costs. Product Liabilities shall not include liabilities associated with recalls and/or the voluntary or involuntary withdrawal of the Compound and/or a Product.
- 1.143 "<u>Promotional Materials</u>" means all written, printed, graphic, electronic, audio or video presentations of information, including journal advertisements, sales visual aids, formulary binders, reprints, direct mail, direct-to-consumer advertising, disease awareness materials, internet postings, broadcast advertisements and sales reminder aides (for example, note pads, pens and other such items, if appropriate) intended for use or used by or on behalf of a Party, its Affiliates or its sublicensees in connection with the Commercialization of a Product in the Territory.

- 1.144 "<u>Product Regulatory Approval</u>" means any Regulatory Documentation filed in the Territory which is related to a Product in the Licensed Field, whether in existence as of the Effective Date or filed with the applicable Regulatory Authority during the Term, including any supplements or amendments thereto.
- 1.145 "Product Trademarks" has the meaning set forth in Section 5.5(a).
- 1.146 "PVA" has the meaning set forth in Section 9.8(a)(i).
- 1.147 "Receiving Party" has the meaning set forth in Section 14.1.
- 1.148 "<u>Regulatory Approval</u>" means any approval or authorization, including Pricing Approvals, of any Regulatory Authority that is necessary for the Manufacture, use, storage, import, transport and/or sale of a Product in accordance with Applicable Laws.
- 1.149 "Regulatory Approval Application" means an NDA or BLA, or any corresponding application for Regulatory Approval in the Territory, including: (a) with respect to the European Union, an MAA filed with the EMA pursuant to the Centralized Approval Procedure or with the applicable Regulatory Authority of a country in Europe with respect to the decentralized procedure, mutual recognition or any national approval procedure; and (b) an MAA filed with the PMDA, including, in each case, all supplements, amendments, variations, extensions and renewals thereof.
- 1.150 "Regulatory Authority" means any applicable Governmental Authority involved in granting Regulatory Approval in a country or jurisdiction in the Territory, including in the U.S., the FDA and any other applicable Governmental Authority in the U.S. having jurisdiction over a Product; in the EU, the EMA or any competent Government Authority in the EU; in Japan, the PMDA; and any other applicable Governmental Authority having jurisdiction over a Product.
- 1.151 "Regulatory Documentation" means, with respect to each Research Product or Licensed Product, all: (a) Regulatory Materials, including all data contained therein and all supporting documents created for, submitted to or received from an applicable governmental agency or Regulatory Authority relating to such Regulatory Materials; and (b) other documentation or Information Controlled by a Party which is necessary or reasonably useful in order to Exploit such Product in the applicable Field in the Territory, including any registrations and licenses, regulatory drug lists, advertising and promotion documents shared with Regulatory Authorities, adverse event files, complaint files and Manufacturing records.
- 1.152 "Regulatory Exclusivity" means any exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a Product in a country or jurisdiction in the Territory, other than a Patent right, including orphan drug exclusivity, pediatric exclusivity, rights conferred in the U.S. under the Hatch Waxman Act, in the EU under Directive 2001/83/EC, as amended, and Regulation (EC) No. 1901/2006, as amended, or in the Biologics Price Competition Act as set forth in the Patient Protection & Affordable Care Act, or rights similar thereto in other countries or regulatory jurisdictions in the Territory.

CONFIDENTIAL TREATMENT REQUESTED

- 1.153 "Regulatory Materials" means, with respect to each Product, all documentation, correspondence, submissions and notifications submitted to or received from a Regulatory Authority that are necessary or reasonably useful in order to Exploit such Product in the applicable field in the Territory. For the avoidance of doubt, Regulatory Materials shall include, with respect to each Product, all INDs, Regulatory Approval Applications, Regulatory Approvals, Pricing Approvals and amendments and supplements for any of the foregoing, as well as the contents of any minutes from meetings (whether in person or by audio conference or videoconference) with a Regulatory Authority.
- 1.154 "<u>Representative Expert</u>" has the meaning set forth in Section 16.3(b).
- 1.155 "Research Materials" has the meaning set forth in Section 6.6(a).
- 1.156 "Research Plan" means a [***] Research Plan or Option Product Research Plan, as applicable.
- 1.157 "Research Product," means a [***] Product, Candidate Product or Option Product, as applicable.
- 1.158 "Research Support" has the meaning set forth in Section 7.1.
- 1.159 "Senior Officer" means the Head of Research & Development or his or her designee, in the case of Takeda and, the Chief Executive Officer or his or her designee, in the case of Ultragenyx.
- 1.160 "Takeda [***] License" means the licenses granted to Takeda in Section 3.2.
- 1.161 "Takeda Field" means [***].
- 1.162 "<u>Takeda Indemnitee</u>" has the meaning set forth in Section 17.1.
- 1.163 "<u>Takeda Option</u>" has the meaning set forth in Section 8.1.
- 1.164 "<u>Takeda Option Field</u>" means all human indications other than the Takeda Field for Licensed [***] Products, and all human indications for Licensed Analog Products, Licensed Option Products and Ultragenyx Pipeline Products.
- 1.165 "<u>Takeda Option Negotiation Period</u>" has the meaning set forth in Section 8.2(d).
- 1.166 "<u>Takeda Option Notice</u>" has the meaning set forth in Section 8.2(c).
- 1.167 "<u>Takeda Option Term</u>" means the period beginning on the Effective Date and ending on the earlier of (a) [***] after the Effective Date or (b) with respect to a Licensed [***] Product, Licensed Analog Product, Licensed Option Product, or Ultragenyx Pipeline Product, as

CONFIDENTIAL TREATMENT REQUESTED

the case may be: (i) [***] after Takeda's receipt of the applicable Final Phase II Data Package for the applicable Licensed [***] Product, Licensed Analog Product or Licensed Option Product, (ii) [***] after Takeda's receipt of the Final Phase II Data Package (or Final Phase III Data Package in the case of [***]) for the applicable Ultragenyx Pipeline Product (other than [***]) and (iii) [***] after Takeda's receipt of the Final Phase II Data Package for [***]. Notwithstanding the foregoing, (a) in the event of a [***] of Ultragenyx [***], the Takeda Option Term will expire with respect to all applicable products (i.e., any Licensed [***] Product, Licensed Analog Product, Licensed Option Term will expire with respect to all applicable products (i.e., any Licensed [***] Product, Licensed Analog Product, Licensed Option Product, or Ultragenyx Pipeline Product) [***] after the closing of such [***].

- 1.168 "<u>Takeda Patents</u>" means the Licensed [***] Patent and any Patent that claims priority (in accordance with Section 1.129) to the Licensed [***] Patent during the Term, and the Ultragenyx Pipeline Improvement Patents Controlled by Takeda or its Affiliates. The Takeda Patents as of the Execution Date are set forth on Exhibit 1.168.
- 1.169 "Takeda Product Infringement" has the meaning set forth in Section 12.6(b)(i).
- 1.170 "<u>Takeda ROFN Territory</u>" means Japan.
- 1.171 "<u>Takeda Royalty Term</u>" means, on a country-by-country and Exercised Product-by- Exercised Product basis, the period commencing on the First Commercial Sale of such Exercised Product in a country in the Takeda Territory by Takeda, its Affiliates, or sublicensees that occurs after Takeda's exercise of the Takeda Option and ending upon the later of (a) ten (10) years after First Commercial Sale of such Exercised Product, (b) the expiration of the last Valid Claim that Covers the composition, or method of making or using, such Exercised Product and issued from the following, as applicable to the particular Exercised Product: a (i) Licensed [***] Patent, (ii) Option Product Patent that Covers a Licensed Option Product that is subject to an active Option Product License Agreement or (iii) Ultragenyx Pipeline Patent that Covers an Ultragenyx Pipeline Product, or (c) the expiration of the applicable Regulatory Exclusivity for such Exercised Product.
- 1.172 "<u>Takeda Territory</u>" means, (i) with respect to Licensed Products and Licensed Option Products, Japan and Asia and (ii) with respect Ultragenyx Pipeline Products, Japan.
- 1.173 "<u>Tax Conditions</u>" means, with respect to the premium being paid by Takeda to Ultragenyx under the Common Stock Purchase Agreement, Ultragenyx's confirmation of receipt of the tax residence certificate (IRS Form 6166) from the U.S. Internal Revenue Service specified in Section 11.11(c) and appropriate submission of such certificate and required forms and information with the Osaka Regional Taxation Bureau.

21

CONFIDENTIAL TREATMENT REQUESTED

- 1.174 "Term" has the meaning set forth in Section 15.1.
- 1.175 "<u>Terminated Product</u>" means any: (a) Option Product for which an Option Product License Agreement has not been executed during the Option Negotiation Period in accordance with Section 6.12(a); (b) Research Product terminated pursuant to Section 6.7(d) or 18.5; (c) Licensed [***] Compound or Licensed [***] Product that reverts to Takeda pursuant to Section 4.3(f); or (d) Licensed Product or Research Product terminated pursuant to Section 15.2, 15.4 or 15.5.
- 1.176 "<u>Territory</u>" means worldwide.
- 1.177 "Third Party" means a Person other than Takeda and Ultragenyx and their respective Affiliates.
- 1.178 "<u>Ultragenyx [***] Know-How</u>" means all Information related to the Licensed [***] Compound Controlled by Ultragenyx during the Term.
- 1.179 "<u>Ultragenyx</u> [***] <u>License</u>" means the licenses granted to Ultragenyx in Section 3.1.
- 1.180 "<u>Ultragenyx [***] Patents</u>" means all Patents Controlled by Ultragenyx or its Affiliates as of the Execution Date or during the Term that are necessary or reasonably useful for the Exploitation of the Licensed [***] Compound or Licensed Analog Compound in the Licensed Field in the Territory, but expressly excluding any Licensed Product Improvement Patents. The Ultragenyx [***] Patents as of the Execution Date are set forth on <u>Exhibit 1.188</u>.
- 1.181 "<u>Ultragenyx [***] Technology</u>" means the Ultragenyx [***] Patents and Ultragenyx [***] Know-How.
- 1.182 "<u>Ultragenyx Field</u>" means the Licensed Field, excluding the Takeda Field.
- 1.183 "<u>Ultragenyx In-License Agreement</u>" means [***] and (g) any other applicable agreement between Ultragenyx (or its Affiliates) and a Third Party under which Takeda is granted a sublicense or other right under this Agreement.
- 1.184 "<u>Ultragenyx Indemnitee</u>" has the meaning set forth in Section 17.2.
- 1.185 "<u>Ultragenyx Know-How</u>" means all Information Controlled by Ultragenyx during the Term that is necessary or reasonably useful to Exploit a Compound or a Product in the Licensed Field.

CONFIDENTIAL TREATMENT REQUESTED

- 1.186 "<u>Ultragenyx Intellectual Property</u>" means, collectively, Ultragenyx Know-How and Ultragenyx Patents.
- 1.187 "<u>Ultragenyx Option</u>" has the meaning set forth in Section 6.11.
- 1.188 "<u>Ultragenyx Patents</u>" means all Ultragenyx [***] Patents, Licensed Product Improvement Patents Controlled by Ultragenyx or its Affiliates, Option Product Improvement Patents Controlled by Ultragenyx or its Affiliates and Ultragenyx Pipeline Patents. The Ultragenyx Patents as of the Execution Date are set forth on <u>Exhibit 1.188</u>.
- 1.189 "<u>Ultragenyx Pipeline Compound</u>" means the active ingredient in an Ultragenyx Pipeline Product.
- 1.190 "<u>Ultragenyx Pipeline Improvements</u>" means any Invention related to an Ultragenyx Pipeline Product made (a) solely by, or on behalf of, Takeda or its Affiliates or sublicensees under this Agreement or (b) solely by Ultragenyx or its Affiliates under this Agreement. For clarity, (i) employees of Takeda or its Affiliates or sublicensees, or their respective agents or independent contractors receiving consideration from Takeda or its Affiliates or sublicensees in the course of conducting activities under this Agreement, shall be considered "solely by, or on behalf of" pursuant to this Section 1.190, and (ii) neither Ultragenyx nor any of its Affiliates shall, under any circumstances under this Agreement, be considered an agent or independent contractor of Takeda or any of its Affiliates or sublicensees for purposes of this Section 1.190.
- 1.191 "<u>Ultragenyx Pipeline Improvement Patents</u>" means Patents that Cover Ultragenyx Pipeline Improvements.
- 1.192 "<u>Ultragenyx Pipeline Patents</u>" means all Patents Controlled by Ultragenyx as of the Execution Date and during the Term that: (a) claim the composition of matter of, or the method of making or using an Ultragenyx Pipeline Product; or (b) are otherwise necessary or reasonably useful to Exploit an Ultragenyx Pipeline Product in the Licensed Field. The Ultragenyx Pipeline Patents for the Takeda Territory as of the Execution Date are set forth on Exhibit 1.188.
- 1.193 "<u>Ultragenyx Pipeline Products</u>" means all products that have entered into Clinical Trials and are Controlled by Ultragenyx or its Affiliates during the Collaboration Term and that Ultragenyx or its Affiliates have rights to Commercialize in the Takeda ROFN Territory, [***]. For purposes of this Section 1.193, "Controlled" shall not include [***]

CONFIDENTIAL TREATMENT REQUESTED

[***].	
1.194	" <u>Ultragenyx Product Infringement</u> " has the meaning set forth in Section 12.6(b)(i).
1.195	" <u>UX[***</u>]" means the compound having Ultragenyx reference number UX[***] as further described on <u>Exhibit 1.195</u> .
1.196	" $\underline{UX[***]}$ " means the compound having Ultragenyx reference number $\underline{UX[***]}$ as further described on $\underline{Exhibit\ 1.195}$.
1.197	" $\underline{UX[***]}$ " means the compound having Ultragenyx reference number $\underline{UX[***]}$ as further described on $\underline{Exhibit\ 1.195}$.
1.198	" <u>UX[***</u>]" means the compound having Ultragenyx reference number UX[***] as further described on <u>Exhibit 1.195</u> .
1.199	" <u>UX[***</u>]" means the compound having Ultragenyx reference number UX[***] as further described on <u>Exhibit 1.195</u> .
agency of comp	"Valid Claim" means a claim of an issued and unexpired Patent included within the Takeda Patents, the Ultragenyx Patents ents, to the extent such claim has not been revoked, held invalid or unenforceable by a patent office, court or other governmental setent jurisdiction in a final order, from which no further appeal can be taken, and which claim has not been disclaimed, denied e invalid or unenforceable through reissue, re-examination or disclaimer.
1.201	"Validation Research Plan" has the meaning set forth in Section 6.2(b).

"<u>Validation Research Plan</u>" has the meaning set forth in Section 6.2(b).

ARTICLE 2 - OVERVIEW; MANAGEMENT

- 2.1 Joint Steering Committee for Licensed Products.
- Formation and Purpose. Within thirty (30) days after the Effective Date, the Parties shall promptly establish and convene a Joint (a) Steering Committee (the "Joint Steering Committee" or "JSC") in accordance with Section 2.3(c)(i) that will direct and oversee activities relating to the Licensed Products under this Agreement. The JSC shall consist of representatives and operate by the procedures in accordance with Section 2.3. Except as otherwise provided herein, the role of the Joint Steering Committee shall be:
- to encourage and facilitate ongoing communication and cooperation between the Parties with respect to the Exploitation by the Parties of Licensed Products in the Licensed Field;

24

CONFIDENTIAL TREATMENT REQUESTED

(ii) each Party relating to additional compounds Covered b	to serve as a forum for sharing discoveries and exchanging data and results generated by y the Licensed $[***]$ Patent;
(iii) compounds that are Covered by the Licensed [***]	to evaluate and approve the inclusion as Licensed Analog Compounds of additional Patent but that do not meet the definition of Licensed Analog Compounds [***];
(iv) of additional compounds that are Covered by the Lice	to evaluate and approve the exclusion from the definition of Licensed Analog Compounds ensed [***] Patent [***];
(v)	to review and discuss [***] Development Plans and any proposed amendments or revisions

- to the [***] Development Plans;
- (vi) to review and discuss Commercialization Plans including the review and discussion of any amendments to such Commercialization Plans;
- (vii) to review and discuss Licensed Product regulatory issues, including those raised by the joint regulatory affairs working group established pursuant to Section 2.1(a)(viii) and Section 9.4(a);
- (viii) to establish other such working groups or subcommittees, as needed to further the purposes of the Agreement relating to Licensed Products, as mutually agreed by the Parties in writing;
 - (ix) to resolve any disputes referred to the JSC; and
 - (x) to approve or decide such other matters as provided in this Agreement.

(b) JSC Decisions; Final Decision Authority.

- (i) The JSC will make good faith efforts to make all decisions by consensus. Except as set forth in Section 2.1(b)(ii), actions to be taken by the Joint Steering Committee shall be taken only following unanimous vote, with each Party's representatives collectively having one (1) vote. If the Joint Steering Committee fails to reach unanimous agreement on a matter before it for decision for a period in excess of fifteen (15) days from the date first presented to the JSC in writing, either Party may submit such matter for resolution to the Senior Officers of the Parties for attempted resolution by good faith negotiation within thirty (30) days after such notice is received by the Senior Officers.
- (ii) If the Senior Officers of the Parties are unable to resolve such dispute within such thirty (30) day period, such dispute shall be resolved during the Term as follows. For the avoidance of doubt, the right of a Party to make final decisions with respect to any issue

25

CONFIDENTIAL TREATMENT REQUESTED

shall not otherwise diminish or eliminate such Party's obligations under this Agreement, including its obligation to exercise Commercially Reasonable Efforts where required herein.

(A) Subject to Sections 2.1(b)(ii)(D) and 2.1(b)(ii)(E) and provided that such decision does not result in an increase in the scope of work or costs associated with the performance of any activities by Takeda under this Agreement, Ultragenyx will have final decision making authority over [***]; and

(B) Takeda will have final decision making authority over [***].

(C) Takeda will have final decision making authority over [***].

26

CONFIDENTIAL TREATMENT REQUESTED

(D) Option Term for the co-Development and co-Commercializa will have final decision making authority over [***].	If Ultragenyx exercises the [***] Option within the [***] ation of Licensed [***] Products in the Takeda Field in the Territory, Takeda
	If Ultragenyx does not exercise the [***] Option within the rialization of Licensed [***] Products in the Takeda Field in the Territory, (a) rity over [***], and (b) Takeda will continue to have final decision making
(F)	Takeda shall have final decision making authority over [***];
(G) [***].	Ultragenyx shall have final decision making authority over

(iii) Neither Party shall have the final decision making authority for any other matter under the purview of the JSC and not covered by subsections (A)-(G), and the status quo shall persist with respect to such matter if the Parties are unable to agree. For clarity, the Parties anticipate that Licensed Option Products and Exercised Products will be governed by separate committees and final decision making authority to be established pursuant to the applicable Option Product License Agreement or Exercised Product License Agreement, respectively.

Discontinuation of JSC. Upon the second (2nd) anniversary of the Effective Date or any time thereafter, Ultragenyx shall have the right, upon written notice to Takeda, to

27

discontinue its participation in the JSC. Once Ultragenyx has provided such notice to Takeda, the JSC shall have no further obligations under this Agreement and, thereafter, Takeda shall have final decision making authority with respect to the topics that were otherwise determined by the JSC, subject to the other terms and conditions of this Agreement.

2.2 Joint Research Committee for Collaboration Activities.

(a) Formation and Purpose. Within thirty (30) days after the Effective Date, the Parties shall promptly establish and convene a Joint Research Committee (the "Joint Research Committee" or "JRC") in accordance with Section 2.3(c)(i) for the overall coordination and oversight of the Collaboration Activities. The JRC shall consist of representatives and operate by the procedures in accordance with Section 2.3. Except as otherwise provided herein, the Joint Research Committee shall be responsible for supporting the [***] in assessing, prioritizing, and advancing Takeda's rare genetic disease products, including the following specific activities (collectively, "Collaboration Activities"):

(ii) review and approve the Option Product Research Plans and any amendments thereto;

(iii) review and approve any amendments to the [***] Research Plan;

(iv) evaluate and prioritize [***];

(v) support the overall direction of Candidate Product and Option Product strategy;

(vi) identify, define, and support collaborations with key experts and investigators and other third parties in support of the prioritized Candidate Products, Option Products and related indications;

(vii) identify and implement opportunities [***];

(viii) determine the [***]; and

(ix) oversee and manage the secondee program provided for in Section 2.6.

(b) **Termination of Responsibilities.** Upon execution of an Option Product License Agreement for an Option Product, the JRC will no longer have any responsibility over or decision making authority relating to such Option Product.

28

CONFIDENTIAL TREATMENT REQUESTED

(i) The JRC will make good faith efforts to make all decisions by consensus Except as set forth in Section 2.2(c)(ii), actions to be taken by the Joint Research Committee shall be taken only following unanimous vote, with each Party's representatives collectively having one (1) vote. If the Joint Research Committee fails to reach unanimous agreement on a matter before it for decision for a period in excess of fifteen (15) days from the date first presented to the JRC in writing, either Party may submit such matter for resolution to the Senior Officers of the Parties for attempted resolution by good faith negotiation within thirty (30) days after such notice is received among the Senior Officers. (ii) If the Senior Officers of the Parties are unable to resolve such dispute within such thirty (30) day period, such dispute shall be resolved during the Collaboration Term as follows. For the avoidance of doubt, the right of a Party to make final decisions with respect to any issue shall not otherwise diminish or eliminate such Party's obligations under this Agreement, including its obligation to exercise Commercially Reasonable Efforts where required herein.

(A) Ultragenyx will have final decision making authority over [***];

(B) The Parties must mutually agree on the scope of Research

(B) The Parties must mutually agree on the scope of Research Support to be provided by Takeda. If the Parties are unable to unanimously agree on the scope of the Research Support to be provided, then no Research Support shall be provided;

(C) Takeda will have final decision making authority over [***];

(D) Neither Party shall have the final decision making authority for any other matter under the purview of the JRC and not covered by subsections (A)-(C), and the status quo shall persist with respect to such matter if the Parties are unable to agree. For clarity, the Parties anticipate that Licensed Option Products will be governed by a separate committee and final decision making authority to be established pursuant to the Option Product License Agreement.

2.3 Committee Membership and Procedures.

(a) **Membership.** Takeda and Ultragenyx shall each designate an equal number of representatives to serve on the JSC and the JRC (each, a "<u>Committee</u>") by written notices to the other Party. Promptly after the Effective Date, each Party shall designate three (3)

29

CONFIDENTIAL TREATMENT REQUESTED

representatives for the JSC and three (3) representatives for the JRC. Each Committee may elect to vary the number of representatives from time to time during the Term; provided that each Committee shall maintain an equal number of representatives from each Party. Each representative shall have the appropriate level of experience in the subject area of the Committee, and at least one (1) representative shall have sufficient seniority within the applicable Party's organization to have the necessary decision-making authority in order for the Committee to fulfill its responsibilities. Either Party may designate substitutes for its Committee representatives if one (1) or more of such Party's designated representatives is unable to be present at a meeting. From time to time each Party may replace its Committee representatives by written notice to the other Party specifying the prior representative(s) and their replacement(s).

(b) Chairperson. Each Committee will have two chairpersons, one designated by each of the Parties. The chairpersons shall be responsible for calling and convening meetings, but shall have no special authority over the other members of the Committee, and shall have no additional voting rights. The chairpersons (or their designates) shall jointly: (i) prepare and circulate an agenda reasonably in advance of each upcoming meeting; and (ii) prepare and issue minutes of each Committee meeting within thirty (30) days thereafter. Such minutes shall not be finalized until each Committee representative reviews and approves such minutes in writing; provided that any minutes shall be deemed approved unless a member of such Committee objects to the accuracy of such minutes within fifteen (15) days after the circulation of the minutes.

(c) Meetings.

(i) Committee Meetings. Each Committee shall meet at least once each Calendar Quarter. Additional meetings of the Committees may be held with the consent of each Party (such consent not to be unreasonably withheld, conditioned or delayed), as required under this Agreement. In the case of any dispute referred to a Committee, such meeting shall be held within five (5) Business Days following referral to the Committee, or as soon as reasonably possible.

(ii) General Requirements. Meetings of a Committee shall be effective only if a majority of representatives of each Party are present or participating. Other than the initial meeting, which shall be held in person, a Committee may meet either (A) in person at either Party's facilities or at such locations as the Parties may otherwise agree; or (B) by audio or video teleconference. Additional non-members of a Committee having relevant experience may from time to time be invited to participate in a Committee meeting, provided that such participants shall have no voting rights or powers. Non-member participants who are not employees of a Party or its Affiliates shall only be allowed to attend if: (i) the other Party's representatives have consented to the attendance (such consent not to be unreasonably withheld, conditioned or delayed); and (ii) such non-member participant is subject to confidentiality and non-use obligations at least as restrictive as those set forth in this Agreement. Each Party shall be responsible for all of its own expenses incurred in connection with participating in the Committees including all travel and all expenses associated with an initial alliance kick-off meeting. All other expenses incurred by a Committee in furtherance of a meeting, such as expenses associated with off-site meetings, shall be shared equally by the Parties.

30

CONFIDENTIAL TREATMENT REQUESTED

- **Alliance Managers.** Promptly following the Effective Date, each Party shall designate in writing an Alliance Manager to serve as the primary point of contact for the Parties regarding all collaboration and transition activities contemplated under this Agreement. Each Alliance Manager shall facilitate communication and coordination of the Parties' activities under this Agreement relating to the Products and shall plan the Committee meetings. The Alliance Managers shall be allowed to attend Committee meetings as non-voting observers.
- 2.5 **Authority**. The Parties agree that, in voting on matters as described in this ARTICLE 2, it shall be conclusively presumed that unless otherwise explicitly stated, each voting member of a Committee has the authority and approval of such member's respective senior management in casting his or her vote. Each Committee shall have only the powers assigned expressly to it in this ARTICLE 2 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement.
- **Takeda Secondee.** Takeda shall have the right, at its own expense, to place one employee of Takeda or its Affiliates, who is reasonably acceptable to Ultragenyx, as a secondee with Ultragenyx at any time during the Collaboration Term; provided that such secondee shall enter into a confidentiality agreement with Ultragenyx prior to placement. Takeda may, one or more times during the Collaboration Term, substitute such employee with another employee of Takeda or its Affiliates.

ARTICLE 3 - LICENSES FOR [***] AND ANALOGS

- 3.1 **Licenses from Takeda to Ultragenyx.** Subject to the terms and conditions of this Agreement, Takeda hereby grants to Ultragenyx in the Territory during the Term:
- (a) an exclusive (even as to Takeda and its Affiliates, subject to the retention of rights to conduct activities under the [***] Development Plan) license, with the right to grant sublicenses solely in accordance with Section 3.3, under the Licensed [***] Technology, Licensed Product Improvements Controlled by Takeda or its Affiliates, Licensed Product Improvement Patents Controlled by Takeda or its Affiliates, and Joint Intellectual Property to Exploit the Licensed [***] Products in the Ultragenyx Field;
- (b) a co-exclusive license, without the right to grant sublicenses, under the Licensed [***] Technology, Licensed Product Improvements Controlled by Takeda or its Affiliates, Licensed Product Improvement Patents Controlled by Takeda or its Affiliates, and Joint Intellectual Property to conduct activities under the [***] Development Plan in the Takeda Field in the Territory; and
- (c) an exclusive (even as to Takeda and its Affiliates) license, including the right to grant sublicenses solely in accordance with Section 3.3, under the Licensed [***] Technology, Licensed Product Improvements Controlled by Takeda or its Affiliates, Licensed Product Improvement Patents Controlled by Takeda or its Affiliates, and Joint Intellectual Property to Exploit the Licensed Analog Compounds and Licensed Analog Products in the Licensed Field in the Territory; provided, however, that, notwithstanding the licenses granted in this Section 3.1(c), at any time during the Term Ultragenyx shall not, and shall cause its Affiliates not to (i)

31

CONFIDENTIAL TREATMENT REQUESTED

directly or indirectly Exploit any Licensed Analog Product in the Takeda Field or (ii) license, authorize, appoint, or otherwise enable any Third Party to, directly or indirectly, Exploit any Licensed Analog Product in the Takeda Field.

- 3.2 **Licenses from Ultragenyx to Takeda.** Subject to the terms and conditions of this Agreement, Ultragenyx hereby grants to Takeda in the Territory during the Term:
- (a) an exclusive (even as to Ultragenyx and its Affiliates, subject to the retention of rights to conduct activities under the [***] Development Plan) license, with the right to grant sublicenses under multiple tiers solely in accordance with Section 3.3, under the Ultragenyx [***] Technology, Licensed Product Improvements Controlled by Ultragenyx or its Affiliates, Licensed Product Improvement Patents Controlled by Ultragenyx or its Affiliates, and Joint Intellectual Property to (i) Exploit the Licensed [***] Products in the Takeda Field in the Territory, and (ii) Exploit any structures Covered by the Licensed [***] Patent, other than with respect to Licensed Analog Compounds, in the Takeda Field in the Territory.
- (b) a co-exclusive license, without the right to grant sublicenses, under the Ultragenyx [***] Technology, Licensed Product Improvements Controlled by Ultragenyx or its Affiliates, Licensed Product Improvement Patents Controlled by Ultragenyx or its Affiliates, and Joint Intellectual Property to conduct activities under the [***] Development Plan in the Ultragenyx Field in the Territory and to perform the activities under the [***] Development Plan.
- Sublicensing. Each Party shall have the right to grant sublicenses, through multiple tiers, of the rights granted to such Party under Sections 3.1(a) and 3.1(c) (in the case of Ultragenyx) and Section 3.2(a) (in the case of Takeda), to its Affiliates and to Third Parties; provided, however that (a) subject to Section 5.2, Ultragenyx shall not grant a sublicense of the rights granted to it under (i) Section 3.1(a) to a Third Party without the prior written consent of Takeda (not to be unreasonably withheld, conditioned or delayed) or (ii) Section 3.1(c) in the Takeda Field and (b) Takeda shall not grant a sublicense of the rights granted to it under Section 3.2(a) to a Third Party without the prior written consent of Ultragenyx (not to be unreasonably withheld, conditioned or delayed). Each sublicense shall refer to and be subordinate to this Agreement and, except to the extent the Parties otherwise agree in writing, any sublicense must be consistent in all material respects with the terms and conditions of this Agreement. Upon termination of this Agreement, any sublicense granted by Ultragenyx to a Third Party shall continue and be transferred to Takeda and any sublicense granted by Takeda to a Third Party shall continue and be transferred to Ultragenyx; provided that such sublicenses comply with the requirements of this Section 3.3. Each Party shall remain responsible for the performance of this Agreement and the performance of its sublicensees hereunder.
- 3.4 **No Implied Licenses**. No license or other right is or shall be created or granted hereunder by implication, estoppel, or otherwise. All licenses and rights are or shall be granted only as expressly provided in this Agreement. All rights not expressly granted by a Party under this Agreement are reserved by the Party and may not be used by the other Party for any purpose.

32

CONFIDENTIAL TREATMENT REQUESTED

ARTICLE 4 - LICENSED PRODUCT DEVELOPMENT

4.1 **Overview of Product Development**. The Parties desire and intend to collaborate with respect to the Development of the Licensed Product in the Licensed Field in the Territory, to the extent set forth in this Agreement. Takeda's Development of the Licensed [***] Products in the Takeda Field and Ultragenyx's Development of the Licensed [***] Products in the Ultragenyx Field and Licensed Analog Products in the Licensed Field shall be conducted in a manner consistent with the [***] Development Plans and using Commercially Reasonable Efforts.

4.2 Transition and Exchange of Know-How

- (a) Transition from Takeda to Ultragenyx. As soon as practicable after the Effective Date, the Parties will cooperate and act in good faith to support the transition of the Licensed [***] Product from Takeda to Ultragenyx in the Ultragenyx Field and, solely for purposes of Ultragenyx's performance of its obligations under Section 4.3(a)(ii), in the Takeda Field, at no additional consideration payable to Takeda, including the (i) transition and, to the extent appropriate, assignment of Regulatory Materials and Regulatory Approvals covering the Licensed [***] Product in the Ultragenyx Field and, solely for purposes of Ultragenyx's performance of its obligations under Section 4.3(a)(ii), in the Takeda Field, from Takeda to Ultragenyx, (ii) sharing of the Licensed [***] Know-How with Ultragenyx to the extent necessary or reasonably useful for the use of the Licensed [***] Product and the Licensed Analog Products for and implementation of the Initial [***] Development Plan, and (iii) transferring to Ultragenyx, at no cost to Ultragenyx, those biological materials or chemical compounds related to the Licensed [***] Product Controlled by Takeda as of the Execution Date as are necessary for Ultragenyx to perform the activities allocated to it under the Initial [***] Development Plan. Takeda will also use Commercially Reasonable Efforts, at Ultragenyx's sole cost and expense, to assign or sublicense to Ultragenyx any existing Third Party agreements that are necessary or reasonably useful for the Exploitation of a Licensed [***] Product in the Ultragenyx Field in the Territory. Within forty-five (45) days after the receipt of an invoice from Takeda reflecting the costs and expenses of such assignment or sublicense, Ultragenyx shall pay the invoiced amounts to Takeda.
- (b) Know-How Sharing by Ultragenyx. Ultragenyx shall provide to Takeda, promptly after the Effective Date and during the Term upon Ultragenyx Know-How being obtained or generated by Ultragenyx, at no additional cost or expense to Takeda, all such Ultragenyx Know-How as is necessary or reasonably useful to enable Takeda: (a) to perform its obligations under this Agreement; (b) to Exploit the Licensed [***] Product in the Takeda Field, and (c) to Exploit any structures Covered by the Licensed [***] Patent, other than with respect to Licensed Analog Compounds, in the Takeda Field in the Territory.

4.3 **Development Activities**.

(a) Throughout the Term, Ultragenyx will use Commercially Reasonable Efforts to
(i) Exploit a Licensed [***] Product or Licensed Analog Product in the Ultragenyx Field in the Territory and (ii) complete Development activities for a Licensed [***] Product in the Takeda

33

CONFIDENTIAL TREATMENT REQUESTED

(b) If the Parties mutually agree to conduct other Development activities with respect to a Licensed [***] Product other than as set forth in the Initial [***] Development Plan, then the Parties shall prepare a plan (including timeline and budget) covering the Development activities to be completed, the Party responsible for completing such activities, and the Party responsible for the associated costs (together with the Initial [***] Development Plan, the "[***] Development Plans").

Field, in each case at Ultragenyx's sole expense and pursuant to the Initial [***] Development Plan.

(c) If Ultragenyx elects to pursue Development of a Licensed Analog Product, Ultragenyx will use Commercially Reasonable Efforts to Exploit such Licensed Analog Product in the Ultragenyx Field in the Territory at Ultragenyx's sole expense and pursuant to a [***] Development Plan for such Licensed Analog Product.

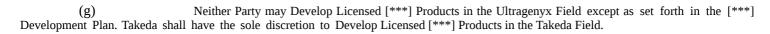
(d) At Ultragenyx's sole expense, Takeda, using Commercially Reasonable Efforts, will (i) conduct initial manufacturing process development and scale-up activities for the Licensed Products as set forth in the Initial [***] Development Plan and in accordance with the agreed upon budget contained therein, (ii) will work with Ultragenyx to transfer Licensed [***] Know-How as necessary or reasonably useful for Development and for the purposes of completing Regulatory Applications, initiating Clinical Trials and for transitioning manufacturing activities to Ultragenyx, and (iii) conduct such other Development and Manufacturing activities as may be mutually agreed by the Parties.

(e) Each Party shall conduct its activities under this Agreement in good scientific manner and in compliance in all material respects with all Applicable Laws, including, GCP, GLP, and GMP.

(f) If Ultragenyx breaches its obligations under Section 4.3(a) or 4.3(c) or is otherwise no longer actively conducting Development of a Licensed [***] Compound and Licensed [***] Product in any indication in the Ultragenyx Field, then [***] of the date Ultragenyx stopped actively conducting such Development, the Ultragenyx [***] License for the Licensed [***] Compound and Licensed [***] Product shall terminate and, [***] of such event, such license shall revert to Takeda and the terms of Section 15.7(c) shall apply with respect to such Compound and Product; provided, that, upon the reversion of rights to Takeda, Takeda shall not develop such Product in the Ultragenyx Field except in accordance with Takeda's exercise of the Takeda Option or right of first negotiation pursuant to ARTICLE 8. If, prior to the effective date of such reversion, Ultragenyx determines it wishes to license such Compound or Product from Takeda in the Ultragenyx Field, Ultragenyx may provide written notice to Takeda. Following receipt of such notice, Takeda and Ultragenyx will negotiate in good faith such license agreement for a period of [***] thereafter, which period may be extended by mutual agreement. Any resulting license agreement will be subject to Takeda's exercise of the Takeda Option or right of first negotiation pursuant to ARTICLE 8.

34

CONFIDENTIAL TREATMENT REQUESTED



4.4 Clinical Trial Registry.

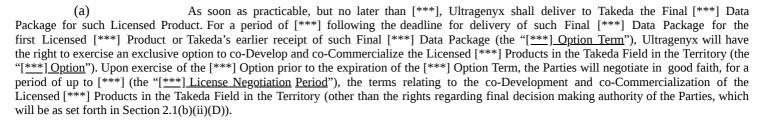
- (a) Ultragenyx shall be responsible for registering any Clinical Trial performed pursuant to the [***] Development Plans in the appropriate clinical trial registry (e.g., clinicaltrials.gov) and posting the results of such Clinical Trials as required by Applicable Laws.
- (b) The posting of any results to a clinical trial registry in accordance with this Section 4.4 shall be considered a "publication" and subject to the Parties' obligations set forth in Section 14.9.
- 4.5 Records; Disclosure of Data and Results. In conformity with standard pharmaceutical industry practices and the terms and conditions of this Agreement, each Party shall prepare and maintain, or shall cause to be prepared and maintained, complete and accurate written records, accounts, notes, reports and data with respect to activities conducted pursuant to the [***] Development Plans for a minimum of three (3) years following the end of the Calendar Year to which they pertain (or such longer period as may be required by Applicable Laws) and, upon the other Party's reasonable written request, shall send legible copies (in English and in electronic format) of the aforesaid to the other Party, to the extent not already provided, throughout the Term and for a minimum of twelve (12) months following the Term. Upon reasonable advance notice, at the request of the JSC, each Party agrees to make its employees and consultants reasonably available at their respective places of employment to consult with the other Party on issues arising in connection with the [***] Development Plans. In accordance with the reporting format and schedule approved by the JSC, each Party shall promptly and fully disclose to the other Party in writing all data, including preclinical data, Clinical Trial data, formulation data and manufacturing data, generated by or on behalf of such Party with respect to the Products in the Licensed Field. Without limiting the foregoing: (a) Ultragenyx shall keep Takeda regularly and fully informed by reporting to the JSC on a quarterly basis regarding the Development of Licensed Products in the Ultragenyx Field in the Territory by Ultragenyx, its Affiliates and sublicensees, including information regarding the status of Clinical Trials, filing of Regulatory Materials and receipt of Regulatory Approval with respect to the Products in the Ultragenyx Field in the Territory; (b) on at least an annual basis (but in any event, no later than December 1 of each Calendar Year), each Party, as applicable, shall submit to the JSC proposed updates and amendments, as appropriate, to the [***] Development Plans; and (c) Takeda shall keep Ultragenyx regularly informed by reporting to the JSC on a quarterly basis regarding the Development of Licensed Products in the Takeda Field by Takeda, its Affiliates and sublicensees, including information regarding the status of any Clinical Trials, filing of Regulatory Materials and receipt of Regulatory Approval with respect to the Products in the Takeda Field in the Territory.

ARTICLE 5- [***] CO-DEVELOPMENT AND CO-COMMERCIALIZATION

5.1 Co-Development and Co-Commercialization Negotiation for Takeda Field.

35

CONFIDENTIAL TREATMENT REQUESTED



- (b) If Ultragenyx exercises the [***] Option within the [***] Option Term and the Parties reach agreement regarding the co-Development and co-Commercialization of the Licensed [***] Product in the Takeda Field within the [***] License Negotiation Period, such agreement, including any needed modification to the Ultragenyx [***] License and Takeda [***] License, will be entered into by the Parties or their designated Affiliates. Such agreement shall provide that, if Ultragenyx terminates the Development of Licensed [***] Products in the Ultragenyx Field, then Ultragenyx shall have the right to terminate such co-Development and co-Commercialization of Licensed [***] Products in the Takeda Field upon providing Takeda with the following prior written notice: (i) if the Licensed [***] Product is in Development at the time of termination, [***], and (ii) if the Licensed [***] Product is being Commercialized at the time of termination, [***].
- (c) If Ultragenyx exercises the [***] Option within the [***] Option Term and the Parties fail to reach an agreement regarding the co-Development and co-Commercialization of the Licensed [***] Product in the Takeda Field within the [***] License Negotiation Period, then Takeda and Ultragenyx shall have the right to submit their proposed terms for such co-Development and co-Commercialization of the Licensed [***] Products in the Takeda Field in the Territory to binding arbitration as set forth in Section 16.3; provided, however, that the rights regarding the final decision making authority of the Parties as set forth in Section 2.1(b)(ii)(D) will not be subject to modification in such arbitration.
- 5.2 **Takeda Right of First Negotiation for the Ultragenyx Field.** Notwithstanding Ultragenyx's right to sublicense under Section 3.3, Ultragenyx does not have the right to enter into an agreement with any Third Party for the co-Development and/or co-Commercialization (including co-promotion) of the Licensed Product in the Ultragenyx Field except in accordance with the terms of this Section 5.2. If Ultragenyx intends to co-Develop and/or co-Commercialize (including co-promote) with a Third Party a Licensed Product in the Ultragenyx Field, Ultragenyx will provide Takeda with prior written notice of such intent and, for a period of [***] after receipt of such notice, Takeda will have a right of first negotiation to enter into a definitive agreement with Ultragenyx for such co-Development and/or co-Commercialization (including co-promotion). If the Parties fail to enter into a definitive

36

CONFIDENTIAL TREATMENT REQUESTED

agreement prior to the expiration of [***], Ultragenyx will have the right to enter into a definitive agreement with a Third Party (including via sublicensing as set forth in Section 3.3) for the co-Development and/or co-Commercialization (including co- promotion) of the Licensed Product in the Ultragenyx Field; provided, that, [***], Ultragenyx shall not enter into such a definitive agreement with a Third Party on terms, when viewed as a whole, that are less favorable to Ultragenyx than the terms last offered to Ultragenyx by Takeda.

5.3 **Commercialization Plans.** Each Party shall submit a Commercialization Plan to the JSC for discussion no less [***] prior to the anticipated date of such Party obtaining Regulatory Approval for a Licensed Product. Thereafter, each Party shall provide a copy of the thencurrent Commercialization Plan to the JSC at least once each Calendar Year during the Licensed Product Royalty Term and Takeda Royalty Term, as applicable.

5.4 Commercialization Activities.

- (a) Ultragenyx Commercialization. Ultragenyx shall use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Ultragenyx Field in the Territory throughout the Term. Subject to any modifications based on agreements reached pursuant to Sections 5.1 and 5.2, Ultragenyx's Commercially Reasonable Efforts requirements and the provisions of Section 2.1(b), Ultragenyx has sole discretion relating to all aspects of the Commercialization of Licensed Products in the Ultragenyx Field in the Territory. As between the Parties, Ultragenyx shall bear all of the costs and expenses incurred in connection with all such Commercialization activities. On an annual basis, and no later than March 1 of each Calendar Year following the First Commercial Sale of a Licensed Product in the Ultragenyx Field in the Territory, Ultragenyx shall present a reasonably detailed written report to the JSC summarizing Ultragenyx's overall Commercialization activities undertaken during the previous Calendar Year with respect to the Licensed Products in the Ultragenyx Field.
- (b) Takeda Commercialization. Subject to any modifications based on agreements reached pursuant to Sections 5.1 and 5.2 and the provisions of Section 2.1(b), Takeda has sole discretion relating to the Commercialization of Licensed [***] Products in the Takeda Field in the Territory. As between the Parties, Takeda shall bear all of the costs and expenses incurred in connection with all such Commercialization activities.

5.5 Trademarks.

- (a) **Ownership.** Each Party shall own, throughout the world, each Product trademark that it develops for a Product in its Field in the Territory (each a "Product Trademark"). All goodwill attributable to a Party's Product Trademark generated by the Commercialization of a Product bearing such mark shall inure to the benefit of such Party.
- (b) Use. Neither Party shall be obligated to use the other Party's Product Trademark or House Marks except to the extent required by Applicable Law or regulatory requirement. Neither Party shall, during the Term or thereafter, adopt, register or use any trademark, trade

37

CONFIDENTIAL TREATMENT REQUESTED

name, brand name, symbol or logo that is identical, or confusingly similar, to the other Party's Product Trademarks.

(c) Filing; Maintenance. Each Party shall solely be responsible for, and shall solely bear all costs associated with maintenance and enforcement of, such Party's Product Trademark.

ARTICLE 6 - RESEARCH COLLABORATION

6.1 **Research Collaboration Generally**. The Parties will conduct research of Takeda's [***] Compound and Candidate Products as set forth in this Agreement. As further described below, the Candidate Products will be selected from the Takeda-Controlled compounds listed on Exhibit 4.1 attached hereto, as may be amended from time to time by Takeda in its sole discretion (the "Listed Compounds").

6.2 Nomination of Candidate Products and Validation Research.

- (a) **Nomination**. Either Party may nominate compounds from the Listed Compounds for consideration and approval by the JRC as candidate products under this Agreement (upon such approval, each such Listed Compound shall thereafter be a "<u>Candidate Product</u>"). The JRC may select up to five (5) Candidate Products for validation pursuant to Section 6.2(b) at any one time. If five (5) Candidate Products have been selected at any one time, neither Party may nominate any additional Listed Compound to be considered as a Candidate Product unless and until the Parties determine, after the completion or termination of research activities under the applicable Validation Research Plan, that a Candidate Product will not be nominated as an Option Product.
- (b) Validation Research Plan. Takeda will design, with input from Ultragenyx, a research plan and budget for the initial validation for each Candidate Product (each, a "Validation Research Plan"), with each such Validation Research Plan intended to sufficiently include the activities required to provide information and data necessary for the JRC to determine whether to nominate a Candidate Product as an Option Product. Each Validation Research Plan will be submitted to the JRC for approval (for which Takeda will have final decision-making authority in accordance with Section 2(c)(ii)(C)) and will be funded by Takeda and performed by or on behalf of Takeda, in Takeda's sole discretion.

6.3 [***] Research Plan and Transition

(a) During the Collaboration Term with respect to the [***] Products, the Parties will use Commercially Reasonable Efforts to Exploit the [***] Products, at Ultragenyx's sole expense, pursuant to the initial research plan and budget for the [***] Products attached hereto as Exhibit 6.3(a) (the "[***] Research Plan"). Pursuant to the [***] Research Plan and in accordance with the associated budget, at Ultragenyx's sole expense, Takeda will use Commercially Reasonable Efforts to conduct initial Manufacturing process development and scale-up of the [***] Products, as agreed by the Parties. For clarity, there will not be any Validation Research Plan for the [***] Products.

38

CONFIDENTIAL TREATMENT REQUESTED

(b)	During the Collaboration Term with respect to the [***] Products, the Parties shall cooperate and act in g	3000
faith to support the transition of	the [***] Products from Takeda to Ultragenyx in the Licensed Field to the extent necessary or reasonate	ably
useful for Ultragenyx to perform	he [***] Research Plan, including the transition of Option Product Know-How with respect to the [*	***
Products. [***].		

<u>6.4</u> **Option Product Research Plan.** During the Collaboration Term with respect to each Option Product for which there is an agreed Option Product Research Plan, Ultragenyx will use Commercially Reasonable Efforts to Exploit each Option Product in accordance with the applicable Option Product Research Plan.

6.5 Limited Licenses During the Collaboration Term.

(a) License to Ultragenyx.

- (i) Upon selection of a Candidate Product as an Option Product by the JRC and as of the Effective Date with respect to [***] Products, Takeda hereby grants to Ultragenyx a limited, co-exclusive (with Takeda and its Affiliates), non-transferable, non-sublicensable, royalty-free license under the Option Product Technology, Option Product Improvements Controlled by Takeda or its Affiliates, Option Product Improvement Patents Controlled by Takeda or its Affiliates, and Joint Intellectual Property to Exploit the Option Product solely in accordance with the activities to be performed by Ultragenyx under the Option Product Research Plan.
- (ii) The foregoing license under Section 6.5(a)(i) will continue on an Option Product-by-Option Product basis until the earlier of (A) execution of an Option Product License Agreement, (B) failure by the Parties to enter into an Option Product License Agreement by the expiration of the applicable Option Negotiation Period, or (C) expiration or termination of the Collaboration Term, at which time such Option Product shall be a Terminated Product and all rights to such Option Product will revert to Takeda in accordance with Section 15.7(c); provided that, if in the case of (C), an Option Negotiation Period is then ongoing, the Collaboration Term with respect to such Option Product will automatically extend until the earlier of (1) expiration of such Option Negotiation Period or (2) execution of the applicable Option Product License Agreement.
- (b) License to Takeda. During the Collaboration Term, with respect to each Research Product, Ultragenyx hereby grants to Takeda a limited, non-exclusive, non- transferable, non-sublicensable, royalty-free license, under all Ultragenyx Intellectual Property, Option Product Improvements Controlled by Ultragenyx and Joint Intellectual Property for use in the Licensed Field in the Territory solely to perform its obligations under each Research Plan and to the extent necessary or reasonably useful for Takeda to evaluate a Candidate Product.
- (c) **No Implied Licenses.** No license or other right is or shall be created or granted hereunder during the Collaboration Term with respect to any Research Product by implication,

39

CONFIDENTIAL TREATMENT REQUESTED

estoppel, or otherwise. All rights not expressly granted by a Party under this Agreement are reserved by such Party and may not be used by the other Party for any purpose.

6.6 **Research Materials Transfer.**

- (a) In order to facilitate the activities contemplated by this Agreement, Takeda shall transfer to Ultragenyx, at no cost to Ultragenyx (i) those quantities of [***] Compound Controlled by Takeda as of the Execution Date as are necessary for Ultragenyx to perform the activities allocated to it under the [***] Research Plan and (ii) reasonable quantities of biological materials or chemical compounds Controlled by Takeda at the time a Candidate Product becomes an Option Product for Development of such Option Product (collectively, the "Research Materials") by Ultragenyx in furtherance of the applicable Research Plans. Such transfer shall be pursuant to a mutually agreed upon Research Materials transfer plan and schedule (including, as necessary, a separate agreement with respect to such transfer which the Parties shall enter as soon as practicable (A) after the Effective Date in the case of the foregoing clause (i) or (B) after a Candidate Product becomes an Option Product in the case of the foregoing clause (ii)). Except as otherwise provided for under this Agreement, all such Research Materials will remain the sole property of Takeda, will be used only in furtherance of the activities conducted in accordance with the applicable Research Plans, without the prior written consent of Takeda, and will be used in compliance with Applicable Law. The Research Materials supplied under this Agreement must be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. Takeda will provide Ultragenyx the most current material safety data sheet for the Research Materials upon transfer of any Research Materials.
- (b) Except as expressly set forth in this Agreement, THE RESEARCH MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE RESEARCH MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

6.7 General Terms Applicable to Research Plans and Research Activities.

- (a) Annual Review of Research Plans. On an annual basis, the Parties, through the JRC, shall review, and as necessary, update and amend the then-current Research Plans, provided that either Party may at any time between annual updates recommend updates or amendments of the then-current plans and associated budget for consideration by the JRC.
- (b) **Performance Obligations**. With respect to each Research Plan, Ultragenyx and Takeda shall each use Commercially Reasonable Efforts to execute and perform the activities assigned to it and cooperate with the other Party in the performance of such activities. Each Party shall conduct the activities assigned to it under the Research Plan in a good scientific manner and in compliance in all material respects with Applicable Law, including applicable

40

CONFIDENTIAL TREATMENT REQUESTED

national and international (e.g., ICH, GCP, GLP, and GMP) guidelines. If a Research Plan provides for Clinical Trials, the sponsor of such trial shall register and post the results of such trial.

- Records; Disclosure of Data and Results. Each Party shall prepare and maintain, or shall cause to be prepared and maintained, complete and accurate written records, accounts, notes, reports and data with respect to its activities conducted pursuant to a Research Plan in conformity with Applicable Law and standard pharmaceutical industry practices; provided that in no case shall such records be maintained for less than three (3) years following the Calendar Year to which such records pertain (or such longer period as may be required by Applicable Laws). Upon the other Party's written request, the Party receiving such written request shall send legible copies of the aforesaid to the other Party throughout the Term with respect to such Research Product and for a minimum of twelve (12) months following such Term. Upon reasonable advance notice, at the request of the JRC, each Party agrees to make its employees and consultants reasonably available at their respective places of employment to consult with the other Party on issues arising in connection with each Research Plan. In accordance with the reporting format and schedule approved by the JRC, each Party shall promptly disclose to the other Party in writing all data, including preclinical data, clinical trial data (if any), formulation data and Manufacturing data, generated by or on behalf of such Party with respect to a Research Product in the Licensed Field in the Territory.
- (d) **Termination of Research Plan**. In the event the activities under a Research Plan are terminated for any reason, all research thereunder shall cease and the applicable Option Product or [***] Product will be deemed to be a Terminated Product. All Terminated Products shall revert to Takeda pursuant to Section 15.7(c). For clarity, such termination shall not terminate the Collaboration Term for any other purpose under this Agreement.

6.8 Research Program Expenses.

- (a) **Nomination Evaluation**. Each Party shall be responsible for its own FTEs and any Third Party expenses, in each case, incurred with respect to the nomination, evaluation and selection of Candidate Products in accordance with Section 6.2(a).
- (b) [***] Research Plan. Ultragenyx shall reimburse Takeda for Takeda's FTE Costs and out-of-pocket Third Party expenses, in each case, incurred by Takeda in furtherance of the completion of those activities assigned to it under the [***] Research Plan and in accordance with the applicable budget, subject to a maximum reimbursement obligation of [***] of such budget or such greater amount as Ultragenyx may approve in advance.
- (c) Validation Research Plan. Takeda shall be responsible for its own FTEs and any Third Party expenses incurred by Takeda with respect to a Validation Research Plan.
- (d) **Option Product Research Plan.** Ultragenyx shall reimburse Takeda for Takeda's FTE Costs and out-of-pocket Third Party expenses, in each case, incurred by Takeda in furtherance of the completion of those activities assigned to it under an Option Product Research Plan and in accordance with the applicable budget, subject to a maximum reimbursement

41

CONFIDENTIAL TREATMENT REQUESTED

obligation of [***] of such budget or such greater amount as Ultragenyx may approve in advance.

6.9 **Invoices**. Within forty-five (45) days after the end of each Calendar Quarter, Takeda will provide a written report and invoice to Ultragenyx setting forth in reasonable detail its FTEs and its Third Party expenses recorded in furtherance the [***] Research Plan and Option Product Research Plans. Within sixty (60) days after the receipt of such invoice, Ultragenyx shall pay the undisputed portion of any such invoice. For clarity, making such a payment does not preempt Ultragenyx's audit rights under Section 11.12, which remain in full force and effect. If Ultragenyx in good faith identifies items in an invoice which are disputed, Ultragenyx will notify Takeda in writing, noting its objection to the disputed item(s) with specificity, within ten (10) business days of receipt of the invoice. Takeda will respond to such written notification within ten (10) days of receipt of the disputed notification. Thereafter, the Parties shall negotiate in good faith to resolve the dispute with either Takeda supplying Ultragenyx documentation justifying the charge or reducing or deleting the disputed amount. Any dispute over invoiced amounts due that cannot be resolved by direct good faith negotiation between the Parties shall be resolved in accordance with ARTICLE 16 (Dispute Resolution) of this Agreement; provided further, if the Dispute is not resolved pursuant to Section 16.2, the Parties agree that such Dispute shall be resolved pursuant to Section 16.3.

6.10 **Option Products.**

- (a) At any time during the Collaboration Term after the completion of research activities under a Validation Research Plan, either Ultragenyx or Takeda may, through the JRC, nominate a Candidate Product for selection as an Option Product, and the JRC will promptly consider such request. In order for a Candidate Product to become an Option Product, the JRC must agree (by mutual agreement of the Parties' representatives on the JRC) to (i) the selection of the Candidate Product as an Option Product, (ii) a research plan, and budget that identifies the research and development activities which shall be performed and paid for entirely by Ultragenyx (each, an "Option Product Research Plan"), and (iii) key terms, including the territory, field of use, development and commercial responsibilities and financial terms (the "Option Product Key Terms") to serve as the basis for an Option Product License Agreement. For clarity, the Option Product Research Plan for [***] Products is the [***] Research Plan.
- (b) The [***] Products are designated as Option Products as of the Effective Date. The Option Product Key Terms for [***] Products are attached hereto as Exhibit 6.10(b).
- 6.11 **The Ultragenyx Option.** Takeda hereby grants to Ultragenyx, during the applicable Collaboration Term, the exclusive option to obtain, on a product-by-product basis, an exclusive license, with the right to grant sublicenses through multiple tiers, under the Option Product Technology and Joint Intellectual Property to Exploit (a) the [***] Products and (b) up to five (5) other Option Products in the Licensed Field in the Territory (the "<u>Ultragenyx Option</u>"), subject to the terms and conditions set forth in this Agreement including ARTICLE 8.
- 6.12 Exercising the Option.

42

CONFIDENTIAL TREATMENT REQUESTED

- (a) At any time during the Collaboration Term, Ultragenyx may exercise the Ultragenyx Option regarding an Option Product by notifying Takeda in writing of its intent to exercise the Option with respect to a specific Option Product and negotiate the terms of a license agreement (the "Option Notice"). During the period of time beginning on the effective date of each such Option Notice and ending [***] thereafter, which period may be extended by mutual agreement (the "Option Negotiation Period"), the Parties will conduct good faith negotiations with the intent to agree upon license terms and conclude a definitive license agreement (the "Option Product License Agreement") in accordance with the applicable Option Product Key Terms and other terms that reflect the expected commercial opportunity and development stage of the Option Product. Any such Option Product License Agreement will include provisions to address approvals of any Governmental Authority which are required before effectiveness of such Option Product License Agreement.
- (b) If the Parties cannot conclude an Option Product License Agreement during the Option Negotiation Period, Takeda and Ultragenyx shall each have the right to submit the Option Product Key Terms and other terms for a final decision regarding the terms of the Option Product License Agreement pursuant to binding arbitration under Section 16.3. All rights to any Option Product for which the Parties do not enter into an Option Product License Agreement shall revert to Takeda and such Option Product shall be deemed a Terminated Product subject to Section 15.7(c).

ARTICLE 7 – TAKEDA RESEARCH SUPPORT

- Research Support. During the Collaboration Term and upon mutual agreement of the Parties, Takeda may provide research support as set forth in this Section 7.1 ("Research Support") to Ultragenyx, at Ultragenyx's sole cost. Such Research Support shall be related to the development of Ultragenyx Pipeline Products (in each case, other than Exercised Products) or Licensed Option Products (in each case, in connection with an Option Product License Agreement), and shall include medicinal chemistry, testing of compounds in disease animal models, drug formulation and clinical development support. If Ultragenyx and Takeda agree that Takeda should provide such Research Support, the confidentiality obligations, access to premises, and other details related to Takeda personnel providing such Research Support to Ultragenyx shall be addressed in a separate agreement between the Parties and such personnel.
- 7.2 **Expenses and Invoices.** Ultragenyx shall reimburse Takeda for Takeda's FTE Costs and out-of-pocket Third Party expenses, in each case, incurred by Takeda for the provision of the Research Support and in accordance with the applicable budget, subject to a maximum reimbursement obligation of [***] of such budget or such greater amount as Ultragenyx may approve in advance. Within forty-five (45) days after the end of each Calendar Quarter, Takeda will provide a written report and invoice to Ultragenyx setting forth in reasonable detail its FTEs and its Third Party expenses recorded for the Research Support. Within sixty (60) days after the receipt of such invoice, Ultragenyx shall pay the undisputed portion of any such invoice. For clarity, making such a payment does not preempt Ultragenyx's audit rights under Section 11.12, which remain in full force and effect. If Ultragenyx in good faith identifies items in an invoice which are disputed, Ultragenyx will notify Takeda in writing,

43

CONFIDENTIAL TREATMENT REQUESTED

noting its objection to the disputed item(s) with specificity, within ten (10) business days of receipt of the invoice. Takeda will respond to such written notification within ten (10) days of receipt of the disputed notification. Thereafter, the Parties shall negotiate in good faith to resolve the dispute with either Takeda supplying Ultragenyx documentation justifying the charge or reducing or deleting the disputed amount. Any dispute over invoiced amounts due that cannot be resolved by direct good faith negotiation between the Parties shall be resolved in accordance with ARTICLE 16 (Dispute Resolution) of this Agreement; provided further, if the Dispute is not resolved pursuant to Section 16.2, the Parties agree that such dispute shall be resolved pursuant to Section 16.3.

7.3 **Patent Ownership.** If Research Support is provided pursuant to Section 7.1 related to an Ultragenyx Pipeline Product (other than an Exercised Product), then, notwithstanding Section

12.1 or any other separate written agreement between the Parties with respect to such Research Support, as between the Parties and regardless of inventorship, Ultragenyx shall own all right, title and interest in and to any Patents related to such Ultragenyx Pipeline Product (other than an Exercised Product in the Exercised Countries) that arise out of such Research Support. For purposes of clarity, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of activities of the type covered by the definition of Research Support related to the Product(s) that are the subject of the applicable license agreement.

ARTICLE 8 - TAKEDA'S LICENSE OPTION

- 8.1 **The License Option.** In partial consideration for the premium paid by Takeda to Ultragenyx under the Common Stock Purchase Agreement, Ultragenyx hereby grants to Takeda during the applicable Takeda Option Term, the exclusive option to obtain (the "<u>Takeda Option</u>"), on a product-by-product and country-by-country basis, an exclusive license (even as to Ultragenyx and its Affiliates) to (a) any or all of the Licensed Products in the Ultragenyx Field,
- (b) any or all Licensed Option Products in the Licensed Field, and (c) one (1) Ultragenyx Pipeline Product in the Licensed Field, in each case in any or all of the countries in the Takeda Territory. For clarity, if Takeda elects not to exercise the Takeda Option with respect to (i) any Licensed [***] Product, Licensed Analog Product, Licensed Option Product, or Ultragenyx Pipeline Product, or (ii) any country in the Takeda Territory, as the case may be, prior to the expiration of the Takeda Option Term with respect to such Product and/or such country, as applicable, then Takeda shall no longer have any rights under the Takeda Option with respect to such Product and/or such country, as applicable.

8.2 Exercising the License Option.

(a) **Preparation and Delivery of the Data Packages**. Ultragenyx shall prepare and deliver to Takeda as soon as reasonably practicable after completion of the applicable Clinical Trials (a) the Final Phase II Data Package for each Licensed [***] Product, Licensed Analog Product, Licensed Option Product and Ultragenyx Pipeline Product (other than [***]) and (b) the Final Phase III Data Package for [***].

44

CONFIDENTIAL TREATMENT REQUESTED

pursuant to Section 8.2(a) and during the applicable Takeda whether it will submit the Takeda Option Notice. During this revaluable to Takeda: (i) its employees, consultants and independ	Data Package . Following Takeda's receipt of the applicable Data Package Option Term, Takeda may review and assess the Data Package to determine new period, upon Takeda's reasonable request, Ultragenyx shall promptly make the contractors (subject to the availability of any independent contractors) who preparation of the Data Package; and (ii) any additional Information under ucts that is reasonably useful in evaluating the Data Package.
Products, one or more Licensed Analog Products, one or more Licensed Analog Products, one or more Licensed Analog Products, one or more Licensed Country basis in the Takeda Territory at any time during the application Notice") identifying the applicable Products ("Exercised Takeda may exercise the Takeda Option with respect to each	censed Option Products, and one Ultragenyx Pipeline Product on a country-byable Takeda Option Term by providing written notice to Ultragenyx (the "Takeda Products") and countries ("Exercised Countries"); provided, however, that Licensed Product only once (i.e., if the Takeda Option is exercised with oplicable countries, then additional countries may not be added by additional need Product).
which period may be extended by mutual agreement (the "Takeda	ginning on the effective date of the Takeda Option Notice and ending [***], Option Negotiation Period"), the Parties will conduct good faith negotiations to License Agreement"). Such Exercised Product License Agreement shall include
Countries, which, to the extent of any conflict, shall supersede Option Product License Agreement: Ultragenyx hereby grants to right to grant sublicenses through multiple tiers, under the Ultr	ng license grant with respect to the Exercised Products in the Exercised the Ultragenyx [***] License and Takeda [***] License and the terms of any Takeda an exclusive license (even as to Ultragenyx and its Affiliates), with the agenyx Intellectual Property and Joint Intellectual Property, to Exploit the excised Product is a Licensed Product) or the Licensed Field (where such eline Product) in the Exercised Countries;
(ii) financial to (and no other consideration payable by Takeda);	erms in ARTICLE 11 (and related definitions) applicable to Exercised Products
(iii) provisions effectiveness of the Exercised Product License Agreement;	to address approvals of any Governmental Authority which are required before
(iv) provisions Exercised Products similar to those contained in ARTICLE 12:	to address the prosecution, enforcement and defense of Patents that cover

45

(v) the right for Takeda to terminate for convenience upon [***] written notice;

(vi) the right for Takeda to, in lieu of termination for Ultragenyx's material breach or insolvency, receive rights on the basis set forth in Section 15.7(a)(ii)(B);

- (vii) provisions that upon the expiration of the Takeda Royalty Term for each Exercised Product in each Exercised Country, Takeda shall have a non-exclusive, fully-paid up and irrevocable license under the Ultragenyx Intellectual Property with respect to such Exercised Product in such Exercised Country in the Ultragenyx Field (for Exercised Products that are Licensed Products) and in the Licensed Field (for Exercised Products that are Option Products or Ultragenyx Products); and ARTICLE 18.
 - (viii) to the extent applicable, Miscellaneous provisions as contained in
- (e) If the Parties cannot conclude the Exercised Product License Agreement during the Takeda Option Negotiation Period, Takeda and Ultragenyx shall each have the right to submit the terms for a final decision regarding the terms (other than those specified in Section 8.2(d)) of the Exercised Product License Agreement pursuant to binding arbitration under Section 16.3. For clarity, the terms set forth in Section 8.2(d) must be included within the Exercised Product License Agreement and are not subject to arbitration and Ultragenyx shall be required to enter into an Exercised Product License Agreement including those terms if the Takeda Option is exercised pursuant to Section 8.2(c).
- Takeda Right of First Negotiation on Ultragenyx Pipeline Products. As additional consideration for the premium being paid by Takeda to Ultragenyx under the Common Stock Purchase Agreement, and notwithstanding anything to the contrary contained in this Agreement, if, during the [***] period following expiration of the applicable Takeda Option Term, Ultragenyx intends to license (all or a subset of all rights) or otherwise transfer any Ultragenyx Pipeline Product to a Third Party in the Takeda ROFN Territory, Ultragenyx will provide Takeda with prior written notice of such intent and, for a period of [***] after receipt of such notice, Takeda will have a right of first negotiation to enter into a definitive agreement with Ultragenyx for such license (of all or a subset of all rights) or other transfer in the Takeda ROFN Territory. If the Parties fail to enter into a definitive agreement prior to the expiration of the [***] period, Ultragenyx will have the right to enter into a definitive agreement with a Third Party for the license (of all or a subset of all rights) or other transfer of such Ultragenyx Pipeline Product in the Takeda ROFN Territory.
- 8.4 **Transition of Responsibilities After Exercise of the Takeda Option**. Ultragenyx shall, in accordance with a transition plan set forth in the Exercised Product License Agreement, transfer to Takeda all activities and responsibilities related to the Exercised Products in the Exercised Countries. The Parties shall exercise Commercially Reasonable Efforts to complete the transfer in accordance with such transition plan. Any dispute between the Parties regarding the transition shall be resolved as set forth in the Exercised Product License Agreement.

46

CONFIDENTIAL TREATMENT REQUESTED

8.5	Development and Commercialization After Exercise of the Takeda Option. After exercise of the Takeda Option, Takeda will u
Commercially	Reasonable Efforts to Exploit the Exercised Products in the Takeda Option Field in the Exercised Countries at its sole cost at
expense; prov	ided, however, notwithstanding the above, Takeda's financial commitment toward global Development costs for Licensed Optic
Products and	an Ultragenyx Pipeline Products will be in accordance with the terms set forth in Section 8.6.

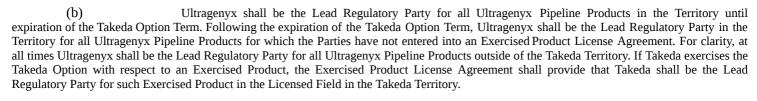
- 8.6 **Cost Sharing for Development Activities in Takeda Territory**. After exercise of the Takeda Option with respect to a Licensed Option Product and/or an Ultragenyx Pipeline Product:
- (a) the Parties will share the costs of future global Development activities for such Licensed Option Product or Ultragenyx Pipeline Product, as applicable, including costs for Clinical Trials and clinical drug supply and chemistry, manufacturing and controls-related activities in accordance with mutually agreed upon Development plans, budgets and cost sharing structures; provided that Takeda shall only be required to share global Development costs where the Development activities are necessary or reasonably useful to support the Development, Regulatory Approval and Commercialization of such product in the Takeda Territory, in which case Takeda will contribute [***]. For clarity, Takeda will not be required to share in the costs of future global Development activities where the Development activities, including Clinical Trials, are not necessary and are not used to support the Development, Regulatory Approval and Commercialization of such product in the Takeda Territory; and
- (b) Notwithstanding the foregoing, Takeda shall be solely responsible for all Development costs where the Development activities are required specifically and solely for Regulatory Approval of a Licensed Option Product or Ultragenyx Pipeline Product, as applicable, in the Takeda Territory. If such Development activities are also necessary or reasonably useful for Regulatory Approval of a Licensed Product, Licensed Option Product or Ultragenyx Pipeline Product, as applicable, outside the Takeda Territory, the Parties will negotiate in good faith to agree upon an equitable sharing of costs for such Development activities.

ARTICLE 9 - REGULATORY

- **Lead Regulatory Party**. Primary regulatory responsibility under this Agreement shall be assigned to one of the Parties (such Party, the "<u>Lead Regulatory Party</u>") as set forth in this Section 9.1.
- (a) Ultragenyx shall be the Lead Regulatory Party for all Licensed Products until expiration of the [***] Option Term. Following expiration of the [***] Option Term, whether or not Ultragenyx has exercised the [***] Option (i) Takeda shall be the Lead Regulatory Party for Licensed [***] Products in the Takeda Field unless otherwise agreed by the Parties, and (ii) Ultragenyx shall be the Lead Regulatory Party for Licensed [***] Products in the Ultragenyx Field and shall be the Lead Regulatory Party for Licensed Analog Products in the Ultragenyx Field.

47

CONFIDENTIAL TREATMENT REQUESTED



- The Parties will agree as to which Party shall be the Lead Regulatory Party for the [***] Products and each Candidate Product prior to the expiration of the Collaboration Term; provided, however, that Takeda shall be the Lead Regulatory Party (i) if the Parties are unable to agree, (ii) at any time after Ultragenyx provides Takeda written notice that it will not exercise the Ultragenyx Option with respect to the [***] Products and (iii) for the planned Scientific Advice with the Dutch Medicines Evaluation Board and US Orphan Drug Designation follow-up (as needed) for [***]. Ultragenyx shall be the Lead Regulatory Party for each Option Product for which the Parties have entered into an Option Product License Agreement and Takeda shall be the Lead Regulatory Party for each Option Product for which the Parties have not entered into an Option Product License Agreement.
- (d) In accordance with the foregoing, upon entering into an Option Product License Agreement or Exercised Product License Agreement, it is understood that the terms of such Option Product License Agreement or Exercised Product License Agreement will govern with respect to such Option Product covered by such Option Product License Agreement or Exercised Product covered by such Exercised Product License Agreement, as applicable.

9.2 Initial Transfer of Data and Regulatory Materials.

(a) Transfer to Ultragenyx

(i) As soon as practicable after the Effective Date, but in any event no later than sixty (60) days after the Effective Date, Takeda shall timely transfer to Ultragenyx copies of (A) all Regulatory Materials (in electronic or other format) in its possession related to the use of the Licensed [***] Products in the Ultragenyx Field (and, solely for purposes of Ultragenyx's performance of its obligations under Section 4.3(a)(ii), in the Takeda Field) and (B) the briefing book, FDA meeting minutes, Takeda meeting minutes, and FDA correspondence associated with [***], the US Orphan Drug Designation Request and subsequent regulatory correspondence, and the briefing book and correspondence for Scientific Advice with the Dutch Medicines Evaluation Board, in each case for the [***] Products in the Licensed Field and existing as of such date of transfer. Following each such transfer and at a time to be mutually agreed by the Parties, the Parties shall take all steps necessary (a) for Ultragenyx to own or have the right of reference to the INDs and Regulatory Approvals necessary to conduct Development of the Licensed [***] Product in the Ultragenyx Field and (b) for Takeda to own or have the right of reference to the INDs and Regulatory Approvals necessary to conduct Development of the Licensed [***] Product in the Takeda Field.

48

CONFIDENTIAL TREATMENT REQUESTED

(ii) Within sixty (60) days after the Effective Date, Takeda shall make available to Ultragenyx separate copies (in electronic or other format) of the study reports from all non-clinical trials and Clinical Trials in the Territory, in each case, whether completed as of the Effective Date or then in-progress, that are Controlled by Takeda (to the extent not previously provided to Ultragenyx), as such reports become available to Takeda, and to the extent that they relate to the use of the Licensed [***] Products for the Territory.

(b) Transfer to Takeda

(i) As soon as practicable after the effective date of an Exercised Product License Agreement for a given Exercised Product, but in any event no later than sixty (60) days after such date, Ultragenyx shall timely transfer to Takeda copies of all Regulatory Materials (in electronic or other format) in its possession related to the use of the Exercised Product in the Exercised Countries and which support the Product INDs, the Product Regulatory Approvals and associated correspondence, existing as of such date of transfer. Promptly after such transfer, Ultragenyx shall take all steps necessary to transfer ownership of all such Product INDs and Product Regulatory Approvals in the Takeda Territory to Takeda, including, if applicable, submitting to the PMDA a letter or other necessary documentation (with a copy to Takeda) notifying the PMDA of the transfer of such ownership. From time to time after the IND Date, and solely to the extent not previously disclosed, Ultragenyx shall, and shall cause its Affiliates to, without additional compensation, disclose and make available to Takeda, in whatever form Takeda may reasonably request, all Regulatory Materials Controlled by Ultragenyx and related to the use of an Exercised Product in the Exercised Countries.

(ii) Within sixty (60) days after the Parties enter into an Exercised Product License Agreement for a given Exercised Product, Ultragenyx shall make available to Takeda separate copies (in electronic or other format) of the study reports from all non-clinical trials and Clinical Trials in the Territory, in each case, whether completed as of the Effective Date, that are Controlled by Ultragenyx (to the extent not previously provided to Takeda), as such reports become available to Ultragenyx, and to the extent that they relate to the use of the Exercised Products in the Exercised Countries.

9.3 Preparation of Regulatory Materials.

(a) After the Effective Date (or, as applicable, the IND Date), the Lead Regulatory Party shall have the sole right and responsibility, and shall exercise Commercially Reasonable Efforts, to prepare, obtain, and maintain, as applicable, the Regulatory Materials, including the Product INDs, the Product Regulatory Approvals, and other submissions, and to conduct communications with the FDA, for the relevant Products in the applicable indication in the Territory or applicable portion thereof, except in the case of Licensed [***] Products from the Effective Date until expiration of the [***] Option Term, during which time Takeda shall hold the IND and Ultragenyx (i.e., the Lead Regulatory Party) shall receive a right of reference from Takeda. Except with respect to Licensed [***] Products from the Effective Date until expiration of the [***] Option Term, all Product INDs and Product Regulatory Approvals generated after the Effective Date, including any supplements or amendments to those Product INDs and Product Regulatory Approvals in existence as of the Effective Date, with respect to such Products in the

49

CONFIDENTIAL TREATMENT REQUESTED

applicable indication in the Territory or applicable portion thereof under this Agreement shall be owned by, and shall be the sole property and held in the name of, Lead Regulatory Party or its designee.

- (b) Other than the Scientific Advice Briefing Book for the [***] Products which has been prepared as of the Execution Date but not yet been submitted, the Lead Regulatory Party shall provide the other Party with an opportunity to review and comment on all material Regulatory Materials submitted by the Lead Regulatory Party to a Regulatory Authority after the Effective Date, in each case reasonably in advance of when the Lead Regulatory Party intends to submit such Regulatory Materials to the applicable Regulatory Authority. The other Party shall provide its comments within [***], or such other period of time mutually agreed to by the Parties. The Lead Regulatory Party shall consider in good faith any such comments of the other Party. The Lead Regulatory Party shall provide the other Party with a copy in electronic form of all material Regulatory Materials filed with the Regulatory Authority related to the use of the relevant Products.
- (c) The Lead Regulatory Party shall notify the other Party within no less than [***] of any request for a meeting or substantive telephone conference call with a Regulatory Authority with respect to any Product IND or Product Regulatory Approval. Upon the other Party's request, the Lead Regulatory Party shall request that the FDA or other Regulatory Authority permit at least [***] of the other Party's employees to attend any such meeting or conference call. To the extent permitted by the FDA or other Regulatory Authority, the other Party shall have the right to participate in any such meeting or conference call. The foregoing rights and obligations apply with respect to meetings or conferences initiated by the Lead Regulatory Party or by a Regulatory Authority. The Lead Regulatory Party shall promptly furnish the other Party with copies of all substantive correspondence related to the relevant Product the Lead Regulatory Party has had with the Regulatory Authority, and contact reports concerning substantive conversations or minutes from any substantive meetings with a Regulatory Authority related to such Product.
- (d) Notwithstanding the foregoing, Takeda, in consultation with Ultragenyx, shall be responsible for the preparation of any components of Regulatory Materials to be filed by Ultragenyx that relate to the Manufacture of a Licensed Product or Option Product. Takeda shall use Commercially Reasonable Efforts to prepare such components in a timely manner and provide such components to Ultragenyx with sufficient time for Ultragenyx to review and comment on such components; provided, however, that Takeda may use an alternative arrangement (such as a drug master file) to preserve the confidentiality of such components to the extent required by any Third Party agreements or, in Takeda's reasonable discretion, if otherwise necessary to protect Takeda confidential information and such alternative arrangement is permissible under Applicable Laws; provided, further, that if Ultragenyx reasonably requests additional information with respect to the Development or Commercialization of a Licensed Product or Option Product otherwise treated as confidential in such alternative arrangement (such as a drug master file), Takeda shall reasonably consider such request. In the event that Ultragenyx elects to Manufacture a Licensed Product or Option Product, Ultragenyx shall notify Takeda of such election and, to the extent covered by the license rights granted in Sections 3.1(a)

50

CONFIDENTIAL TREATMENT REQUESTED

and 3.1(c) (for Licensed Products) or Section 6.5(a) (for Option Products), Takeda shall promptly transfer to Ultragenyx or its Third Party designee all Regulatory Materials, processes and technical information Controlled by Takeda or its Affiliates that are reasonably necessary and useful for the Manufacture of such Licensed Product or Option Product, and thereafter Ultragenyx shall be responsible for the preparation of any components of Regulatory Materials to be filed related to the Manufacture by Ultragenyx or its Third Party designee of such Licensed Product or Option Product.

9.4 Cooperation, Consultation and Review.

- (a) The Parties shall cooperate with each other to achieve the regulatory objectives contemplated herein in a timely, accurate and responsive manner and shall assist the other Party as reasonably requested in connection with the preparation and filing of Regulatory Materials in the Licensed Field, whether in or outside of the Territory. The Parties shall establish a joint regulatory working group to manage Licensed Product regulatory activities and issues. It is the intention of the Parties that the joint regulatory working group shall meet (in person or via teleconference) on an as-needed basis after the Effective Date and throughout the Term, but at a minimum on a quarterly basis. The Parties agree and acknowledge that the activities of Ultragenyx with respect to (i) Licensed [***] Products in the Ultragenyx Field and (ii) Licensed Analog Products in the Licensed Field and the activities of Takeda with respect to (A) Licensed [***] Products in the Takeda Field and (B) Licensed Products outside of the Licensed Field, shall be coordinated such that they are consistent with the overall objective of facilitating Regulatory Approvals.
- (b) The other Party shall assist the Lead Regulatory Party, as is reasonably necessary, in order for the Lead Regulatory Party to obtain and maintain the Product INDs and the Product Regulatory Approvals, including in connection with the preparation and filing of Regulatory Materials necessary to maintain such Product INDs and Product Regulatory Approvals.
- 9.5 **Regulatory Costs and Expenses**. Each Party shall bear its own costs and expenses incurred related to the preparation, maintenance, formatting and filing of the Regulatory Materials.
- 9.6 **Rights of Reference to Regulatory Materials**. Each Party hereby grants to the other Party a right of reference to all Regulatory Materials, including any data relied on in support of such Regulatory Materials, solely for the purpose of seeking, obtaining and maintaining Regulatory Approvals for the Products, consistent with the roles of the Parties set forth in this Agreement.
- 9.7 **Labeling Information Exchange/Labeling Agreement.** The Parties shall cooperate to develop methods and/or procedures for sharing information related to Labeling. Specific details regarding the management of Labeling information, including CCDS will be delineated in a separate Labeling agreement that shall be agreed upon by the Parties.
- 9.8 Adverse Event Reporting and Safety Data Exchange.

51

CONFIDENTIAL TREATMENT REQUESTED

(a) Safety Information Exchange; Pharmacovigilance Agreement.

(i) The Parties shall cooperate to develop methods and/or procedures for sharing information relating to the clinical experiences in accordance with safety reporting requirements of the respective Regulatory Authorities and as necessary for a Party to comply with Applicable Laws. Specific details regarding the management of safety information including adverse events reports related to the Development and the Commercialization of the Products will be delineated in a separate global pharmacovigilance agreement (the "PVA") that shall be agreed to by the Parties as soon as reasonably practicable, but in any event not later than [***] of the Effective Date. The Lead Regulatory Party shall be responsible for the compliance and filing of all required safety reports to the Regulatory Authorities in the Territory, including annual safety reports, throughout the Term.

(ii) The PVA shall provide as follows:

- (A) Unless otherwise agreed by the Parties, the Lead Regulatory Party shall maintain the global safety database for the Products, and mirror databases will be maintained by the other Party; provided, however, that Takeda shall maintain the global safety database regarding Licensed [***] Products, and Ultragenyx shall maintain the global safety database regarding Licensed Analog Products. For clarity, to the extent a Party is no longer actively Developing or Commercializing a Licensed [***] Product, then the global safety database shall be transferred to the Party that continues to actively Develop or Commercialize such Licensed [***] Product.
- (B) Each Party shall timely report to the other Party all clinical experiences, safety monitoring, and pharmacovigilance surveillance observed in the Territory, which in all cases shall be (i) for clinical studies: as soon as practicable, [***] and (ii) for commercial Products: [***]; exchange of information shall be on a Council for International Organizations of Medical Sciences Suspect Adverse Reaction Report Form ("CIOMS Form").
- (C) The other Party shall prepare and provide to the Lead Regulatory Party on a timely basis safety updates in order for the Lead Regulatory Party to meet the safety report submission requirements necessary to maintain the Product INDs and the Product Regulatory Approvals.
- (b) Regulatory Reporting of Safety Information. The Parties shall work together to achieve consensus with respect to safety issues related to the Products, including urgent safety information, and to report said opinion to safety boards, investigators, and to applicable Regulatory Authorities. In the event that, after reasonable medical and scientific consultation, the Parties cannot achieve consensus with respect to safety issues to be reported to any applicable Regulatory Authority, the Lead Regulatory Party shall have final decision making 52

CONFIDENTIAL TREATMENT REQUESTED

authority with respect to the Products in the Licensed Field in the Territory. Notwithstanding anything to the contrary in this Agreement, either Party may report safety matters to a Regulatory Authority that it reasonably determines are necessary to report prior to the conclusion of the dispute resolution procedure.

- 9.9 **Regulatory Authority Communications Received by a Party**. Each Party shall inform the other Party in a timely manner, not to exceed [***], of the notification of any action by, or notification or other information which it receives (directly or indirectly) from any Regulatory Authority which: (i) raises any material concerns regarding the safety or efficacy of a Product; (ii) indicates or suggests a potential material liability of either Party to Third Parties in connection with a Product; (iii) is reasonably likely to lead to a recall or market withdrawal of a Product; or (iv) relates to expedited reports of adverse events with respect to a Product, or Product Complaints, and which may have a material impact on obtaining or maintaining Regulatory Approval or the continued Commercialization of a Product, as then conducted. The other Party will fully cooperate with and assist such Party in complying with regulatory obligations and communications, including by providing to such Party, in a timely manner after a request, such information and documentation in the other Party's possession as may be necessary or helpful for the Party to prepare a response to an inquiry from a Regulatory Authority. Each Party will provide the other Party in a timely manner with a copy of all correspondence received from a Regulatory Authority specifically regarding the matters referred to above.
- 9.10 Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party's facility or a facility under contract with such Party with regard to a Product in the Territory, then the audited Party shall notify the other Party as soon as practicably possible after receipt of such notification of such audit or inspection and provide copies of any materials provided to it by the applicable Regulatory Authority; provided, that the audited Party shall not be required to notify the other Party of audits or inspections that are of a routine nature or that do not relate to a Product, except where such audits result in communications or actions of such Regulatory Authority which have a direct impact upon a Product. In addition, if a Regulatory Authority conducts an unannounced inspection or audit of a Party's facility or a facility under contract with such Party with regard to a Product in the Territory, then the audited Party shall notify the other Party within [***] of commencement of such audit or inspection. The audited Party shall cooperate, and shall use reasonable efforts to cause the contract facility to cooperate, with such Regulatory Authority and the other Party during such inspection or audit. Following receipt of the inspection or audit observations of such Regulatory Authority (a copy of which the audited Party will immediately provide to the other Party), the audited Party will also provide the other Party with copies of any written communications received from Regulatory Authorities with respect to such facilities in a timely manner after receipt, to the extent such written communications relate directly to a Product or the Manufacture thereof, and will prepare the response to any such observations. The audited Party will provide the other Party with a copy of any proposed response to such communications and will consider in good faith such other Party's reasonable comments with respect to such proposed response. The audited Party agrees to conform its activities under this Agreement to any commitments made in such a response.

53

CONFIDENTIAL TREATMENT REQUESTED

Recalls and Voluntary Withdrawals. Each Party shall notify the other Party promptly but in no event later than [***] following its determination that any event, incident, or circumstance has occurred that may result in the need for a recall, market suspension, or market withdrawal of a Product under any MAA or Regulatory Approval for the Product held by such Party and filed with Regulatory Authorities in the Territory, and shall include in such notice the reasoning behind such determination, and any supporting facts. Such Party shall have the sole right to make the final determination whether to voluntarily implement any such recall, market suspension, or market withdrawal in the Territory; provided that prior to any implementation of such a recall, market suspension, or market withdrawal, the such Party shall, to the extent practical, consult with the other Party and shall consider the other Party's comments in good faith. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 9.11, such Party shall be solely responsible for the execution thereof, and the other Party shall reasonably cooperate in all such recall efforts. Subject to ARTICLE 17, such Party shall be responsible for all costs of any such recall, market suspension, or market withdrawal; provided that, the other Party shall be responsible for the costs of any recall, market suspension, or market withdrawal with respect to a Product in the Territory to the extent such recall, market suspension, or market withdrawal is attributable to the other Party's breach of its obligations hereunder or its negligence, recklessness or willful misconduct.

ARTICLE 10 - MANUFACTURING AND SUPPLY

10.1 **Supply Agreement**. The Parties shall enter into mutually agreeable supply agreements as soon as appropriate after the Effective Date covering the manufacture and research supply (other than as provided in Section 6.6), clinical supply or Commercial supply of Compounds or Products needed for Development or Commercialization.

ARTICLE 11 - PAYMENT

11.1 Licensed Product Development Milestones Payable to Takeda.

(a) Ultragenyx shall pay to Takeda a milestone payment within forty-five (45) days after the first achievement of each of the following milestones for each Licensed Product, calculated as follows:

(i) [***];

(ii) upon Regulatory Approval of [***];

(iii) upon both (A) Regulatory Approval of [***] and (B) Pricing Approval [***]

(iv) [***];

54

CONFIDENTIAL TREATMENT REQUESTED

		(vi)	upon both (A) Regulatory Approval of [***] and (B) Pricing Approval [***]
milestone Licensed I			ach milestone payment in this Section 11.1 shall be payable only upon the first achievement of such luct and no amounts shall be due for subsequent or repeated achievements of such milestone for the same
11.2	Licensed	Product Sales	Milestones Payable to Takeda.
following	` /		tragenyx shall pay to Takeda a milestone payment within [***] after the first achievement of each of the gated annual Net Sales of all Licensed Products, calculated as follows:
and Sublic	censees in	(i) a given Calenda	upon the Net Sales in the Territory of all Licensed Products made by Ultragenyx, its Affiliates ir Year equaling or exceeding [***];

upon Regulatory Approval of [***]; and

(ii) upon the Net Sales in the Territory of all Licensed Products made by Ultragenyx, its Affiliates and Sublicensees in a given Calendar Year equaling or exceeding [***]; and

(iii) upon the Net Sales in the Territory of all Licensed Products made by Ultragenyx, its Affiliates and Sublicensees in a given Calendar Year equaling or exceeding [***].

(b) Each milestone payment in this Section 11.2 shall be payable only upon the first achievement of such milestone for all Licensed Products in aggregate and no amounts shall be due for subsequent or repeated achievements of such milestone. If two or more milestone events are achieved in the same Calendar Year, Ultragenyx shall pay to Takeda each milestone payment corresponding to the respective milestone event.

11.3 **Licensed Product Royalties Payable to Takeda.** Subject to Section 11.8 below, and during the applicable Licensed Product Royalty Term, Ultragenyx shall pay to Takeda, on a Licensed Product-by-Licensed Product basis, a running royalty at the following incremental royalty rates, on Net Sales of each Licensed Product in the Territory in a Calendar Year:

Net Sales in the Territory

Royalty Rate

For that portion of annual Net Sales less than \$[***]

For that portion of annual Net Sales greater than or

[***]%

(v)

55

CONFIDENTIAL TREATMENT REQUESTED

equal to \$[***] but less than \$[***]	
For that portion of annual Net Sales greater than or equal to \$[***] but less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***]	[***]%

11.4 Exercised Product Milestones and Fees Payable to Ultragenyx.

- (a) Pursuant to the applicable Exercised Product License Agreement, Takeda shall pay to Ultragenyx a milestone payment of [***] within [***] after the first Regulatory Approval in the first indication in Japan for [***] if such product is an Exercised Product that has not been terminated at the time of such Regulatory Approval. The milestone payment in this Section 11.4(a) shall be payable only upon the first achievement of such milestone for each such Exercised Product and no amounts shall be due for subsequent or repeated achievements of such milestone for such Exercised Product. For clarity, the maximum aggregate amount payable by Takeda for each Exercised Product pursuant to this Section 11.4(a) is [***].
- (b) For all Ultragenyx Pipeline Products other than [***], during the Takeda Option Negotiation Period for such Ultragenyx Pipeline Products, the Parties will negotiate in good faith (for inclusion in the applicable Exercised Product License Agreement) commercially reasonable financial terms in addition to the royalties contemplated in Section 11.6 (such as one or more of the following: option exercise fees, sales and development milestones, reimbursement for historical research and development costs allocable to Japan, and milestones due to Third Party licensors) for such Ultragenyx Pipeline Products, taking into consideration factors such as the investment in the collaboration under this agreement already made by Takeda, including the premium paid by Takeda to Ultragenyx under the Common Stock Purchase Agreement. If the Parties cannot reach agreement on such commercially reasonable financial terms during the Takeda Option Negotiation Period, either Takeda or Ultragenyx may seek a final decision regarding the commercially reasonable financial terms pursuant to binding arbitration as set forth in Section 16.3.
- 11.5 **Licensed Product Royalties Payable to Ultragenyx for the Exercised Countries**. Subject to Section 11.8 below, and during the applicable Licensed Product Royalty Term, pursuant to the applicable Exercised Product License Agreement, Takeda shall pay to Ultragenyx, on a Licensed Product-by-Licensed Product basis, a running royalty at the following incremental royalty rates, on aggregate, Net Sales of each Exercised Product that is a Licensed Product in the Exercised Countries in a Calendar Year:
- (a) If the Takeda Option for such Licensed Product is exercised by Takeda prior to Takeda's receipt of the Final Phase II Data Package for such Licensed Product:

56

CONFIDENTIAL TREATMENT REQUESTED

Net Sales in the Exercised Countries	Royalty Rate
For that portion of annual Net Sales less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***] but less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***] but less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***]	[***]%

(b) If the Takeda Option for such Licensed Product is exercised by Takeda after Takeda's receipt of the Final Phase II Data Package for such Licensed Product:

Net Sales in the Exercised Countries	Royalty Rate
For that portion of annual Net Sales less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***] but less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***] but less than \$[***]	[***]%
For that portion of annual Net Sales greater than or equal to \$[***]	[***]%

- 11.6 Licensed Option Product and Ultragenyx Pipeline Product Royalties Payable to Ultragenyx for the Exercised Countries. During the Takeda Option Negotiation Period for a Licensed Option Product or Ultragenyx Pipeline Product, the Parties will negotiate in good faith (for inclusion in the applicable Exercised Product License Agreement) tiered royalty rates on annual Net Sales of such Licensed Option Product or Ultragenyx Pipeline Product to be paid by Takeda to Ultragenyx during the Takeda Royalty Term. If the Parties cannot reach agreement on such tiered royalty rates during the Takeda Option Negotiation Period, either Takeda or Ultragenyx may seek a final decision regarding the royalty rates pursuant to binding arbitration as set forth in Section 16.3.
- 11.7 **Royalty Reduction for Generic Product Entry in a Country**. On a Licensed Product- by-Licensed Product basis, the royalty rates set forth in Sections 11.3 and 11.5 for Net Sales of a Product in a country shall be reduced by [***] in each Calendar Quarter during which the Generic Competition Percentage with respect to such Licensed Product in such country in such Calendar Quarter is greater than or equal to [***].

11.8 Payment for Third Party Licenses.

- (a) Each Party will be responsible for paying all Third Party license fees, royalties, and/or milestones, with respect to Third Party licenses entered into by such Party or its Affiliates prior to or on the Effective Date or during the Term, for intellectual property that is necessary or reasonably useful for the Exploitation of any Licensed Product. For such Third Party licenses to Preexisting Third Party IP, the paying Party will be entitled to deduct up to [***] of such amounts due to any such Third Party from royalties payable to the other Party hereunder on such Licensed Product. For such Third Party licenses obtained during the Term, the paying Party will be entitled to deduct [***] of such amounts due to any such Third Party from royalties payable to the other Party hereunder on such Licensed Product. Notwithstanding the foregoing, in no event shall such royalty payable to Takeda in any Calendar Quarter as a result of this reduction be less than [***] of the amount that would otherwise be due.
- (b) Ultragenyx shall be responsible for paying all Third Party license fees, royalties, and/or milestones, with respect to Third Party licenses for intellectual property that is necessary or reasonably useful for the Exploitation of any Ultragenyx Pipeline Product, where such licenses are entered into (i) prior to or on the Effective Date or (ii) unless and until such Ultragenyx Pipeline Product is an Exercised Product, during the Term. Each Party will be responsible for paying all Third Party license fees, royalties, and/or milestones, with respect to Third Party licenses for intellectual property that is necessary or reasonably useful for the Exploitation of any Ultragenyx Pipeline Product that is an Exercised Product entered into by such Party or its Affiliates on or after the date on which it becomes an Exercised Product. For such Third Party licenses obtained by Takeda or its Affiliates, Takeda will be entitled to deduct [***] of such amounts due to any such Third Party from royalties payable to Ultragenyx on such Exercised Product. Notwithstanding the foregoing, in no event shall the royalty payable to Ultragenyx in any Calendar Quarter on such Exercised Product as a result of this reduction be less than [***] of the amount that would otherwise be due.
- (c) Notwithstanding the foregoing, for intellectual property held by a Third Party that is necessary or reasonably useful for the Exploitation of any Exercised Products in both the Exercised Countries and other countries in the Territory, the Parties will coordinate license negotiations with such Third Party for rights in both the Exercised Countries and other countries in the Territory.
- Manner of Royalty Payment. Each Party will calculate and report royalty payments due by such Party to the other Party under Section 11.3 or 11.5, as applicable, each Calendar Quarter. Each Party shall pay all royalty payments due under Section 11.3 or 11.5, as applicable, within sixty (60) days after the end of each Calendar Quarter and shall include with each payment a report containing the following information for the applicable Calendar Quarter: (a) the amount of gross sales (in U.S. dollars) of the Products in the Territory; (b) an itemized calculation of Net Sales in the Territory showing deductions, to the extent applicable, provided for in the definition of "Net Sales"; (c) a calculation of the royalty payment due on such sales;

(d) an accounting of the number of units and prices for the Products sold; and (e) application of

58

CONFIDENTIAL TREATMENT REQUESTED

the reductions, if any, made in accordance with the terms of Section 11.7 and 11.8. Within twenty (20) Business Days after the end of each Calendar Quarter, each Party shall provide a preliminary report as described above for the most recent Calendar Quarter then ended. Each Party shall reasonably cooperate to reconcile any deviations and confirm the accuracy to the extent necessary under Applicable Laws, GAAP or IFRS.

11.10 **Exchange Rate**. The rate of exchange to be used in computing the amount of currency equivalent in U.S. Dollars owed to a Party under this Agreement shall be equal to the weighted average exchange rate, over the applicable Calendar Quarter, between each currency of origin and U.S. Dollars as reported by OANDA (www.oanda.com), or an equivalent resource as agreed by the Parties, on the last Business Day of the Calendar Quarter in which the applicable Net Sales were made.

11.11 Taxes

- (a) Cooperation and Coordination. The Parties acknowledge and agree that it is their mutual objective and intent to appropriately calculate, to the extent feasible and legal, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use all commercially reasonable efforts to cooperate and coordinate with each other to achieve such objective. Ultragenyx shall cooperate with Takeda in seeking any tax exemption or credits that may be available to Takeda with respect to any research which Takeda or its affiliates perform or fund under this Agreement, including any credits under section 45C of the U.S. Internal Revenue Code of 1986, as amended.
- (b) Payment of Tax. A Party receiving a payment pursuant to this ARTICLE 11 shall pay any and all taxes levied on such payment. A Party making a payment pursuant to this ARTICLE 11 shall make a reasonable effort to obtain the lowest tax rate under Applicable Laws for taxes required to be deducted and withheld. If Applicable Laws require that taxes be deducted and withheld from a payment made pursuant to this ARTICLE 11, after a Party making a payment makes a reasonable effort to obtain the lowest tax rate, the remitting Party shall: (i) deduct those taxes from the payment; (ii) pay the taxes to the proper taxing authority; and (iii) send evidence of the obligation together with proof of payment to the other Party within sixty (60) days following that payment.
- (c) Tax Residence Certificate. A Party receiving a payment pursuant to this ARTICLE 11 shall provide the remitting Party appropriate certification from relevant revenue authorities that such Party is a tax resident of that jurisdiction, if such receiving Party wishes to claim the benefits of an income tax treaty to which that jurisdiction is a party. Upon the receipt thereof, any deduction and withholding of taxes shall be made at the appropriate treaty tax rate.
- (d) Assessment. Either Party may, at its own expense, protest any assessment, proposed assessment, or other claim by any Governmental Authority for any additional amount of taxes, interest or penalties or seek a refund of such amounts paid if permitted to do so by Applicable Laws. The Parties shall cooperate with each other in any protest by providing records and such additional information as may reasonably be necessary for a Party to pursue such protest.

59

CONFIDENTIAL TREATMENT REQUESTED

- (e) Withholding. If a Party that owes a payment under this Agreement assigns its rights and obligations to any Person and if, solely as a result of such assignment, the withholding or deduction of tax required by Applicable Laws with respect to payments under this Agreement is increased, then, subject to Section 11.11(f), any amount payable under this Agreement shall be increased to take into account such withheld or deducted taxes as may be necessary so that, after making all required withholdings and deductions (including withholdings and deductions on amounts payable under this Section 11.11(e)), the payee receives an amount equal to the sum it would have received had no such increased withholding or deduction been made. For the avoidance of doubt, if a payee under this Agreement assigns its rights and obligations under this Agreement, the payee shall not be entitled to any additional payments with respect to Taxes arising as a result of such payee's assignment.
- (f) Credit. To the extent a payee obtains any credit for Taxes for which it has received a payment pursuant to Section 11.11(e) against any liability for tax in the year in which the receipt is taxable, any preceding years, or any succeeding years within the term of this Agreement, thereby reducing out-of-pocket tax payments by the Section 11.11(e)-payee in such year or years, calculated on a "with and without" basis, the Section 11.11(e)-payee shall promptly reimburse the Section 11.11(e)-payor an amount equal to its tax savings resulting from such credit and the Section 11.11(e)-payee shall timely provide the Section 11.11(e)-payor with reasonable evidence as may reasonably be requested to determine whether any amounts are subject to reimbursement pursuant to this Section 11.11(f).
- Audit. Each Party will maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the calculation of royalty and other payments under this Agreement. Upon reasonable prior notice, such records shall be available during regular business hours for a period of three (3) years from the end of the Calendar Year to which they pertain for examination at the expense of the requesting Party, and not more often than once each Calendar Year, by an independent certified public accountant selected by the requesting Party and reasonably acceptable to the other Party, for the sole purpose of verifying the accuracy of the financial reports furnished by the other Party pursuant to this Agreement. Any such auditor shall not disclose the other Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the other Party or the amount of payments due by the other Party under this Agreement during the prior thirty six (36) months. Any amounts shown to be owed but unpaid shall be paid within thirty (30) days from the accountant's report, plus interest (as set forth in Section 11.13) from the original due date. Any amounts shown to have been overpaid shall be refunded within thirty (30) days from the accountant's report. The requesting Party shall bear the full cost of such audit unless such audit discloses an underpayment by other Party of more than five percent (5%) of the amount due, in which case the other Party shall bear the full cost of such audit.
- 11.13 **Manner of Payment, Late Payment.** All payments due to a Party hereunder shall be made in U.S. Dollars by wire transfer of immediately available funds into an account designated by such Party. If a Party does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to such Party until the date of payment at the per annum rate of one percent (1%) over the then-current prime rate quoted by

60

CONFIDENTIAL TREATMENT REQUESTED

Citibank in New York City or the maximum rate allowable by Applicable Laws, whichever is lower.

11.14 **Finance and Accounting Working Group**. The Parties shall cooperate with each other to achieve the finance and accounting objectives contemplated herein in a timely, accurate and responsive manner. The Parties shall establish a finance and accounting working group to manage financial and accounting affairs related to the Products, which, for at least the first twelve (12) months after the Effective Date, shall meet monthly unless otherwise agreed upon by the Parties.

ARTICLE 12 – INTELLECTUAL PROPERTY MATTERS

12.1 **Ownership of Inventions**.

- (a) **Sole Ownership.** Subject to the terms of this Agreement, each Party shall own any Inventions made solely by its own employees, agents, or independent contractors or its Affiliate's or sublicensees' employees, agents, or independent contractors in the course of conducting its activities under this Agreement, together with all intellectual property rights therein.
- (b) **Joint Ownership**. The Parties shall jointly own any Inventions that are made jointly by employees, agents, or independent contractors of each Party or its Affiliates in the course of performing activities under this Agreement, together with all intellectual property rights therein (the "Joint Inventions").
- (c) **Inventorship.** For purposes of this Agreement, inventorship shall be determined in accordance with U.S. patent laws.

12.2 Assignment Obligation and Disclosure of Inventions.

- (a) Each Party shall cause all Persons who perform activities for such Party under this Agreement to be under an obligation to assign (or, if such Party is unable to cause such Person to agree to such assignment obligation despite such Party using commercially reasonable efforts to negotiate such assignment obligation, provide a license under) their rights in any Information and Inventions resulting therefrom to such Party, except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions which have standard policies against such an assignment (in which case a suitable license, or right to obtain such a license, shall be obtained).
- (b) Takeda will promptly disclose to Ultragenyx in writing, the conception, discovery, development or making of any Joint Inventions and any Inventions Covering Ultragenyx Pipeline Improvements by Persons who perform activities for Takeda under this Agreement.

61

CONFIDENTIAL TREATMENT REQUESTED

- (c) Ultragenyx will promptly disclose to Takeda in writing the conception, discovery, development or making of any Joint Inventions and any Inventions Covering Licensed Product Improvements, or Option Product Improvements.
- (d) Each Party will promptly disclose to the other Party in writing, the conception, discovery, development or making of any Joint Inventions by Persons who perform activities for it under this Agreement.

12.3 **Prosecution of Patents.**

(a) Licensed [***] Patents, Licensed Product Improvement Patents, and Joint Patents relating to Licensed **Products.** Except as otherwise provided in this Section 12.3(a), as between the Parties, Takeda shall have the sole right and authority to prepare, file, prosecute and maintain the Licensed [***] Patent, Licensed Product Improvement Patents, and, where relating to Licensed Products, Joint Patents (collectively, the "[***] Patent Prosecution") on a worldwide basis (including the right to defend in patent office proceedings such as inter partes reviews, post grant reviews and oppositions). Takeda shall bear all costs of preparation, filing, prosecution and maintenance of the [***] Patent Prosecution in the Territory. Provided that Ultragenyx's rights with respect to the applicable Licensed Product have not terminated, Takeda, upon Ultragenyx's request, shall provide Ultragenyx a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding the [***] Patent Prosecution and drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Takeda shall consider Ultragenyx's comments regarding such communications and drafts in good faith with a view to maximizing the Patent protection and scope in the Territory in the Ultragenyx Field. If Ultragenyx's rights with respect to the applicable Licensed Product have not terminated and Takeda determines in its sole discretion to abandon or not maintain any Licensed [***] Patent, Licensed Product Improvement Patent, or, where relating to Licensed Products, Joint Patent that is being prosecuted or maintained by Takeda in the Territory and that is applicable to the in the Ultragenyx Field, then Takeda shall provide Ultragenyx with written notice of such determination within a period of time reasonably necessary to allow Ultragenyx to determine, in its sole discretion, its interest in such Patent(s) (which notice by Takeda shall be given no later than sixty (60) days prior to the final deadline for any pending action or response that may be due with respect to such Patent(s) with the applicable patent authority). If Ultragenyx provides timely written notice expressing its interest in continuing to support such Patent(s), Ultragenyx shall have the right to pursue the filing or support the continued prosecution or maintenance of such Patents and Takeda shall provide to Ultragenyx, subject to reimbursement of Takeda's out-of-pocket costs, all unpublished patent applications and any other information and documents necessary to permit Ultragenyx to take such action to establish or preserve any such Patents. If Ultragenyx pursues the filing or support of such Patents and Takeda continues to pursue a Licensed [***] Product in the Takeda Field, it shall provide Takeda a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding such Patents and drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Ultragenyx shall consider Takeda's comments regarding such communications and drafts in good faith.

62

CONFIDENTIAL TREATMENT REQUESTED

Option Product Patents, Option Product Improvement Patents, and Joint Patents Relating to Research **Products.** Except as otherwise provided in this Section 12.3(b), as between the Parties, Takeda shall have the sole right and authority to prepare, file, prosecute and maintain the Option Product Patents, Option Product Improvement Patents and, where relating to Research Products, Joint Patents on a worldwide basis (including the right to defend in patent office proceedings such as inter partes reviews, post grant reviews and oppositions). Takeda shall bear all costs of preparation, filing, prosecution and maintenance of Option Product Patents, Option Product Improvement Patents and, where relating to Research Products, Joint Patents in the Territory. During the Collaboration Term, Takeda, upon Ultragenyx's request, shall provide Ultragenyx a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding Option Product Patents, Option Product Improvement Patents and, where relating to Research Products, Joint Patents and drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Takeda shall consider Ultragenyx's comments regarding such communications and drafts in good faith with a view to maximizing the Patent protection and scope in the Territory in the Licensed Field; provided that final decision making authority rests with Takeda. If, during the Collaboration Term, Takeda determines in its sole discretion to abandon or not maintain any Option Product Patent, Option Product Improvement Patent and, where relating to Research Products, Joint Patent that is being prosecuted or maintained by Takeda in the Territory, then Takeda shall provide Ultragenyx with written notice of such determination within a period of time reasonably necessary to allow Ultragenyx to determine, in its sole discretion, its interest in such Patent(s) (which notice by Takeda shall be given no later than sixty (60) days prior to the final deadline for any pending action or response that may be due with respect to such Patent(s) with the applicable patent authority). If Ultragenyx provides timely written notice expressing its interest in continuing to support such Patent(s), Ultragenyx shall have the right to pursue the filing or support the continued prosecution or maintenance of such Patents and Takeda shall provide to Ultragenyx, subject to reimbursement of Takeda's out- of-pocket costs, all unpublished patent applications and any other information and documents necessary to permit Ultragenyx to take such action to establish or preserve any such Patents. If Ultragenyx pursues the filing or support of such Patents, it shall provide Takeda a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding such Patents and drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Ultragenyx shall consider Takeda's comments regarding such communications and drafts in good faith. Notwithstanding the foregoing, following the execution of an Option Product License Agreement and/or Exercised Product License Agreement covering an Option Product, the terms of such license agreement(s) shall govern the handling of the preparation, filing, prosecution and maintenance of Patents covering the Option Product(s).

(c) Ultragenyx Pipeline Patents, Ultragenyx Pipeline Improvement Patents, Ultragenyx [***] Patents and Joint Patents Related to Ultragenyx Pipeline Products. Except as otherwise provided in this Section 12.3(c), as between the Parties, Ultragenyx shall have the sole right and authority to prepare, file, prosecute and maintain the Ultragenyx Pipeline Patents, Ultragenyx Pipeline Improvement Patents, Ultragenyx [***] Patents and, where relating to Ultragenyx Pipeline Products, the Patents included in the Joint Inventions (the "Joint Patents"),

63

CONFIDENTIAL TREATMENT REQUESTED

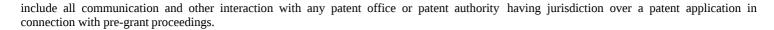
on a worldwide basis (including the right to defend in patent office proceedings such as inter partes reviews, post grant reviews and oppositions). Ultragenyx shall bear all costs of preparation, filing, prosecution and maintenance of Ultragenyx Pipeline Patents, Ultragenyx Pipeline Improvement Patents, Ultragenyx [***] Patents and, where relating to Ultragenyx Pipeline Products, Joint Patents in the Territory. During the Takeda Option Term, Ultragenyx, upon Takeda's request, shall provide Takeda a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding Ultragenyx Pipeline Patents, Ultragenyx Pipeline Improvement Patents, Ultragenyx [***] Patents and, where relating to Ultragenyx Pipeline Products, Joint Patents and drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Ultragenyx shall consider Takeda's comments regarding such communications and drafts in good faith with a view to maximizing the Patent protection and scope in the Territory; provided that final decision making authority rests with Ultragenyx. During the Takeda Option Term, if Ultragenyx determines in its sole discretion to abandon or not maintain any Ultragenyx Pipeline Patent, Ultragenyx Pipeline Improvement Patent, Ultragenyx [***] Patent and, where relating to Ultragenyx Pipeline Products, Joint Patent that is being prosecuted or maintained by Ultragenyx in the Takeda Territory, then Ultragenyx shall provide Takeda with written notice of such determination within a period of time reasonably necessary to allow Takeda to determine, in its sole discretion, its interest in such Patent(s) (which notice by Ultragenyx shall be given no later than sixty (60) days prior to the final deadline for any pending action or response that may be due with respect to such Patent(s) with the applicable patent authority). If Takeda provides timely written notice expressing its interest in continuing to support such Patent(s), Takeda shall have the right to pursue the filing or support the continued prosecution or maintenance of such Patents and Ultragenyx shall provide to Takeda, subject to reimbursement of Ultragenyx's out- of-pocket costs, all unpublished patent applications and any other information and documents necessary to permit Takeda to take such action to establish or preserve any such Patents. If Takeda pursues the filing or support of such Patents, it shall provide Ultragenyx a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding such Patents and drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Takeda shall consider Takeda's comments regarding such communications and drafts in good faith. Notwithstanding the foregoing, following the execution of an Exercised Product License Agreement covering an Ultragenyx Pipeline Product, the terms of such license agreement shall govern the handling of the preparation, filing, prosecution and maintenance of Patents covering such Ultragenyx Pipeline Product.

(d) Cooperation in Prosecution. Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts provided above in this Section 12.3, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution, as well as further actions as set forth below.

(i) The Parties shall respectively prepare, file, maintain and prosecute the Patents as set forth in this Section 12.3. As used herein, "prosecution" of such Patents shall

64

CONFIDENTIAL TREATMENT REQUESTED



(ii) All communications between the Parties relating to the preparation, filing, prosecution or maintenance of the Patents as set forth in this Section 12.3, including copies of any draft or final documents or any communications received from or sent to patent offices or patenting authorities with respect to such Patents, shall be considered Confidential Information and subject to the confidentiality provisions of ARTICLE 14.

12.4 Patent Term Extensions in the Territory.

- (a) The Parties will discuss and approve for which, if any, of the Patents under this Agreement the Parties should seek Patent Term Extensions in the Territory. If the Parties are unable to reach agreement for which, if any, of such Patents the Parties should seek Patent Term Extension, the final decision shall rest with the Party who first receives Regulatory Approval for the Licensed Product or Option Product, as applicable, with respect to which the Patent Term applies for such Party's territory. The Party with final decision-making authority shall act with reasonable promptness in light of the stage of the Products to apply for any such Patent Term Extensions, in accordance with such decision. The Party that does not apply for an extension hereunder will cooperate fully with the other Party in making such filings or actions, including making available all required Regulatory Materials (including underlying data) and Information and executing any required authorizations to apply for such Patent Term Extension. All expenses incurred in connection with activities of each Party with respect to the Patent(s) for which such Party seeks Patent Term Extensions pursuant to this 12.4 shall be entirely borne by the Party applying for such Patent Term Extension.
- 12.5 **Orange Book Listing.** The Party that is the NDA holder for the applicable Product shall be responsible for listing and maintaining all applicable Patents in the Orange Book, including payment of all costs and expenses related to such maintenance incurred after the Effective Date. The listing and maintaining Party shall provide the other Party with its planned listings in advance of their submission with sufficient time for the other Party to review and provide comments. The listing and maintaining Party shall consider any such comments in good faith. Upon request of the listing and maintaining Party, the other Party shall cooperate in the filing of appropriate information with the FDA listing such Patents in the Orange Book.

12.6 Infringement of Patents by Third Parties.

- (a) **Notification**. Each Party shall promptly notify the other Party in writing of any existing, alleged or threatened infringement of the Licensed [***] Patents, Licensed Product Improvement Patents, Ultragenyx [***] Patents, Option Product Improvement Patents, Ultragenyx Pipeline Improvement Patents, and Joint Patents in the Licensed Field in the Territory of which it becomes aware, and shall provide all Information in such Party's possession or control demonstrating such infringement.
 - (b) Infringement Action.

65

CONFIDENTIAL TREATMENT REQUESTED

(i) Takeda shall have the first right, but not the obligation, to bring an appropriate suit or other action against any Third Party engaged in any existing, alleged or threatened infringement related to the Joint Patents, Licensed [***] Patents, Licensed Product Improvement Patents, Ultragenyx [***] Patents, Option Product Patents, and Option Product Improvement Patents, in each case where relating to Licensed Products or Research Products (a "Takeda Product Infringement"), subject to Section 12.6(b)(ii) through 12.6(b)(iv); provided that if a Takeda Product Infringement concerns the enforcement of any Valid Claim against a Third Party making, using, selling, offering for sale, or importing solely within the Ultragenyx Field, Takeda must receive Ultragenyx's prior consent with respect to all strategic decisions in connection with such Takeda Product Infringement, such consent not to be unreasonably withheld, conditioned, or delayed; and provided further that if Takeda is not Developing or Commercializing the Licensed [***] Product in the Takeda Field, then the foregoing first right with respect to a Takeda Product Infringement shall become Ultragenyx's first right hereunder. Ultragenyx shall have the first right, but not the obligation, to bring an appropriate suit or other action against any Third Party engaged in any existing, alleged or threatened infringement related to the Joint Patents, Ultragenyx Pipeline Patents and Ultragenyx Pipeline Improvement Patents, in each case where relating to an Ultragenyx Pipeline Product (an "Ultragenyx Product Infringement"), subject to Section 12.6(b)(ii) through 12.6(b) (iv). Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of the infringement actions relating to the Patents covering such Licensed Option Product or Exercised Product, respectively, that is the subject of such license agreement.

(ii) The Parties shall discuss how to address each Takeda Product Infringement and Ultragenyx Product Infringement and the Party with the first right to enforce shall consider in good faith the input of the other Party in determining how to proceed. The Party with the first right to enforce shall notify the other Party of its election to take any action in accordance with Section 12.6(b) (i) within ten (10) Business Days before any time limit set forth in an Applicable Laws or regulation, including the time limits set forth under the Hatch Waxman Act. In the event such Party does not so elect, it shall so notify the other Party in writing, and the other Party shall have the right to commence a suit or take action to enforce the applicable Patent against such Third Party perpetrating such Takeda Product Infringement or Ultragenyx Product Infringement, as applicable, in the applicable portion of the Territory at its own cost and expense. If one Party elects to bring suit or take action against the Takeda Product Infringement or Ultragenyx Product Infringement, as applicable, then the other Party (at its expense) shall have the right, prior to commencement of the trial, suit or action, to join any such suit or action.

(iii) Each Party shall provide to the Party enforcing any such rights under this Section 12.6(b) reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by Applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any important aspects of such enforcement, including determination of litigation strategy and filing of important papers to the competent court.

66

CONFIDENTIAL TREATMENT REQUESTED

(iv)	Subject to this Section 12.6(b)(iv), the enforcing Party shall be solely responsible for all costs
and expenses arising from a suit or action against	a Takeda Product Infringement or Ultragenyx Product Infringement, as applicable. For the
avoidance of doubt, the enforcing Party shall not be	responsible for the other Party's internal costs (e.g., FTEs) incurred as a result of the other
Party's cooperation with the enforcement action as	provided in Section 12.6(b)(iii). The Party not bringing an action with respect to the Takeda
Product Infringement or Ultragenyx Product Infringe	ement, as applicable, under this Section 12.6(b) shall be entitled to separate representation in
such matter by counsel of its own choice and at its	s own expense, but such Party shall at all times cooperate fully with the Party bringing such
action.	

- (c) Settlement. The enforcing Party may settle any claim, suit or action that it has brought under this Section 12.6 without the prior written consent of the other Party; provided that any such settlement does not negatively impact the non-enforcing Party's rights or interests in such non-enforcing Party's territory or field.
- (d) Allocation of Proceeds. If either Party recovers monetary damages from any Third Party in a suit or action brought under Sections 12.6(b), 12.6(c), or 12.8(b) or any royalties from a license agreement with a Third Party related to any alleged Takeda Product Infringement or Ultragenyx Product Infringement, as applicable, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such suit or action, and any remaining amounts shall be split as follows: (i) if such suit or action is initiated or defended by Ultragenyx, such amounts shall be retained by Ultragenyx, or (ii) if such suit or action was initiated or defended by Takeda, such amounts shall be retained by Takeda.

12.7 Infringement of Third Party Rights in the Territory.

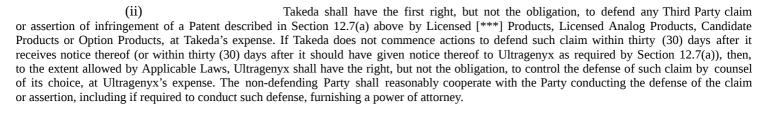
(a) **Notice**. If any Licensed Product used or sold by either Party, its Affiliates, licensees or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent granted in either Party's field or territory, the Party first having notice of the claim or assertion shall promptly notify the other Party, the Parties shall agree on and enter into an "identity of interest agreement" wherein such Parties agree to their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action.

(b) **Defense**.

(i) Ultragenyx shall have the first right, but not the obligation, to defend any Third Party claim or assertion of infringement of a Patent described in Section 12.7(a) above by Ultragenyx Pipeline Products, at Ultragenyx's expense. If Ultragenyx does not commence actions to defend such claim within thirty (30) days after it receives notice thereof (or within thirty (30) days after it should have given notice thereof to Takeda as required by Section 12.7(a)), then, to the extent allowed by Applicable Laws, Takeda shall have the right, but not the obligation, to control the defense of such claim by counsel of its choice, at Takeda's expense. The non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim or assertion, including if required to conduct such defense, furnishing a power of attorney.

67

CONFIDENTIAL TREATMENT REQUESTED



(iii) Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of the defense against infringement by Product(s) that are the subject of the applicable license agreement.

(c) Settlement; Licenses. Neither Party shall enter into any settlement of any claim described in this Section 12.7 that negatively affects the other Party's rights or interests without such other Party's written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Each Party shall have the right to decline to defend or to tender defense of any such claim to the other Party upon reasonable notice, including if the other Party fails to agree to a settlement that such Party proposes. In the event that it is determined by any court of competent jurisdiction that the Exploitation of a Product in the Licensed Field in the Ultragenyx Territory, conducted in accordance with the terms and conditions of this Agreement, infringes, or the JSC determines that such activities are likely to infringe, any patent, copyright, trademark, data exclusivity right or trade secret right arising under Applicable Laws of any Third Party, Ultragenyx shall use Commercially Reasonable Efforts to: (i) procure a license from such Third Party authorizing Ultragenyx to continue to conduct such activities; or (ii) modify such activities so as to render it non-infringing.

12.8 Patent Oppositions and Other Proceedings.

(a) Third-Party Patent Rights. If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, declaration for non-infringement, reexamination or other attack upon the validity, title or enforceability of a Patent owned or controlled by a Third Party and having one or more claims that covers a Product, or the use, sale, offer for sale or importation of a Product (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, a Third Party's claim or assertion of infringement under Section 12.7, in which case the provisions of Section 12.7 shall govern), such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. Ultragenyx shall have the exclusive right, but not the obligation, to bring at its own expense and in its sole control such action in the Territory with respect to Ultragenyx Pipeline Products. Takeda shall have the exclusive right, but not the obligation, to bring at its own expense and in its sole control such action with respect to Licensed [***] Products, Licensed Analog Products and Research Products in the Territory. If the

68

CONFIDENTIAL TREATMENT REQUESTED

Party with the first right does not bring such an action, within ninety (90) days of notification thereof pursuant to this Section 12.8(a) (or earlier, if required by the nature of the proceeding), then the other Party shall have the right, but not the obligation, to bring, at its sole expense, such action. The Party not bringing an action under this Section 12.8(a) shall be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense, and shall cooperate fully with the Party bringing such action. Any awards or amounts received in bringing any such action shall be first allocated to reimburse the initiating Party's expenses in such action and any remaining amounts shall be retained by such Party.

(b) Parties' Patent Rights. If any Licensed [***] Patents, Licensed Product Improvement Patent, Ultragenyx [***] Patents, Option Product Patent, Option Product Improvement Patent, Ultragenyx Pipeline Patent, Ultragenyx Pipeline Improvement Patent, or Joint Patent becomes the subject of any proceeding commenced by a Third Party within the Territory in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 12.6, in which case the provisions of Section 12.6 shall govern), then the Party responsible for filing, preparing, prosecuting and maintaining such Patent as set forth in Section 12.3, shall control such defense at its own cost and expense. The controlling Party shall permit the non-controlling Party to participate in the proceeding to the extent permissible under Applicable Laws, and to be represented by its own counsel in such proceeding, at the non-controlling Party's expense. If the controlling Party decides that it does not wish to defend against such action, then the other Party shall have a backup right to assume defense of such Third-Party action at its own expense. Any awards or amounts received in defending any such Third-Party action shall be allocated between the Parties as provided in Section 12.6(d).

ARTICLE 13 - REPRESENTATIONS AND WARRANTIES

- 13.1 **Mutual Representations, Warranties and Covenants**. Each of the Parties hereby represents and warrants to the other Party as of the Execution Date and covenants that:
- (a) **Organization.** It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.
- (b) **Binding Agreement.** This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).
- (c) **Authorization.** The execution, delivery, and performance of this Agreement by such Party have been duly authorized by all necessary corporate action and do not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Laws or any order, writ, judgment, injunction, decree,

69

CONFIDENTIAL TREATMENT REQUESTED

(d) No Further Approval. Subject to Section 18.1, it is not aware of any government authorization, conse
approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency
instrumentality, domestic or foreign, under any Applicable Laws, currently in effect, necessary for, or in connection with, the transaction
contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of
obligations under this Agreement and such other agreements (save for Regulatory Approvals and similar authorizations from Regulatory
Authorities necessary for the Exploitation of the Compounds and the Products as contemplated hereunder).

determination, or award of any court or governmental body, or administrative or other agency presently in effect applicable to such Party.

- (e) **No Inconsistent Obligations.** Neither Party is under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.
- (f) Transparency Reporting. Each Party shall be responsible for tracking and reporting transfers of value initiated and controlled by its and its Affiliates' employees, independent contractors, and agents pursuant to the requirements of the marketing reporting laws of any Government Authority in the Territory, including Section 6002 of the Patient Protection and Affordable Care Act, commonly referred to as the "Sunshine Act."
- Regulatory Authorities in the Territory, and neither Party nor any of its Affiliates has been debarred by the FDA, is subject to any similar sanction of other Regulatory Authorities in the Territory, and neither Party nor any of its Affiliates has used, or will engage, in any capacity, in connection with this Agreement or any ancillary agreements (if any), any Person who either has been debarred by such a Regulatory Authority, or is the subject of a conviction described in Section 306 of the FFDCA. Each Party shall inform the other in writing promptly if it or any Person engaged by such Party or any of its Affiliates who is performing services under this Agreement or any ancillary agreements (if any) is debarred or is the subject of a conviction described in Section 306 of the FFDCA, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to such Party's Knowledge, is threatened, relating to the debarment or conviction of such Party, any of its Affiliates or any such Person performing services hereunder or thereunder.
- 13.2 **Additional Representations, Warranties and Covenants of Takeda**. Takeda represents and warrants as of the Execution Date and covenants to Ultragenyx that:
- (a) Takeda has all rights necessary to grant the options and licenses under the Licensed [***] Technology and Option Product Technology and rights of cross-reference under Regulatory Materials, in each case, existing as of the Execution Date that it grants to Ultragenyx in this Agreement. For the duration of the Term, Takeda shall not, and shall cause its Affiliates not to, grant to any Third Party rights in the Licensed Field or the Ultragenyx Field, as applicable, in the Territory that encumber, diminish or conflict with the rights granted to

70

CONFIDENTIAL TREATMENT REQUESTED

Ultragenyx hereunder with respect to the Licensed [***] Technology, Option Product Technology, Joint Intellectual Property or Regulatory Materials.
(b) (i) The Patents set forth in <u>Exhibit 1.168</u> represent all Takeda Patents, (ii) to Takeda's Knowledge, the
Compounds set forth in Exhibit 13.2(b) represent all structures Controlled by Takeda that are [***], and
(i) to Takeda's Knowledge, the Compound set forth in Exhibit 1.94 represents the sole Licensed [***] Compound. Takeda (Y) is the sole and
exclusive owner of the entire right, title and interest in the Takeda Patents, and (Z) to Takeda's Knowledge, the sole and exclusive owner of the
entire right, title and interest in the Licensed [***] Compound and Licensed Analog Compounds, and in each of cases (Y) and (Z), free of any
encumbrance, lien, or claim of ownership by any Third Party.

- (c) To Takeda's Knowledge, there is no actual or threatened infringement or misappropriation of the Licensed [***] Technology and Option Product Technology by any Person in the Territory.
- (d) The Takeda Patents are being diligently prosecuted in the Territory in accordance with Applicable Laws. To Takeda's Knowledge, the Takeda Patents have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment.
- (e) To Takeda's Knowledge, each of the Takeda Patents properly identifies each and every inventor of the claims thereof as determined in accordance with Applicable Laws of the jurisdiction in which such Takeda Patent is issued or such application is pending.
- (f) To the extent permissible under Applicable Laws, all employees of Takeda or its Affiliates performing activities under this Agreement are and shall be under an obligation to assign all right, title and interest in and to their Inventions and intellectual property rights therein, to Takeda or its Affiliate(s) as the sole owner thereof. Ultragenyx shall have no obligation to contribute to any remuneration of any inventor employed or previously employed by Takeda or any of its Affiliates in respect of any such Inventions and intellectual property rights therein that are so assigned to Takeda or its Affiliate(s). Takeda will pay all such remuneration due to such inventors with respect to such Inventions and intellectual property rights therein.
- (g) The Inventions claimed or disclosed by the Takeda Patents (i) were not conceived, discovered, developed, or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the U.S. or any agency thereof, (ii) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(f), and (iii) are not otherwise subject to the provisions of the Bayh-Dole Act.
- (h) To Takeda's Knowledge, there are no material claims, judgments, or settlements against, or amounts with respect thereto, owed by Takeda or any of its Affiliates to any Third Parties relating to the Regulatory Materials, Licensed [***] Technology or Option Product Technology in the Territory.

CONFIDENTIAL TREATMENT REQUESTED

(i)	No claim or litigation in the Territory has been brought or, to Takeda's Knowledge, threatened by any Person
alleging, and Takeda has no Kı	nowledge of any claim, whether or not asserted: (i) that any of the Takeda Patents is invalid or unenforceable, (ii)
that the Regulatory Materials,	or the disclosing, copying, making, assigning, or licensing of the Regulatory Materials, violates, infringes, or
otherwise conflicts or interfere	s with, or would violate, infringe, or otherwise conflict or interfere with, any intellectual property or proprietary
right of any Person; or (iii) r	elated to the Development or Commercialization of the Licensed Products or Research Products, including any
claims of Product Liability.	

- (j) Takeda has no Knowledge of any material adverse information with respect to the safety and efficacy of any Licensed Product or Research Product that has not been disclosed to Ultragenyx, and all such information that has been disclosed is true, correct, and complete in all material respects.
- (k) To Takeda's Knowledge, Takeda and its Affiliates have generated, prepared, maintained, and retained all material Regulatory Materials in the Licensed Field that are required to be maintained or retained pursuant to and in accordance with GCP, GLP and other Applicable Laws, and all such information is true, complete and correct in all material respects and what it purports to be.
- (l) Takeda, without the prior written consent of Ultragenyx, during the Term, will not solicit, induce, encourage, or participate in soliciting, inducing, or encouraging any employee of Ultragenyx, or any of its Affiliates, to terminate his or her relationship with Ultragenyx or Ultragenyx's Affiliate. An offer of employment to an employee of Ultragenyx by Takeda which results directly from unsolicited responses to general advertisements for employment will not be deemed to be in violation of this provision.
- (m) In performing its obligations under this Agreement, Takeda shall, and shall cause its Affiliates to, comply with all Applicable Laws, including any applicable anti-corruption or anti-bribery laws or regulation, of any Governmental Authority with jurisdiction over the activities performed by Takeda or its Affiliates in furtherance of such obligations.
- 13.3 **Additional Representations, Warranties and Covenants of Ultragenyx**. Ultragenyx represents and warrants as of the Execution Date and covenants to Takeda that:
- (a) Ultragenyx and its Affiliates have provided or made available to Takeda prior to the Execution Date, true, complete, and correct copies (as of the Execution Date) of all Ultragenyx In-License Agreements.
- (b) Ultragenyx has all rights applicable necessary to grant the options and licenses under the Ultragenyx Intellectual Property and rights of cross-reference under Regulatory Materials, in each case, that it grants to Takeda in this Agreement. For the duration of the Term, Ultragenyx shall not, and shall cause its Affiliates not to, grant to any Third Party rights in the Takeda Field in the Territory or the Licensed Field in the Takeda Territory, as applicable, that encumber, diminish or conflict with the rights granted to Takeda hereunder with respect to the Ultragenyx Intellectual Property, Joint Intellectual Property or Regulatory Materials.

CONFIDENTIAL TREATMENT REQUESTED

(c) owner of the entire right, title and	The Patents set forth in <u>Exhibit 1.188</u> represent all Ultragenyx Patents. Ultragenyx is the sole and exclusive dinterest in the Ultragenyx Patents free of any encumbrance, lien, or claim of ownership by any Third Party.
(d) Intellectual Property by any Perso	To Ultragenyx's Knowledge, there is no actual or threatened infringement or misappropriation of the Ultragenyx on in the Territory.
	The Ultragenyx Patents are being diligently prosecuted in the Territory in accordance with Applicable Laws and rent prosecution practices. To Ultragenyx's Knowledge, the Ultragenyx Patents have been filed and maintained applicable fees have been paid on or before the due date for payment.
(f) claims thereof as determined in a	To Ultragenyx's Knowledge, each of the Ultragenyx Patents properly identifies each and every inventor of the accordance with Applicable Laws of the jurisdiction in which such Ultragenyx Patent is issued or such application

- claims thereof as determined in accordance with Applicable Laws of the jurisdiction in which such Ultragenyx Patent is issued or such application is pending.
- (g) To the extent permissible under Applicable Laws, all employees of Ultragenyx or its Affiliates performing activities under this Agreement shall be under an obligation to assign all right, title and interest in and to their Inventions, and intellectual property rights therein, to Ultragenyx or its Affiliate(s) as the sole owner thereof. Takeda shall have no obligation to contribute to any remuneration of any inventor employed or previously employed by Ultragenyx or any of its Affiliates in respect of any such inventions, Information and discoveries and intellectual property rights therein that are so assigned to Ultragenyx or its Affiliate(s). Ultragenyx will pay all such remuneration due to such inventors with respect to such Inventions and intellectual property rights therein.
- (h) To Ultragenyx's Knowledge, the Inventions claimed or disclosed by the Ultragenyx Patents (i) were not conceived, discovered, developed, or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the U.S. or any agency thereof, (ii) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(f), and (iii) are not otherwise subject to the provisions of the Bayh-Dole Act.
- (i) To Ultragenyx's Knowledge, there are no material claims, judgments, or settlements against, or amounts with respect thereto, owed by Ultragenyx or any of its Affiliates to any Third Parties relating to the Regulatory Materials or the Ultragenyx Intellectual Property in the Territory.
- (j) Ultragenyx has no Knowledge of any material adverse information with respect to the safety and efficacy of any Compound or Product that has not been disclosed to Takeda, and all such information that has been disclosed is true, correct, and complete in all material respects.
- (k) No claim or litigation in the Territory has been brought or, to Ultragenyx's Knowledge, threatened by any Person alleging, and Ultragenyx has no Knowledge of any claim, whether or not asserted: (i) that any of the Ultragenyx Patents is invalid or unenforceable, (ii) that the Regulatory Materials, the Ultragenyx Intellectual Property, or the disclosing, copying,

CONFIDENTIAL TREATMENT REQUESTED

making, assigning, or licensing of the Regulatory Materials or the Ultragenyx Intellectual Property, violates, infringes, or otherwise conflicts or interferes with, or would violate, infringe, or otherwise conflict or interfere with, any intellectual property or proprietary right of any Person; or (iii) related to the Development or Commercialization of the Products, including any claims of Product Liability.

- (l) In performing its obligations under this Agreement Ultragenyx shall, and shall cause its Affiliates to, comply with all Applicable Laws, including any applicable anti-corruption or anti-bribery laws or regulation, of any Governmental Authority with jurisdiction over the activities performed by Ultragenyx or its Affiliates in furtherance of such obligations.
- (m) Ultragenyx, without the prior written consent of Takeda, during the Term, will not solicit, induce, encourage, or participate in soliciting, inducing, or encouraging any employee of Takeda, or any of its Affiliates, to terminate his or her relationship with Takeda or Takeda's Affiliate. An offer of employment to an employee of Takeda by Ultragenyx which results directly from unsolicited responses to general advertisements for employment will not be deemed to be in violation of this provision.
 - (n) [***].
- (o) Ultragenyx has provided Takeda with true and correct copies (as of the Execution Date) of all Ultragenyx In-License Agreements in effect as of the Execution Date. None of Ultragenyx, its Affiliates and, to their Knowledge, any Third Party, is in breach of any Ultragenyx In-License Agreement and none of Ultragenyx, its Affiliates and, to their Knowledge, any other party to any Ultragenyx In-License Agreement has threatened to terminate, or has otherwise alleged any material breach under, such agreement and each Ultragenyx In-License Agreement is in full force and effect in accordance with its terms
- 13.4 No Other Representations or Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 13, THE PARTIES MAKE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, INCLUDING ANY EXPRESS OR IMPLIED WARRANTY OF QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT OR AS TO THE VALIDITY OF ANY PATENTS IN THE TERRITORY.

ARTICLE 14 - CONFIDENTIALITY

14.1 **Nondisclosure.** Each Party agrees that, during the Term and for a period of ten (10) years thereafter, a Party (the "<u>Receiving Party</u>") receiving Confidential Information of the other Party (the "<u>Disclosing Party</u>") 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, (b) not disclose such

74

CONFIDENTIAL TREATMENT REQUESTED

below, and (c) not use such Section 14.1 shall not create of in the foregoing, the obligation	any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted Confidential Information for any purpose except those permitted by this Agreement (it being understood that this or imply any rights or licenses not expressly granted under this Agreement). Notwithstanding anything to the contrary ons of confidentiality and non-use with respect to any trade secret within such Confidential Information shall survive or so long as such Confidential Information remains protected as a trade secret under Applicable Laws.
14.2 Exceptions. Receiving Party can show by	The obligations in Section 14.1 shall not apply with respect to any portion of the Confidential Information that the competent evidence:
(a) hereunder;	is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party
` /	is known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any disclosure by the Disclosing Party;
	is subsequently disclosed to the Receiving Party or any of its Affiliates on a non- confidential basis by a Third Party's Knowledge, is not bound by a similar duty of confidentiality or restriction on its use;
\	is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party or any of its r available, either before or after it is disclosed to the Receiving Party;

- (e) is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates without the use of or access to Confidential Information belonging to the Disclosing Party; or
 - (f) is the subject of written permission to disclose provided by the Disclosing Party.
- 14.3 **Authorized Disclosure.** The Receiving Party may disclose Confidential Information belonging to the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances: filing or prosecuting Patents as permitted by this Agreement;
 - (b) filing Regulatory Materials in order to obtain or maintain Regulatory Approvals;
 - (C) prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation;
- $\qquad \qquad \text{complying with Applicable Laws or regulations or court or administrative orders;} \\$
- (e) to its Affiliates, sublicensees or prospective sublicensees, subcontractors or prospective subcontractors, payors, consultants, agents and advisors on a "need-to-know" basis

CONFIDENTIAL TREATMENT REQUESTED

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 by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than those set forth in this ARTICLE 14; provided, however, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 14.3 to treat such Confidential Information as required under this ARTICLE 14.

- (f) If and whenever any Confidential Information is disclosed in accordance with this Section 14.3, such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to clauses (a) through (d) of this Section 14.3, it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use not less than the same efforts to secure confidential treatment of such information as it would to protect its own confidential information from disclosure and shall be jointly and severally liable for any breach of this ARTICLE 14 by such Person.
- 14.4 **Terms of this Agreement.** The Parties acknowledge that this Agreement and all of the respective terms of this Agreement shall be treated as Confidential Information of both Parties.
- **Publicity.** The Parties shall make a joint public announcement of the execution of this Agreement in the form attached as Exhibit 14.5, which shall be issued at a time to be mutually agreed by the Parties. Each Party agrees not to issue any other press release or other public statement disclosing other information relating to this Agreement or the transactions contemplated hereby that contains information not previously publicly disclosed in accordance with this Section 14.5 without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed.
- Securities Filings. Notwithstanding anything to the contrary in this ARTICLE 14, in the event either Party proposes to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction a registration statement or any other disclosure document that describes or refers to the terms and conditions of this Agreement or any related agreements between the Parties, such Party shall notify the other Party of such intention and shall provide the other Party with a copy of relevant portions of the proposed filing at least ten (10) Business Days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto that refer to the other Party or the terms and conditions of this Agreement or any related agreements between the Parties. The Party making such filing shall cooperate in good faith with the other Party to obtain confidential treatment of the terms and conditions of this Agreement or any related agreements between the Parties that the other Party requests to be kept confidential or otherwise afforded confidential treatment, and shall only disclose Confidential Information that it is reasonably advised by outside counsel is legally required to be disclosed. No such notice and provision of a copy shall be required if the description of or reference to this Agreement or a related agreement

76

CONFIDENTIAL TREATMENT REQUESTED

between the Parties contained in the proposed filing has been included in any previous filing made by the either Party in accordance with this Section 14.6 or otherwise approved by the other Party.

- 14.7 **Relationship to Confidentiality Agreement.** As of the Effective Date, this Agreement supersedes the Confidentiality Agreement; provided however, that all "Confidential Information" disclosed or received by the Parties thereunder shall be deemed Confidential Information hereunder and shall be subject to the terms and conditions of this Agreement.
- **Equitable Relief.** Given the nature of the Confidential Information and the competitive damage that could 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 14. 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 14.
- Publications. All publications relating to the use of the Compound and/or a Product in the Licensed Field shall be prepared, presented and/or published in accordance with pharmaceutical industry accepted guidelines including: (a) International Committee of Medical Journal Editors (ICMJE) guidelines, (b) Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, (c) Pharmaceutical Research and Manufacturers of America (PhRMA) guidelines, and (d) Principles on Conduct of Clinical Trials. Each Party will have the right to publish summaries of results of all Clinical Trials conducted by such Party with respect to the use of a Product in the Licensed Field after the Effective Date; provided, however, that the other Party will have the right to review and comment on all proposed publications prior to submission of such publication. The publishing Party shall provide the other Party at least sixty (60) days prior notice to review and comment on the Clinical Trials results, or non-clinical study results to be published for the purposes of preparing any necessary Patent filings.
- Clinical Trial Transparency. Both Parties agree to collaborate to maintain compliance with all Applicable Laws related to clinical trial transparency, as well as any industry guidelines/codes of conduct, or other obligations that may apply to either the sponsor of any clinical trial and/or the owner of any Regulatory Approval, all as relates to any Research Product or Licensed Product. The Parties shall cooperate to maintain clinical trial transparency consistent with each sponsor's clinical trial registration, summary result, and data sharing transparency policies and will support disclosure of Information as needed based on the needs of the sponsors of the study or the Regulatory Approval holder with respect to any Research Product or Licensed Product.

ARTICLE 15 - TERM AND TERMINATION

15.1 **Term.** This Agreement shall become effective as of the Effective Date and shall continue in full force and effect, unless earlier terminated pursuant to this ARTICLE 15, until the later of the (a) expiration of the Collaboration Term, (b) the expiration of the Takeda Option Term, (c) the expiration of the Licensed Product Royalty Term with respect to all Licensed

77

CONFIDENTIAL TREATMENT REQUESTED

Products in the Territory, or (d) the expiration of the Takeda Royalty Term with respect to all Products the Takeda Territory (the "Term").

15.2 **Termination for Material Breach**.

- Either Party (the "Non-breaching Party") may terminate this Agreement in its entirety (except as otherwise provided in this Section 15.2(a)) if the other Party (the "Breaching Party") has materially breached this Agreement, and such material breach has not been cured within sixty (60) days after receipt of written notice of such breach by the Breaching Party from the Non-Breaching Party (the "Cure Period"); provided, however, that, notwithstanding the foregoing, termination pursuant to this Section 15.2(a) shall be on a Compound-by-Compound and Product-by-Product basis unless such material breach materially diminishes, or materially frustrates, the value of this Agreement to the Non-breaching Party, taken as a whole, in which case the Non-breaching Party may terminate this Agreement in its entirety. Any termination of this Agreement with respect to a Compound or Product, or in its entirety, pursuant to this Section 15.2(a) 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. The right of either Party to terminate this Agreement with respect to a Compound or Product, or in its entirety, as provided in this Section 15.2(a) 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.
- (b) If the Parties reasonably and in good faith disagree as to whether there has been a material breach, including whether such breach was material, the Party that disputes whether there has been a material breach may contest the allegation in accordance with ARTICLE 16. Notwithstanding anything to the contrary contained in Section 15.2(a), the Cure Period for any Dispute will run from the date that written notice was first provided to the Breaching Party by the Non-Breaching Party through the resolution of such Dispute pursuant to ARTICLE 16, and it is understood and acknowledged that, during the pendency of a Dispute pursuant to this Section 15.2(b), 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 under this Agreement.
- (C) Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of termination for material breach with respect to the activities that are the subject of such license agreement (which shall be on the basis of this Section 15.2) and any termination of this Agreement shall not affect the existence of such Option Product License Agreement or Exercised Product License Agreement.

15.3 **Termination for Safety Reasons.**

(a) Each Party shall have the right to terminate this Agreement on a Compound-by- Compound and Product-by-Product basis with respect to such Party's field and territory at any time upon providing ninety (90) days prior written notice to the other Party (i) if senior executives responsible for the terminating Party's pharmacovigilance and clinical science functions determine in good faith that the risk/benefit profile of the Compound or Product is such that the Compound or Product cannot continue to be Developed or administered to patients

78

CONFIDENTIAL TREATMENT REQUESTED

safely; or (b) upon the occurrence of	serious adverse	events r	elate	ed to the	use	of the	Con	npound o	or Prod	uct that	caus	e th	ie termii	nati	ng Part	y to
conclude that the continued use of the	e Compound or	Product	by	patients	will	result	in	patients	being	exposed	to	a p	product	in	which	the
isks outweigh the benefits.																

(b) Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of termination for safety reasons with respect to the activities that are the subject of such license agreement (which shall be on the basis of this Section 15.3) and any termination of this Agreement shall not affect the existence of such Option Product License Agreement or Exercised Product License Agreement.

15.4 **Termination for Convenience**.

- (a) Takeda shall have the right to terminate this Agreement with respect to the Takeda Option for any or no reason upon ninety (90) days written notice.
- (b) Provided that Ultragenyx has completed Development activities for a Licensed [***] Product in the Takeda Field as set forth in the Initial [***] Development Plan pursuant to Section 4.3(a), after the end of the Collaboration Term Ultragenyx shall have the right to terminate this Agreement with respect to any or all Licensed Products in any or all countries for which it has rights with respect to such Licensed Products for any or no reason upon ninety (90) days written notice.
- (c) Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of termination for convenience with respect to the activities that are the subject of such license agreement (which shall be on the basis of this Section 15.4) and any termination of this Agreement shall not affect the existence of such Option Product License Agreement or Exercised Product License Agreement.

15.5 **Termination for Patent Challenge**.

- (a) Takeda may terminate this Agreement with respect to the Licensed Products at any time upon providing written notice to Ultragenyx, if Ultragenyx, or any of Ultragenyx's Affiliates, directly, or indirectly through assistance granted to a Third Party, commences any interference or opposition proceeding, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to any Takeda Patent or any other Patent owned or controlled by Takeda that claims or discloses the composition of matter or the method of making or using a Licensed Product.
- (b) Takeda may terminate this Agreement with respect to all Candidate Products and/or Option Products at any time upon providing written notice to Ultragenyx, if Ultragenyx, or any of Ultragenyx's Affiliates, directly, or indirectly through assistance granted to a Third Party, commences any interference or opposition proceeding, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection

79

CONFIDENTIAL TREATMENT REQUESTED

certificate with respect to any Takeda Patent or any other Patent Controlled by Takeda that claims or discloses the composition of matter or the method of making or using a Candidate Product and/or Option Product.

- (c) Ultragenyx may terminate this Agreement with respect to an Ultragenyx Pipeline Product at any time upon providing written notice to Takeda, if Takeda, or any of Takeda's Affiliates, directly, or indirectly through assistance granted to a Third Party, commences any interference or opposition proceeding, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to any Ultragenyx Patent or any other Patent Controlled by Ultragenyx that claims or discloses the composition of matter or the method of making or using such Ultragenyx Pipeline Product.
- (d) Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of termination for patent challenge with respect to the activities that are the subject of such license agreement (which shall be on the basis of this Section 15.5) and any termination of this Agreement shall not affect the existence of such Option Product License Agreement or Exercised Product License Agreement.

15.6 **Termination for Insolvency**.

- (a) Either 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 an insolvency petition in bankruptcy, 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, and such proceeding or action remains un-dismissed or un-stayed for a period of more than ninety (90) days.
- (b) All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any other jurisdiction outside of the Territory (collectively, the "Bankruptcy Laws"), licenses of rights to "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided pursuant to such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee) shall perform all of the obligations in this Agreement intended to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided for under the Bankruptcy Laws, and the non-bankrupt Party elects to retain its rights hereunder as provided for under the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shall provide to the non-bankrupt Party copies of all Patents and Information necessary for the non-bankrupt Party to prosecute, maintain and enjoy its rights under the terms of this

CONFIDENTIAL TREATMENT REQUESTED

Agreement. All rights, powers and remedies of the non-bankrupt Party as 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 Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws. In particular, it is the intention and understanding of the Parties to this Agreement that the rights granted to the Parties under this Section 15.6 are essential to the Parties' respective businesses and the Parties acknowledge that damages are not an adequate remedy.

(c) Notwithstanding the foregoing, following the execution of an Option Product License Agreement or Exercised Product License Agreement, the terms of such license agreement shall govern the handling of termination for insolvency with respect to the activities that are the subject of such license agreement (which shall be on the basis of this Section 15.6) and any termination of this Agreement shall not affect the existence of such Option Product License Agreement or Exercised Product License Agreement.

15.7 Effects of Termination.

(a) Effects of Termination of Agreement in its Entirety

(i) In the event of a termination of this Agreement in its entirety by Ultragenyx pursuant to Section 15.2 (Breach) and 15.6 (Insolvency), Ultragenyx may elect either of the following options (A) or (B) by providing written notice of its election with its notice of termination:

(A) to effectuate actual termination of this Agreement in its entirety, in which case the following shall apply:

(I) all rights and licenses granted to

Ultragenyx hereunder shall terminate immediately;

(II) all rights and licenses granted by Ultragenyx hereunder shall terminate immediately other than the Takeda [***] License, which license shall become non-exclusive under any intellectual property not assigned to Takeda pursuant to the remainder of this Section 15.7(a)(i)(A), and which license shall apply to the Licensed [***] Compound, Licensed Analog Compounds, Licensed Products and Research Products;

(III) Ultragenyx, as soon as reasonably practical after the effective date of such termination, shall provide to Takeda, as applicable and to the extent permitted under any applicable Third Party contract, (1) any Information, including copies of all Clinical Trial data and results, and the like developed by or for the benefit of Ultragenyx relating to a Licensed Product or Research Product, and (2) other documents to the extent relating to the Licensed [***] Compounds, Licensed Analog Compounds, [***] Compounds, Candidate Products, Licensed Products or Research Products that are necessary for their Exploitation. Ultragenyx will cooperate with Takeda to provide a transfer of such Information and documents at Takeda's expense. At Takeda's request, Ultragenyx shall assign to Takeda any and all agreements to which Ultragenyx, or its Affiliate, and a Third Party are parties, and that govern the Exploitation

81

CONFIDENTIAL TREATMENT REQUESTED

activities conducted in connection with such Compounds or Products prior to such termination, or, if such assignment is not permitted under the relevant agreement: (i) grant to Takeda other rights to provide to Takeda the benefit of such non-assignable agreement, at Takeda's expense, to the extent permitted under the terms of such non-assignable agreement; or (ii) to the extent not permitted under the terms of such non-assignable agreement, the Parties shall discuss in good faith an alternative solution to enable Takeda to receive, at Takeda's expense, the benefit of the terms of such non-assignable agreement. In addition to the actions contemplated in this Section 15.7(a)(i)(A)(III), Ultragenyx shall take such other actions and execute such other instruments, assignments and documents, at Takeda's expense, as may be necessary to effect the transfer of rights to such Compound(s) and Product(s) hereunder to Takeda;

(IV) Ultragenyx shall, at Takeda's expense, transfer to Takeda any and all Regulatory Documentation related to a Licensed Product or Research Product, including any Product INDs and Product Regulatory Approvals and, upon Takeda's request, shall make available to Takeda any other relevant information reasonably related to such Regulatory Documentation; and

(V) effective on the date of termination, Ultragenyx, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign) to Takeda all right, title and interest in and to any Licensed Product Improvements, Licensed Product Improvement Patents, Option Product Improvements, and Option Product Improvement Patents, in each case where Controlled by Ultragenyx or its Affiliates. Ultragenyx will, at Takeda's expense, execute and record assignments and other necessary documents consistent with such change in ownership; or

(B) in lieu of actual termination under (A) above, Ultragenyx may elect that all rights and licenses granted to Ultragenyx hereunder shall continue under this Agreement and any milestone or royalty payments that become due to Takeda by Ultragenyx with respect to Licensed Product after such termination shall be [***] and paid to Takeda in accordance with the payment provisions of this Agreement. This Section 15.7(a)(i)(B) may only be exercised once.

(ii) In the event of a termination of this Agreement in its entirety by Takeda pursuant to Section 15.2 (Breach) or 15.6 (Insolvency), Takeda may elect either of the following options (A) or (B) by providing written notice of its election with its notice of termination:

(A) which case the following shall apply:

to effectuate actual termination of this Agreement in its entirety, in

(I) all rights and licenses granted to Takeda hereunder shall terminate immediately, other than the Takeda [***] License, which license shall become non-exclusive under any intellectual property not assigned to Takeda pursuant to the remainder of this Section 15.7(a)(ii)(A), and which licenses shall apply to the Licensed [***] Compound, Licensed Analog Compounds, Licensed Products and Research Products;

(II) all rights and licenses granted by Takeda hereunder

82

CONFIDENTIAL TREATMENT REQUESTED

(III) if not already completed and

provided, Ultragenyx shall complete and provide a report of the Development activities for the Licensed [***] Product in the Takeda Field as set forth in the Initial [***] Development Plan in accordance with Section 4.3(a);

(IV) Ultragenyx, as soon as reasonably

practical after the effective date of such termination, shall provide to Takeda, as applicable and to the extent permitted under any applicable Third Party contract, (1) any Information, including copies of all Clinical Trial data and results, and the like developed by or for the benefit of Ultragenyx relating to a Licensed Product or Research Product, and (2) other documents to the extent relating to the Licensed [***] Compounds, Licensed Analog Compounds, [***] Compounds, Candidate Products, Licensed Products or Research Products that are necessary for their Exploitation. Ultragenyx will cooperate with Takeda to provide a transfer of such material Information and documents at Ultragenyx's expense. At Takeda's request, Ultragenyx shall assign to Takeda any and all Patents and agreements to which Ultragenyx, or its Affiliate, and a Third Party are parties, and that govern the Exploitation activities conducted in connection with such Compounds or Products prior to such termination, or, if such assignment is not permitted under the relevant agreement: (i) grant to Takeda other rights to provide to Takeda the benefit of such non-assignable agreement, at Ultragenyx's expense, to the extent permitted under the terms of such non-assignable agreement; or (ii) to the extent not permitted under the terms of such non-assignable agreement. In addition to the actions contemplated in this Section 15.7(a)(ii)(A)(IV), Ultragenyx shall take such other actions and execute such other instruments, assignments and documents, at Ultragenyx's expense, as may be necessary to effect the transfer of rights to such Compound(s) and Product(s) hereunder to Takeda;

(V) Ultragenyx shall, at its expense,

transfer to Takeda any and all Regulatory Documentation related to a Licensed Product or Research Product, including any Product INDs and Product Regulatory Approvals and, upon Takeda's request, shall make available to Takeda any other relevant information reasonably related to such Regulatory Documentation; and

(VI) effective on the date of termination,

Ultragenyx, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign) to Takeda all right, title and interest in and to any Licensed Product Improvements, Licensed Product Improvement Patents, Option Product Improvements, and Option Product Improvement Patents, in each case where Controlled by Ultragenyx or its Affiliates. Ultragenyx will, at its expense, execute and record assignments and other necessary documents consistent with such change in ownership; or

(B) in lieu of actual termination under (A) above, Takeda may elect that all rights and licenses granted to Takeda hereunder shall continue under this Agreement and any milestones or royalty payments that become due to Ultragenyx by Takeda with respect to

83

CONFIDENTIAL TREATMENT REQUESTED

any Exercised Product after such termination shall be reduced by fifty percent (50%) and paid to Ultragenyx in accordance with the payment provisions of this Agreement. This Section 15.7(a)(ii)(B) may only be exercised once.
(iii) For clarity, an Exercised Product License Agreement or an Option Product License Agreement shall include termination provisions similar to this Section 15.7(a) and shall otherwise govern the effects of termination of such agreement in its entirety.
(b) Effects of Termination of a Compound or Product for Safety Reasons. In the event of a termination of this Agreement with respect to a particular Compound or Product pursuant to Section 15.3 (for the avoidance of doubt, not a Terminated Product) then:
(i) all license rights received by the terminating Party and all obligations of the terminating Party with respect to the terminated Compound or Product shall cease and, with respect to the terminating Party only, this Agreement shall automatically be deemed to be amended to exclude such rights and obligations of the terminating Party with respect to the terminated Compound or Product but shall otherwise survive and continue in effect for the remaining Compounds and Products; and
(ii) the non-terminating Party shall continue to have all rights and obligations under this Agreement with respect to the terminated Compound or Product (including the obligation to make royalty, milestone and other payments to the

(c) **Effects of Termination with Respect to a Terminated Product.** In the event of termination of this Agreement with respect to a Terminated Product (but not in the case of any termination of this Agreement in its entirety) then:

terminating Party) unless it also elects to terminate the particular Compound or Product pursuant to Section 15.3.

(i) all rights and licenses granted hereunder by either Party shall automatically be deemed to be amended to exclude the Terminated Product but shall otherwise survive and continue in effect for the remaining Compounds and Products;

(ii) in the case of termination for convenience pursuant to Section 15.4, if an Option Negotiation Period or Takeda Option Negotiation Period is then ongoing, the Term with respect to such Option Product or Exercised Product, as applicable, will automatically extend until the earlier of (A) expiration of such Option Negotiation Period or Takeda Option Negotiation Period, as applicable, or (B) execution of the applicable Option Product License Agreement;

(iii) if the Terminated Product is a Licensed Product, if not already completed and provided, Ultragenyx shall complete and provide a report of the Development activities for the Licensed [***] Product in the Takeda Field as set forth in the Initial [***] Development Plan in accordance with Section 4.3(a);

(iv) Ultragenyx, as soon as reasonably practical after the effective date of such termination, shall provide to Takeda, as applicable and to the extent permitted under any

84

CONFIDENTIAL TREATMENT REQUESTED

applicable Third Party contract, (A) any Information, including copies of all Clinical Trial data and results, and the like developed by or for the benefit of Ultragenyx relating to a Terminated Product, and (B) other documents to the extent relating to the Terminated Products that are necessary for their Exploitation. Ultragenyx will cooperate with Takeda to provide a transfer of such material Information and documents. Ultragenyx shall assign to Takeda any and all Patents and agreements to which Ultragenyx, or its Affiliate, and a Third Party are parties, and that govern the Exploitation activities conducted in connection with a Terminated Product prior to such termination, or, if such assignment is not permitted under the relevant agreement: (1) grant to Takeda other rights to provide to Takeda the benefit of such non-assignable agreement to the extent permitted under the terms of such non-assignable agreement; or (2) to the extent not permitted under the terms of such non-assignable agreement, the Parties shall discuss in good faith an alternative solution to enable Takeda to receive the benefit of the terms of such non-assignable agreement. In addition to the actions contemplated in this Section 15.7(c)(iv), Ultragenyx shall take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights to such Terminated Products hereunder to Takeda. Each Party shall bear its own expenses under this Section 15.7(c)(iv);

- (v) Ultragenyx shall transfer to Takeda any and all Regulatory Documentation directly and solely related to a Terminated Product, including any Product INDs and Product Regulatory Approvals and, upon Takeda's request, shall make available to Takeda any other relevant information reasonably related to such Regulatory Documentation;
- (vi) effective on the date of termination, Ultragenyx, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign) to Takeda all right, title and interest in and to any Licensed Product Improvements, Licensed Product Improvement Patents, Option Product Improvements, and Option Product Improvement Patents to the extent the foregoing Cover a Terminated Product and are Controlled by Ultragenyx or its Affiliates. Ultragenyx will execute and record assignments and other necessary documents consistent with such change in ownership; and
- (vii) Takeda shall have the right to assume all prosecution, maintenance, and enforcement activities with respect to Patents under this Agreement Covering the Terminated Products. Ultragenyx will cooperate with Takeda and provide Takeda with reasonable assistance and cooperation with the prosecution, maintenance, and enforcement activities with respect to such Patents.
- (d) Effect of Termination on Ultragenyx's Put Rights under the Common Stock Purchase Agreement. Immediately upon (i) written notice of termination of this Agreement in its entirety pursuant to Section 15.2, or 15.6, (ii) written notice of termination of a Licensed Product or Research Product pursuant to Section 15.2, 15.3, 15.4, 15.5, 18.5 or (iii) upon the Ultragenyx [***] License terminating pursuant to Section 4.3(f), Ultragenyx's rights under the Common Stock Purchase Agreement to require the purchase of the Second Tranche Shares and Third Tranche Shares (as such terms are defined in the Common Stock Purchase Agreement) shall be suspended and such rights shall automatically terminate on the effective date of such termination, provided, however, there shall be no suspension or termination of such Ultragenyx

85

CONFIDENTIAL TREATMENT REQUESTED

rights under the Common Stock Purchase Agreement to the extent Ultragenyx terminates the Agreement, a Licensed Product or Research Product pursuant to Section 15.2. Where written notice of termination pursuant to Section 15.2 is provided by Takeda, and Ultragenyx cures all material breaches during the Cure Period, the suspension shall be removed on the effective date of such cure.

15.8 Effect of Expiration

- (a) **Expiration of Collaboration Term.** Upon expiration of the Collaboration Term for a given Research Product:
- (i) All rights to such Research Product shall revert to Takeda except for those rights, if any, granted to Ultragenyx under an Option Product License Agreement;
- (ii) As soon as reasonably practical after the effective date of expiration of the Collaboration Term for a given Research Product, Ultragenyx shall, except where otherwise provided under an Option Product License Agreement, provide to Takeda, as applicable and to the extent permitted under any applicable Third Party contract (1) any Information, including copies of all Clinical Trial data and results, and the like developed by or for the benefit of Ultragenyx relating to such Research Product and (2) other documents to the extent relating to such Research Product that are necessary for their continued Exploitation. Ultragenyx will cooperate with Takeda to provide a transfer of such material Information and documents. At Takeda's request, Ultragenyx shall assign to Takeda any and all Patents and agreements to which Ultragenyx, or its Affiliate, and a Third Party are parties, and that govern the Exploitation activities conducted in connection with such Research Product prior to such expiration, or if such assignment is not permitted under the relevant agreement: (i) grant to Takeda other rights to provide to Takeda the benefit of such non-assignable agreement to the extent permitted under the terms of such non-assignable agreement; or (ii) to the extent not permitted under the terms of such non-assignable agreement. In addition to the actions contemplated in this Section 15.8(a)(ii), Ultragenyx shall take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights to such Product to Takeda. Each Party shall bear its own expenses under this Section 15.8(a)(ii);
- (iii) Ultragenyx shall transfer to Takeda any and all Regulatory Documentation directly and solely related to such Research Product, including any Product INDs and Product Regulatory Approvals and, upon Takeda's request, shall make available to Takeda any other relevant information reasonably related to such Regulatory Documentation; and
- (iv) Takeda shall have the right to assume all prosecution, maintenance, and enforcement activities with respect to Patents under this Agreement Covering such Research Product. Ultragenyx will cooperate with Takeda and provide Takeda with reasonable assistance and cooperation with the prosecution, maintenance, and enforcement activities with respect to such Patents.

86

CONFIDENTIAL TREATMENT REQUESTED

- (b) **Expiration of Licensed Product Royalty Term.** Upon the expiration of the Licensed Product Royalty Term for each Licensed Product in each country in the Territory, Ultragenyx shall have a non-exclusive, fully-paid up and irrevocable license under the Licensed [***] Technology with respect to such Licensed Product in such country in the Ultragenyx Field for Licensed Products.
- (c) Expiration of Exercised Product License Agreement and Option Product License Agreement. Each Exercised Product License Agreement and Option Product License Agreement shall provide that, upon expiration of the applicable royalty term, Takeda shall have a non-exclusive, fully-paid up and irrevocable license with respect to the Exercised Products and Licensed Option Products, respectively.
- Remedies. Notwithstanding anything to the contrary in this Agreement, except as otherwise set forth in this Agreement, termination or expiration of this Agreement shall not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration, nor prejudice either Party's right to obtain performance of any obligation. Each Party shall be free, pursuant to ARTICLE 16, to seek, without restriction as to the number of times it may seek, damages, costs and remedies that may be available to it under Applicable Laws or in equity and shall be entitled to offset the amount of any damages and costs obtained against the other Party in a final determination under Section 16.4, against any amounts otherwise due to such other Party under this Agreement.
- Survival. The following provisions shall survive any expiration or termination of this Agreement for the period of time specified therein (or, if no such period is specified, indefinitely): ARTICLE 1 (Definitions); ARTICLE 16 (Dispute Resolution); and ARTICLE 17 (Indemnification); and Sections 4.5 (Records; Disclosure of Data and Results), 6.6(b) (Research Materials Transfer), 11.9, 11.10, 11.11, 11.12, 11.13 (Payment, Taxes, Audit); 12.1 (Ownership of Inventions); 14.1, 14.2, 14.3, 14.4, 14.5, 14.6, 14.7, 14.8 (Confidentiality); 15.7, 15.8, 15.9, 15.10 (Termination); 18.3, 18.7, 18.8, 18.9, 18.10, 18.14, 18.15, 18.16, and 18.17 (Miscellaneous).

ARTICLE 16 - DISPUTE RESOLUTION

- 16.1 **Exclusive Dispute Resolution Mechanism.** Except for disputes for which a Party has final decision making authority under this Agreement, including Sections 2.1(b)(ii), 2.2(c)(ii) and 12.4, the Parties agree that the procedures set forth in this ARTICLE 16 shall be the exclusive mechanism for resolving any dispute, controversy, or claim between the Parties that may arise from time to time pursuant to this Agreement relating to either Party's rights or obligations hereunder (each, a "<u>Dispute</u>", and collectively, the "<u>Disputes</u>") that is not resolved through good faith negotiation between the Parties.
- Resolution by Executive Officers. In the event of any Dispute, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within ten (10) Business Days after receipt of writing notice of such Dispute by a Party, either Party may, by written notice to the other Party, refer the Dispute to the Senior Officers of the other Party for

87

CONFIDENTIAL TREATMENT REQUESTED

attempted resolution by good faith negotiation within thirty (30) days after such notice is received. Except where exclusive decision-making authority rests with a Party under this Agreement (including Sections 2.1(b)(ii), 2.2(c)(ii) and 12.4), each Party may, in its sole discretion, seek resolution of any and all Disputes that are not resolved under this Section 16.2 using (a) arbitration pursuant Section 16.3 where arbitration pursuant to Section 16.3 is specifically provided for in this Agreement or (b) otherwise, pursuant to Section 16.4.

- **Baseball Arbitration.** Any Dispute for which arbitration pursuant to this Section 16.3 is specifically provided for in this Agreement shall be finally decided by expedited arbitration in accordance with the following abbreviated dispute resolution procedures:
- (a) If the Dispute is not resolved within thirty (30) days after referral to the Party's respective Senior Officers pursuant to Section 16.2, either Party may send the other Party a written notice that it wishes to resolve the Dispute by using a neutral Third Party who is an Expert with at least fifteen (15) years of experience in area of the Dispute (the "Neutral Expert"). The date of the other Party's receipt of such written notices shall be the "Notice Date."
- (b) Within fifteen (15) Business Days of the Notice Date, each Party shall notify the other Party in writing of its appointed Expert (each, a "Representative Expert"). The Representative Experts for each Party shall jointly appoint the Neutral Expert within fifteen (15) Business Days.
- (c) Within ten (10) Business Days after the appointment of the Neutral Expert, each Party shall submit to the other Party and the Neutral Expert a written summary regarding its position with respect to the Dispute. Contemporaneously with the submission of its written summary regarding its position, each Party shall provide the other Party and the Neutral Expert with copies of all documents it relied upon in its written summary; provided that each Party may redact any portion of such documents which are covered by an applicable privilege or do not relate to the subject matter of this Agreement. Within three (3) Business Days of receipt of the other Party's written summary regarding its position, each Party may submit an opposition statement of no more than five (5) pages in length (excluding exhibits and declarations). Neither Party will be allowed to conduct any discovery. Neither Party may have any communications (either written or oral) with the other Party's Representative Experts or the Neutral Expert other than for the sole purpose of engaging the expert panel or as expressly permitted in this Section 16.3; provided, that oral presentations and follow-up written submissions may be made to the Neutral Expert at such Neutral Expert's request. The Neutral Expert may consult in writing with the Representative Experts regarding the submissions made by either Party; provided that both Representative Experts are aware of such consultation and provided an opportunity to respond. Evaluating each Party's written submissions, the Neutral Expert shall, within ten (10) Business Days of receipt of the written opposition statement, select in total, either Takeda's submission or Ultragenyx's submission. Such decision shall be final, binding and not appealable.
- (d) The Party whose submission is not selected shall be solely responsible for the expenses and fees of the Neutral Expert and the reasonable costs and fees of the other Party's Representative Expert.

88

CONFIDENTIAL TREATMENT REQUESTED

- 16.4 **Litigation.** Any unresolved Dispute that was subject to Section 16.2, shall be brought exclusively in a court of competent jurisdiction, federal or state, located in New York, New York, and in no other jurisdiction. Each Party hereby consents to personal jurisdiction and venue in, and agrees to service of process issued or authorized by, such court.
- 16.5 **Preliminary Injunctions.** Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrator(s) on the ultimate merits of any Dispute.
- 16.6 **Patent and Trademark Disputes.** Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the scope, construction, validity, and enforceability of any Patent or trademark relating to a Product that is the subject of this Agreement shall be determined in a court or other tribunal, as the case may be, of competent jurisdiction under the applicable patent or trademark laws of the country in which such Patent or trademark rights were granted or arose.
- 16.7 **Confidentiality.** Any and all activities conducted under ARTICLE 16, including any and all proceedings and decisions under Section 16.4, shall be deemed Confidential Information of each of the Parties, and shall be subject to ARTICLE 14.
- 16.8 WAIVER OF RIGHT TO JURY TRIAL. In connection with the Parties' rights under Section 16.4, EACH PARTY, TO THE EXTENT PERMITTED BY APPLICABLE LAWS, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES. THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE.

ARTICLE 17 - INDEMNIFICATION

Indemnification by Ultragenyx. Ultragenyx hereby agrees to defend, indemnify and hold harmless Takeda and its Affiliates, and each of their respective directors, officers, employees, agents and representatives (each, a "Takeda Indemnitee") from and against any and all claims, suits, actions, demands, liabilities, expenses and/or loss, including reasonable legal expense and attorneys' fees (collectively, the "Losses"), to which any Takeda Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (each, a "Claim") to the extent such Losses arise directly or indirectly out of: (i) the practice by Ultragenyx or its Affiliate of any license granted to it under ARTICLE 3; (ii) the Exploitation of a Compound or a Product by Ultragenyx, its Affiliates or its sublicensees on or after the Effective Date, including, for the avoidance of doubt, any Product Liabilities arising from the use of a Product in the Licensed Field in the Territory on or after the Effective Date and any Losses that may arise due to Ultragenyx, its Affiliates or its sublicensees continuing to Exploit a Compound or Product in its territory or field that is the subject matter of a termination by Takeda pursuant to Section 15.3; (iii) the Exploitation of any Ultragenyx Pipeline Product by Ultragenyx, its Affiliates or its licensees before the Effective Date, including, for the avoidance

89

CONFIDENTIAL TREATMENT REQUESTED

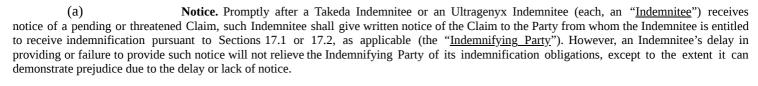
of doubt, any Product Liabilities arising from the use of a Ultragenyx Pipeline Product; (iv) the breach by Ultragenyx of any warranty, representation, covenant or agreement made by Ultragenyx in this Agreement; (v) the negligence, gross negligence or willful misconduct (including to the extent such negligence, gross negligence or willful misconduct gives rise to Product Liabilities under any legal theory) of Ultragenyx, its Affiliate or its sublicensee, or any officer, director, employee, agent or representative thereof; except, with respect to each of subsections (i) through (v) above, to the extent such Losses arise directly or indirectly from the negligence, gross negligence or willful misconduct of any Takeda Indemnitee or the breach by Takeda of any warranty, representation, covenant or agreement made by Takeda in this Agreement. Notwithstanding the foregoing, following the execution of an Exercised Product License Agreement or Option Product License Agreement, the terms of such license agreement shall govern the indemnification terms with respect to such Product(s) that are the subject of such license agreement.

17.2 Indemnification by Takeda. Takeda hereby agrees to defend, indemnify and hold harmless Ultragenyx and its Affiliates and each of their respective directors, officers, employees, agents and representatives (each, an "Ultragenyx Indemnitee") from and against any and all Losses to which any Ultragenyx Indemnitee may become subject as a result of any Claim to the extent such Losses arise directly or indirectly out of: (i) the practice by Takeda or its Affiliate of any license granted to it under ARTICLE 3; (ii) the Exploitation of a Product by Takeda, its Affiliates or its sublicensees on or after the Effective Date, including, for the avoidance of doubt, any Product Liabilities arising from the use on or after the Effective Date of a Licensed [***] Product in the Takeda Field in the Territory and any Losses that may arise due to Takeda, its Affiliates or its sublicensees continuing to Exploit a Compound or Product in its territory or field that is the subject matter of a termination by Ultragenyx pursuant to Section 15.3; (iii) the Exploitation of any Licensed [***] Product, [***] Product or Candidate Product by Takeda, its Affiliates or its licensees before the Effective Date, including, for the avoidance of doubt, any Product Liabilities arising from the use of a Licensed [***] Product, [***] Product or Candidate Product by Takeda, its Affiliates or its licensees before the Effective Date, (iv) the breach by Takeda of any warranty, representation, covenant or agreement made by Takeda in this Agreement; (iv) the negligence, gross negligence or willful misconduct (including to the extent such negligence, gross negligence or willful misconduct gives rise to product liability Claims under any legal theory) of Takeda or its Affiliate or its licensee (other than Ultragenyx or its Affiliate or sublicensee), or any officer, director, employee, agent or representative thereof; except, with respect to each of subsections (i) through (iv) above, to the extent such Losses arise directly or indirectly from the negligence, gross negligence or willful misconduct of any Ultragenyx Indemnitee or the breach by Ultragenyx of any warranty, representation, covenant or agreement made by Ultragenyx in this Agreement. Notwithstanding the foregoing, following the execution of an Exercised Product License Agreement or Option Product License Agreement, the terms of such license agreement shall govern the indemnification terms with respect to such Product(s) that are the subject of such license agreement.

17.3 **Indemnification Procedures**.

90

CONFIDENTIAL TREATMENT REQUESTED



- (b) **Defense.** Upon receipt of notice under Section 17.3(a) from the Indemnitee, the Indemnifying Party will have the duty to either compromise or defend, at its own expense and by counsel (reasonably satisfactory to Indemnitee), such Claim. The Indemnifying Party will promptly (and in any event not more than twenty (20) days after receipt of the Indemnitee's original notice) notify the Indemnitee in writing that it acknowledges its obligation to indemnify the Indemnitee with respect to the Claim pursuant to this ARTICLE 17 and of its intention either to compromise or defend such Claim. Once the Indemnifying Party gives such notice to the Indemnitee, the Indemnifying Party is not liable to the Indemnitee for the fees of other counsel or any other expenses subsequently incurred by the Indemnitee in connection with such defense, other than the Indemnitee's reasonable costs of investigation and cooperation. However, the Indemnitee will have the right to employ separate counsel and to control the defense of a Claim at its own expense.
- (c) Cooperation. The Indemnitee will cooperate fully with the Indemnifying Party and its legal representatives in the investigation and defense of any Claim. The Indemnifying Party will keep the Indemnitee informed on a reasonable and timely basis as to the status of such Claim (to the extent the Indemnitee is not participating in the defense of such Claim) and conduct the defense of such Claim in a prudent manner.
- (d) **Settlement.** If an Indemnifying Party assumes the defense of a Claim, no compromise or settlement of such Claim may be effected by the Indemnifying Party without the Indemnitee's written consent (which consent will not be unreasonably withheld, conditioned or delayed), unless: (i) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnitee; (ii) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party; and (iii) the Indemnitee's rights under this Agreement are not adversely affected. If the Indemnifying Party fails to assume defense of a Claim within a reasonable time, the Indemnitee may settle such Claim on such terms as it deems appropriate with the consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed), and the Indemnifying Party will be obligated to indemnify the Indemnitee for such settlement as provided in this ARTICLE 17.
- 17.4 **Insurance.** Each Party shall, at its own expense, procure and maintain during the Term and for a period of five (5) years thereafter, insurance policy/policies, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such insurance shall not be construed to create a limit of a Party's liability with respect to its indemnification obligations

CONFIDENTIAL TREATMENT REQUESTED

under this ARTICLE 17. Each Party shall provide the other Party with written evidence of such insurance or self-insurance upon request. Each Party shall provide the other Party with prompt written notice of cancellation, non-renewal or material change in such insurance or self- insurance that could materially adversely affect the rights of such other Party hereunder, and shall provide such notice within thirty (30) days after any such cancellation, non-renewal or material change.

17.5 Limitation of Liability. EXCEPT FOR A PARTY'S OBLIGATIONS SET FORTH IN THIS ARTICLE 17, AND ANY BREACH OF ARTICLE 14 (CONFIDENTIALITY), IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES OR SUBLICENSES) IN CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 18 - MISCELLANEOUS

18.1 HSR Act.

Each of Ultragenyx and Takeda shall, within ten (10) Business Days after Execution Date, file with the United (a) States Federal Trade Commission and the Antitrust Division of the United States Department of Justice, any HSR Filing required of it under the HSR Act with respect to the subject matter of this Agreement, which forms shall specifically request early termination of the initial HSR Act waiting period. The Parties will cooperate with one another to the extent necessary in the preparation of any such HSR Filing. The Parties hereto commit to instruct their respective counsel to cooperate with each other and use good faith, diligent efforts to facilitate and expedite the identification and resolution of any such issues and, consequently, the expiration of the applicable HSR Act waiting period, such good faith diligent efforts to include counsel's undertaking: (i) to keep each other appropriately informed of communications received from and submitted to personnel of the reviewing antitrust authority; and (ii) to confer with each other regarding appropriate contacts with and response to personnel of the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice. Each Party will be responsible for its own costs and expenses and Ultragenyx will be responsible for all filing fees associated with any HSR Filing. In respect of any HSR Filing, each of Ultragenyx and Takeda will use its good faith, diligent efforts to eliminate any concern on the part of any court or governmental authority regarding the legality of the proposed transaction, including cooperating in good faith with any government investigation and the prompt production of documents, information, and witnesses requested in the course of such of any such investigation, including those contained in a Request for Additional Information and Documentary Materials (as that term is defined in the HSR Act), and to cause the Effective Date of this Agreement to occur as soon as practical, as provided in Section 18.1(b). Nothing in this Section shall require either Party to consent to the divestiture or other disposition of any of its or its Affiliates' assets or to consent to any other structural or conduct remedy, and each Party and

92

CONFIDENTIAL TREATMENT REQUESTED

its Affiliates shall hav	e no obligati	ion to cont	est, admin	stratively	or in court,	any ruling,	order or	other a	action o	of the 1	United	States	Federal	Trade
Commission and the	Antitrust Di	ivision of	the United	States De	epartment o	f Justice or	any Thir	d Party	respec	cting th	ne trans	actions	contem	plated
by this Agreement.														

- (b) Except for the specific provisions expressly identified in Section 18.1(c), this Agreement shall not be effective until the (i) the HSR Conditions are met and (ii) the earlier of (A) the date on which the Tax Conditions are met, or (B) July 18, 2016, at which time this Agreement shall be effective automatically in its entirety (such date the "Effective Date").
- (c) Notwithstanding Section 18.1(b) and anything in this Agreement to the contrary, the following provisions of this Agreement shall be in full force and effect as of the Execution Date: Sections 14.5 (Publicity) and 14.6 (Securities Filings), ARTICLE 1 (Definitions) and ARTICLE 18 (other than Sections 18.2, 18.5 and 18.6) (Miscellaneous).
- (d) If the Effective Date has not occurred within one hundred eighty (180) days following the Execution Date, or such date as the Parties may mutually agree, this Agreement may be terminated by either Party on written notice to the other.

18.2 Exports and Restrictions on Competition.

- (a) **Exports.** Except as provided in this Agreement, each Party shall not, and shall cause its Affiliates and sublicensees not to, whether directly or indirectly through a Third Party, export, distribute or sell:
- (i) in the case of Ultragenyx, (A) Licensed [***] Products outside the Ultragenyx Field or outside the Territory, (B) Licensed Analog Products outside the Licensed Field or outside the Territory, (C) Research Products unless and until an Option Product License Agreement is executed for such Products and then only in accordance with such Option Product License Agreement; provided further that, if the Takeda Option has been exercised for a given Product Ultragenyx may not export, distribute or sell such Product in the Takeda Territory.

In the case of Takeda, Ultragenyx Pipeline Products outside of the Takeda

Territory.

(ii)

(b) Non-Competition Obligations. Ultragenyx shall not, and shall cause its Affiliates not to, whether directly or indirectly through a Third Party (including any sublicensee), (i) develop a Competing Product in the Territory at any time prior to the [***] of the Effective Date or (ii) commercialize a Competing Product in the Territory at any time prior to the [***] of the First Commercial Sale of a Product. Ultragenyx shall not be in breach of this Section 18.2(b) by acquiring, merging or consolidating with a Third Party which develops or commercializes a Competing Product; provided, however, that in the event Ultragenyx acquires such Competing Product, it must, unless Takeda agrees to the contrary, within [***] of such acquisition, either divest such Competing Product to a Third Party, discontinue the development or commercialization of such Competing Product, or, if applicable, terminate

93

CONFIDENTIAL TREATMENT REQUESTED

this Agreement with respect to the Licensed Product that is the subject of competition in accordance with Section 15.4.

18.3 **Notice.** Any notice, request, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be hand delivered or sent by a recognized overnight delivery service, costs prepaid, or by facsimile (with transmission confirmed), to the following addresses or to such other addresses as a Party may designate by written notice in accordance with this Section 18.3:

If to Takeda:

Takeda Pharmaceutical Company Limited 1-1, Doshomachi 4-

chome,

Chuo-ku, Osaka 540-8645

Attention: Head of Global Business Development Facsimile: (+81) 3-3278-2323

Copy to:

Takeda Pharmaceuticals U.S.A., Inc. One Takeda Parkway

Deerfield, IL 60015

Attention: General Counsel, Legal Department Facsimile: 224-554-7831

If to Ultragenyx:

Ultragenyx Pharmaceutical Inc. 60 Leveroni Court

Novato, CA 94949

Attention: Chief Business Officer

Copy to:

Cooley LLP

3175 Hanover Street Palo Alto, CA 94304 Attention: Glen Sato

Fax: 650-849-7400

Designation of Affiliates. Each Party may discharge any obligations and exercise any rights hereunder through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party

94

CONFIDENTIAL TREATMENT REQUESTED

may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

18.5 Change of Control of Ultragenyx.

- (a) **Notice**. Ultragenyx (or its successor) shall provide notice to Takeda of any Change of Control of Ultragenyx within [***] Business Days after the date upon which the Ultragenyx Change of Control closes or otherwise becomes effective.
- (b) **Effects of Change of Control of Ultragenyx**. In the event of a Change of Control of Ultragenyx, the following shall apply:
- (i) The Takeda Option Term applicable in the event of a Change of Control of Ultragenyx shall apply.
- (ii) On or before the date that is one hundred eighty (180) days after the date upon which a Change of Control of Ultragenyx closes or otherwise becomes effective, Takeda may take or require that Ultragenyx, or its successor, take or perform, as applicable, any one or more of the following actions: (A) Ultragenyx and its successor shall adopt reasonable written procedures, approved by Takeda, to prevent disclosure of Takeda's Confidential Information, (B) the definition of Licensed Analog Compounds shall be amended to be limited to those Compounds listed on Exhibit 1.99 as of the effective date of the Ultragenyx Change of Control, provided that if Ultragenyx has paid costs in connection with the Development of a Licensed Analog Compound, such Licensed Analog Compound shall be listed on Exhibit 1.99, as amended, (C) Section 5.1 shall be amended to require Takeda's written consent in order for Ultragenyx and its successor to exercise its rights to co-Commercialize and Co-Develop thereunder to the extent Ultragenyx has not previously exercised such right(s), and (D) Takeda may terminate, in its sole discretion, one or more of the ongoing Validation Research Plans and Research Plans, in which case any associated licenses to Ultragenyx and its successor under Section 6.5 shall terminate, and any Research Products designated by Takeda shall be deemed Terminated Products; provided that to the extent that Ultragenyx has paid costs in connection with the Development of a Research Product on or before such date, such Validation Research Plan or Research Plan, as applicable, and associated licenses to Ultragenyx or its successor shall continue in full force and effect and such Research Products shall not be deemed Terminated Products under this Section 18.5(b)(ii). For clarity, termination pursuant to this Section 18.5(b)(ii) shall not terminate the Collaboration Term for any purposes under this Agreement other than the foregoing clause (D).
- 18.6 **Force Majeure.** Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a Force Majeure affecting such Party. If a Force Majeure persists for more than ninety (90) days,

95

CONFIDENTIAL TREATMENT REQUESTED

then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such Force Majeure.

- Assignment. Prior to the Effective Date, neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other. On or after the Effective Date, neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other; provided that no such consent is required for (a) assignment to Affiliates or (b) in connection with the sale of all or substantially all of the assets to which this Agreement relates, whether in a merger, sale of stock, sale of assets or any other transaction (subject, in the case of Ultragenyx, to Section 18.5). Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section shall be null, void and of no legal effect.
- **Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.
- 18.9 **English Language.** This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement, shall be in the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.
- 18.10 **Waiver and Non-Exclusion of Remedies.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Laws or otherwise available except as expressly set forth herein.
- **Further Assurance.** Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof.

96

CONFIDENTIAL TREATMENT REQUESTED

- Relationship of the Parties. It is expressly agreed that Takeda, on the one hand, and Ultragenyx, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Takeda nor Ultragenyx shall have the authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other, without the prior written consent of the other Party to do so. All persons 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. For clarity, (a) if Takeda provides Research Support for an Ultragenyx Pipeline Product (other than Exercised Products) or Licensed Option Product (in connection with an Option Product License Agreement), Takeda shall be deemed an independent contractor in the performance of such Research Support and (b) in no case shall Takeda provide Research Support with respect to a Licensed Product.
- 18.13 **Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile, .pdf or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were the original signatures.
- 18.14 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, and the use of any gender shall be applicable to all genders. Whenever this Agreement refers to a number of days, such number refers to calendar days. The terms "including," "include," or "includes" as used herein shall mean "including, but not limited to," and shall not limit the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. 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 apply against the Party which drafted such terms and provision.
- **Governing Laws.** This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.
- 18.16 Entire Agreement. This Agreement, including the Exhibits hereto, and the Common Stock Purchase Agreement set forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Execution Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof; provided, that, until the Effective Date, the Confidentiality Agreement shall continue in full force and effect in accordance with its terms.

CONFIDENTIAL TREATMENT REQUESTED

Except as provided in the Common Stock Purchase Agreement, there are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. In the event of any inconsistency between the body of this Agreement and the Exhibits to this Agreement, the Common Stock Purchase Agreement, or any subsequent agreements ancillary to this Agreement, unless otherwise expressly stated to the contrary in such Exhibit, Common Stock Purchase Agreement or subsequent ancillary agreement, the terms contained in this Agreement shall control.

18.17 **Headings.** The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

SIGNATURE PAGE FOLLOWS

98

CONFIDENTIAL TREATMENT REQUESTED

THIS AGREEMENT is executed by the authorized representatives of the Parties as of the Execution Date.

ULTRAGENYX PHARMACEUTICAL INC. TAKEDA PHARMACEUTICALCOMPANY LIMITED

By /s/ Emil Kakkis Name: Emil Kakkis By /s/ Misako Hamamura

Name: Misako Hamamura Title: CEO Title: Head of JP Strategy & BD

{Signature Page to License and Collaboration Agreement}

Exhibit 1.6(i)

[***]

Chemical Name: [***]

Molecular Formula: [***] Molecular Weight: [***]

Exhibit 1.6(iii)

[***]

Exhibit 1.82

Initial [***] Development Plan

<u>Initial Development Plan Framework</u>
[***]
<u>Estimated Timeline</u>
[***]
Development Activities and Budget
[***]

Exhibit 1.91 **Knowledge Group**

<u>Ultragenyx Position Titles</u>

Tom Kassberg, SVP and Chief Business Officer Shalini Sharp, SVP and Chief Financial Officer Sunil Agarwal, SVP and Chief Medical Officer Cori Leonard, VP, Yael Weiss, Executive Director, Search and Evaluation, Business Development Rob Anstey, Senior Director, Business Development

Takeda Position Titles

[***]

Exhibit 1.94

[***]

Chemical Name: [***]

2 Molecular Formula: [***]

2 Molecular Weight: [***]

Exhibit 1.99 Licensed Analog Compounds [***]

Exhibit 1.137 **Preexisting Third Party IP**

[***]

[3 pages omitted]

Exhibit 1.141 **Product INDs** [***]

Exhibit 1.168 **Takeda Patents**

Licensed [***] Patent

Patent / Publication	Priority / Application	Inventor(s) / Assignee(s)	<u>Title / Claims</u>	<u>Status</u>
[***]	[***]	[***]	[***]	[***]

[2 pages omitted]

Exhibit 1.188 Ultragenyx Patents

Ultragenyx [***] Patents	
[***]	
Ultragenyx [***] Patents	
[***]	
l J	
[3 pages omitted]	

Exhibit 1.195

[***]

Exhibit 6.1 **Listed Compounds** [***]

Exhibit 6.3(a) [***] Research Plan [***]

[***]
[4 pages omitted]
CONFIDENTIAL TREATMENT REQUESTED Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to omitted portions marked "***".

Exhibit 6.10(b)

[***]	
[4 pages omitted]	

Exhibit 13.2(b)

Exhibit 14.5 Form of Press Release





Contact Ultragenyx Pharmaceutical Inc. Investors & Media Ryan Martins 844-758-7273

<u>For Takeda Pharmaceutical Company Limited:</u> Tsuyoshi Tada – Japan <u>tsuyoshi.tada@takeda.com</u>

+81332782417

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Ultragenyx and Takeda enter into a Collaboration to Develop and Commercialize Therapies for Rare Genetic Diseases

Ultragenyx to license and develop one or more product candidates from Takeda Takeda to make equity investment in Ultragenyx to fund development

NOVATO, CA, June 7, 2016 and OSAKA, JAPAN, June 8, 2016 – Ultragenyx Pharmaceutical Inc. (NASDAQ: RARE), a biopharmaceutical company focused on the development of novel products for rare and ultra- rare genetic diseases, and Takeda Pharmaceutical Company Limited (TSE: 4502), today announced a strategic partnership to develop and commercialize therapies to treat rare genetic diseases.

Ultragenyx will initially receive an exclusive license to one preclinical Takeda product candidate in a pre- determined field of use, and will have an exclusive option to co-develop and co-commercialize the product candidate in additional therapeutic areas. The companies have also established a five-year research collaboration in which Ultragenyx will have the option to license up to five additional Takeda

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product candidates for rare diseases after the parties agree on and conduct initial validation activities under the purview of a Joint Research Committee.

"This broad collaboration provides Ultragenyx with a product opportunity that is approaching clinical- stage development as well as a potential continued source of new product candidates that will help us achieve our goal of bringing a new therapy into the clinic every one to two years," said Emil D. Kakkis, MD, PhD, Chief Executive Officer of Ultragenyx. "Takeda has an impressive early pipeline of therapies with potential across a number of rare genetic diseases, and we are pleased that Takeda has chosen to partner with us to bring these therapies to patients with rare diseases that have few or no treatment options."

"Ultragenyx is a rapidly emerging rare disease company, led by a highly experienced and successful management team," said Andrew Plump, M.D., Ph.D., Chief Medical and Scientific Officer of Takeda. "This partnership provides Takeda access to Ultragenyx's strong patient-centric development and regulatory capabilities in the rare disease space, and could create significant value for both companies by delivering important new therapies to patients."

Takeda will receive an exclusive option to commercialize any licensed products resulting from the collaboration in Asia, including Japan. In addition, Takeda receives an option to exclusively license one Ultragenyx pipeline product in Japan. Each company will receive potential development and sales milestone payments and royalties on net sales of licensed products by the other party.

Takeda will invest up to \$65 million in Ultragenyx in two tranches, the first of which will comprise a \$25million stock purchase along with a \$15 million cash premium at closing. This will be followed at Ultragenyx's option, within 12 months, by a second equity purchase of \$25million with no additional premium. A potential third equity investment by Takeda is contingent upon Ultragenyx achieving a specific development milestone on a second asset. No additional financial details were disclosed.

The completion of the transactions are subject to Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR) review and the satisfaction of other customary closing conditions.

About Ultragenyx

Ultragenyx is a clinical-stage biopharmaceutical company committed to bringing to market novel products for the treatment of rare and ultra-rare diseases, with a focus on serious, debilitating genetic diseases. Founded in 2010, the company has rapidly built a diverse portfolio of product candidates with the potential to address diseases for which the unmet medical need is high, the biology for treatment is clear, and for which there are no approved therapies.

The company is led by a management team experienced in the development and commercialization of rare disease therapeutics. Ultragenyx's strategy is predicated upon time and cost-efficient drug development, with the goal of delivering safe and effective therapies to patients with the utmost urgency.

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For more information on Ultragenyx, please visit the company's website at www.ultragenyx.com.

About Takeda

Takeda Pharmaceutical Company Limited (TSE: 4502) is a global, R&D-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life- changing medicines. Takeda focuses its research efforts on oncology, gastroenterology and central nervous system therapeutic areas. It also has specific development programs in specialty cardiovascular diseases as well as late-stage candidates for vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology, central nervous system and gastroenterology, as well as its presence in emerging markets, fuel the growth of Takeda. More than 30,000 Takeda employees are committed to improving quality of life for patients, working with our partners in health care in more than 70 countries. For more information, visit http://www.takeda.com/news.

Ultragenyx Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding the potential to develop the licensed product candidate in additional therapeutic areas, as well as the potential to develop additional rare disease targets pursuant to the collaboration and the ability to bring new therapies to clinic, are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve substantial risks and uncertainties that could cause our development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the satisfaction of the HSR requirements and the impact on the timing of the closing, whether any products will be successfully developed and commercialized from the collaboration, uncertainties inherent in the drug development process and other matters that could affect the potential for success of the collaboration, including the sufficiency of existing cash, cash equivalents and short-term investments to fund operations. Ultragenyx undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the company in general, see Ultragenyx's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on March 10 2016, and its subsequent periodic reports filed with the Securities and Exchange Commission.

Takeda Forward-Looking Statements

This press release contains "forward-looking statements." Forward-looking statements include all statements other than statements of historical fact, including plans, strategies and expectations for the future, statements regarding the expected timing of filings and approvals relating to the transaction, the expected timing of the completion of the transaction, the ability to complete the transaction or to satisfy the various closing conditions, future revenues and profitability from or

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growth or any assumptions underlying any of the foregoing. Statements made in the future tense, and words such as "anticipate," "expect," "project," "continue," "believe," "plan," "estimate," "pro forma," "intend," "potential," "target," "forecast," "guidance," "outlook," "seek," "assume," "will," "may," "should," and similar expressions are intended to qualify as forward-looking statements. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors and security holders are cautioned not to place undue reliance on these forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to: required regulatory approvals for the transaction may not be obtained in a timely manner, if at all; the conditions to closing of the transaction may not be satisfied; competitive pressures and developments; applicable laws and regulations; the success or failure of product development programs; actions of regulatory authorities and the timing thereof; changes in exchange rates; and claims or concerns regarding the safety or efficacy of marketed products or product candidates in development.

The forward-looking statements contained in this press release speak only as of the date of this press release, and neither Ultragenyx nor Takeda undertakes any obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If one or more of these statements is updated or corrected, investors and others should not conclude that additional updates or corrections will be made.

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CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Emil D. Kakkis, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q/A of Ultragenyx Pharmaceutical Inc.; and
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Dated: December 9, 2016

/s/ Emil D. Kakkis

Emil D. Kakkis, M.D., Ph.D. President and Chief Executive Officer (Principal Executive Officer)

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Shalini Sharp, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q/A of Ultragenyx Pharmaceutical Inc.; and
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Dated: December 9, 2016 /s/ Shalini Sharp

Shalini Sharp

Executive Vice President and Chief Financial Officer (Principal Financial Officer)