UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Amendment No. 1)

(Mark One)

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the year ended December 31, 2013

□ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001-35676

PROTHENA CORPORATION PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland

(State or other jurisdiction of incorporation or organization)

98-1111119

(I.R.S. Employer Identification Number)

Alexandra House The Sweepstakes, Ballsbridge Dublin 4, Ireland

(Address of principal executive offices including zip code) Registrant's telephone number, including area code: 011-353-1-902-3519 Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u> Ordinary Shares, par value \$0.01 per share <u>Name of Each Exchange on Which Registered</u> The NASDAQ Global Select Market

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (\$232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes \boxtimes No \square

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer			Accelerated filer	\mathbf{X}
Non-accelerated filer		(Do not check if a smaller reporting company)	Smaller reporting company	
Indicate by check mark whethe	r the re	egistrant is a shell company (as defined in Rule 12b-2	of the Exchange Act). Yes	No 🗵

As of June 28, 2013, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting shares held by non-affiliates of the registrant was approximately \$187.1 million, based on the last reported sale of the registrant's ordinary shares on the NASDAQ Global Market on such date.

21,902,937 of the Registrant's ordinary shares, par value \$0.01 per share, were outstanding as of March 3, 2014.

EXPLANATORY NOTE

This Form 10-K/A amends the Annual Report on Form 10-K of Prothena Corporation plc for the year ended December 31, 2013, filed on March 7, 2014 (the "Form 10-K"), for the sole purpose of filing an updated version of Exhibit 10.4 hereto.

This Amendment No. 1 to the Form 10-K does not reflect events that may have occurred subsequent to the original filing date, and does not modify or update in any way the disclosures made in the original Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: June 6, 2014

Prothena Corporation plc (Registrant)

/s/ Dale B. Schenk

Dale B. Schenk President and Chief Executive Officer

/s/ Tran B. Nguyen

Tran B. Nguyen Chief Financial Officer

Previously Filed Exhibit Filed File No. Herewith Description **Filing Date** Exhibit No. Form Demerger Agreement, dated as of November 8, 2012 between 2.1 10/A 001-35676 11/30/2012 2.1 Elan Corporation, plc and Prothena Corporation plc 2.2(a) Amended and Restated Intellectual Property License and 8-K 001-35676 12/21/2012 2.1 Contribution Agreement, dated December 20, 2012, by and among Neotope Biosciences Limited, Elan Pharma International Limited, and Elan Pharmaceuticals, Inc. 2.2(b) Amendment Number One to the Amended and Restated S-1/A 333-191218 9/30/2013 2.2(b) Intellectual Property License and Contribution Agreement, retroactively effective December 20, 2012, by and among Neotope Biosciences Limited, Elan Pharma International Limited, Elan Pharmaceuticals, LLC, Elan Corporation, plc, and Crimagua Limited 2.2 2.3 Intellectual Property License and Conveyance Agreement, 8-K 001-35676 12/21/2012 dated December 20, 2012, by and among Neotope Biosciences Limited, Elan Pharma International Limited and Elan Pharmaceuticals, Inc. 2.4 Asset Purchase Agreement, dated December 20, 2012, 8-K 001-35676 12/21/2012 2.3 between Elan Pharmaceuticals, Inc. and Prothena Biosciences Inc Amended and Restated Memorandum and Articles of 10-K 001-35676 3/29/2013 3.1 3.1 Association of Prothena Corporation plc 4.1 Reference is made to Exhibit 3.1 8-K 10.1 10.1(a) Tax Matters Agreement, dated December 20, 2012, by and 001-35676 12/21/2012 between Elan Corporation, plc and Prothena Corporation plc 10.1(b) Amendment No. 1 to Tax Matters Agreement, dated June 25, 2013, by and between Elan Corporation, plc and Prothena Corporation plc 10-Q 001-35676 8/13/2013 10.2 10.2 Transitional Services Agreement, dated December 20, 2012, 10.2 8-K 001-35676 12/21/2012 by and between Elan Corporation, plc and Prothena Corporation plc 10.3 10.3 Subscription and Registration Rights Agreement, dated as of 10/A 001-35676 11/30/2012 November 8, 2012 by and among Prothena Corporation plc, Elan Corporation, plc and Elan Science One Limited Х 10.4† License, Development, and Commercialization Agreement, dated December 11, 2013, by Neotope Biosciences Limited and Prothena Biosciences Inc with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc.

EXHIBIT INDEX

		Previously Filed			_	
Exhibit No.	Description	Form	File No.	Filing Date	Exhibit	Filed Herewith
10.5†	Master Process Development and Clinical Supply Agreement, dated as of June 23, 2010, as amended August 1, 2011, by and among Elan Pharma International Limited, Neotope Biosciences limited and Boehringer Ingelheim Pharma GmbH & Co. KG	10-Q	001-35676	8/13/2013	10.3	
10.6	Research and Development Services Agreement, dated December 20, 2012, by and between Elan Corporation, plc and Prothena Corporation plc	8-K	001-35676	12/21/2012	10.3	
10.7#	Form of Deed of Indemnity	10/A	001-35676	11/30/2012	10.5	
10.8(a)	Lease Agreement, dated as of March 18, 2010 between Are- San Francisco No. 33, LLC and Elan Pharmaceuticals, Inc.	10/A	001-35676	11/30/2012	10.6	
10.8(b)	First Amendment to Lease, dated as of November 18, 2011 between Are-San Francisco No. 33, LLC and Elan Pharmaceuticals, Inc.	10/A	001-35676	11/30/2012	10.7	
10.8(c)	Second Amendment to Lease, dated as of June 1, 2012 between Are-San Francisco No. 33, LLC and Elan Pharmaceuticals, Inc.	10/A	001-35676	11/30/2012	10.8	
10.8(d)	Third Amendment to Lease, dated as of October 3, 2012 between Are-San Francisco No. 33, LLC and Elan Pharmaceuticals, Inc.	10/A	001-35676	11/30/2012	10.9	
10.8(e)	Assignment of Tenant's Interest in Lease and Assumption of Lease Obligations, dated as of December 2, 2012 between Elan Pharmaceuticals, Inc. and Prothena Biosciences Inc	10/A	001-35676	11/30/2012	10.10	
10.8(f)	Fourth Amendment to Lease, dated as of November 30, 2013 between ARE-San Francisco No. 33, LLC and Prothena Biosciences, Inc.	8-K	001-35676	12/05/2013	10.1	
10.9#	Prothena Corporation plc 2012 Long Term Incentive Plan	8-K	001-35676	12/21/2012	10.4	
10.10#	Prothena Biosciences Inc Amended and Restated Severance Plan	10-K	001-35676	3/29/2013	10.12	
10.11#	Prothena Corporation plc Incentive Compensation Plan	8-K	001-35676	12/21/2012	10.6	
10.12	License Agreement, dated as of December 31, 2008 between the University of Tennessee Research Foundation and Elan Pharmaceuticals, Inc.	10/A	001-35676	11/30/2012	10.14	
10.13#	Form of Deed of Indemnity for Former Officers and Directors	10/A	001-35676	12/13/2012	10.15	
10.14#	Employment Agreement, dated January 22, 2013, between Prothena Biosciences Inc and Dale B. Schenk	8-K	001-35676	1/25/2013	10.1	



		Previously Filed				
Exhibit No.	Description	Form	File No.	Filing Date	Exhibit	Filed Herewith
10.15#	Offer letter, dated March 20, 2013, between Prothena Biosciences Inc and Tran Nguyen	8-K	001-35676	3/28/2013	10.1	
10.16#	Offer letter, dated December 22, 2012, between Prothena Biosciences Inc and Gene Kinney	10-K	001-35676	3/29/2013	10.18	
10.17#	Offer letter, dated March 19, 2013, between Prothena Biosciences Inc and Martin Koller	8-K	001-35676	3/28/2013	10.2	
10.18#	Offer letter, dated December 14, 2012, between Prothena Biosciences Inc and Tara Nickerson	10-K	001-35676	3/29/2013	10.2	
10.19#	Offer letter, dated April 19, 2013, between Prothena Biosciences Inc and Karin L. Walker	8-K	001-35676	5/22/2013	10.1	
21.1	List of Subsidiaries	10-K	001-35676	3/7/2014	21.1	
23.1	Consent of KPMG LLP, independent registered public accounting firm	10-K	001-35676	3/7/2014	23.1	
23.2	Consent of independent registered public accounting firm, KPMG	10-K	001-35676	3/7/2014	23.2	
24.1	Power of Attorney (see signature page hereto)	10-K	001-35676	3/7/2014	24.1	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002	10-K	001-35676	3/7/2014	31.1	
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002	10-K	001-35676	3/7/2014	31.2	
31.3	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002					х
31.4	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002					Х
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	10-K	001-35676	3/7/2014	32.1	
32.2*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of					Х

			Previously Filed			_
Exhibit No.	Description	Form	File No.	Filing Date	Exhibit	Filed Herewith
101.INS+	XBRL Instance Document	10-K	001-35676	3/7/2014	101	
101.SCH+	XBRL Taxonomy Extension Schema Document	10-K	001-35676	3/7/2014	101	
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document	10-K	001-35676	3/7/2014	101	
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document	10-K	001-35676	3/7/2014	101	
101.LAB+	XBRL Taxonomy Extension Label Linkbase Document	10-K	001-35676	3/7/2014	101	
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document	10-K	001-35676	3/7/2014	101	

* Exhibit 32.1 and 32.2 are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise specifically stated in such filing.

Indicates management contract or compensatory plan or arrangement.

[†] 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.

⁺ XBRL information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934, and is not subject to liability under those sections, is not part of any registration statement or prospectus to which it relates and is not incorporated or deemed to be incorporated by reference into any registration statement, prospectus or other document.

[*] 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 the omitted portions.

LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENT

BY AND BETWEEN

NEOTOPE BIOSCIENCES LIMITED

AND

PROTHENA BIOSCIENCES INC,

on the one hand,

AND

F. HOFFMANN-LA ROCHE LTD

AND

HOFFMANN-LA ROCHE INC.,

on the other hand

December 11, 2013

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Confidential treatment has been requested with respect to the omitted portions.

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LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENT

This LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENT (the "Agreement") is made and signed as of December 11, 2013 (the "Signing Date") by and between:

NEOTOPE BIOSCIENCE LIMITED, an Irish limited company with a principal place of business at 25-28 North Wall Quay, Dublin 1, Ireland (" **Prothena Ireland** ") with respect to all rights and obligations under this Agreement outside of the United States, and

PROTHENA BIOSCIENCE INC, a Delaware corporation with a principal place of business at 650 Gateway Boulevard, South San Francisco, CA 94080 (" **Prothena US** ") with respect to all rights and obligations under this Agreement in the United States (Prothena US, together with Prothena Ireland, " **Prothena** "), on the one hand, and

F. HOFFMANN-LA ROCHE LTD, a Swiss corporation with a principal place of business at Grenzacherstrasse 124, 4070 Basel, Switzerland (" **Roche Basel** ") with respect to all rights and obligations under this Agreement outside of the United States, and

HOFFMANN-LA ROCHE INC., a New Jersey corporation with a principal place of business at 340 Kingsland Street, Nutley, New Jersey, U.S.A. 07110 ("**Roche Nutley**") with respect to all rights and obligations under this Agreement in the United States (Roche Nutley, together with Roche Basel, "**Roche**"), on the other hand.

Prothena and Roche are sometimes referred to herein individually as a "Party" and collectively as the "Parties

RECITALS

".

WHEREAS, Prothena is a biotechnology company engaged in the research, development, and commercialization of pharmaceutical compounds for use in treating neurological disorders;

WHEREAS, Roche is a pharmaceutical company engaged in the research, development and commercialization of products useful in the treatment of human diseases and conditions;

WHEREAS, Prothena is currently developing a compound known as PRX002 and other antibodies that target alpha-synuclein, a protein associated with the progression of Parkinson's disease and, potentially, other disorders of the nervous system;

WHEREAS, Prothena and Roche desire to collaborate in the development of PRX002 and other antibodies targeting alpha-synuclein;

WHEREAS, Prothena and Roche also desire to conduct a research collaboration focused on other antibodies targeting alpha-synuclein, potentially using Roche's proprietary technology known as the "Brain Shuttle" technology, which is designed to deliver drugs through the blood-brain barrier;

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WHEREAS, Prothena US and Roche Nutley will share the costs of development, and profits and losses resulting from commercialization, of PRX002 in Parkinson's disease (and potentially other antibodies targeting alpha-synuclein and/or other indications) in the United States, and Roche Basel will be responsible for developing and commercializing PRX002 (and potentially other antibodies targeting alpha-synuclein) in other countries, in accordance with the terms and conditions of this Agreement; and

WHEREAS, Prothena and Roche agree and intend that (A) Prothena US and Roche Nutley will be the parties to this Agreement and assume all corresponding rights and obligations with respect to any activities contemplated by this Agreement within the United States for jointly funded products and indications, including (i) the sharing of profit and loss in the United States, and (ii) the co-detailing activities in the United States, and (B) Prothena Ireland and Roche Basel will be the parties to this Agreement and assume all corresponding rights and obligations with respect to any activities contemplated by this Agreement outside the United States.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the covenants and promises contained in this Agreement and intending to be legally bound, the Parties agree as follows:

1. DEFINITIONS .

As used herein, the following terms shall have the following meanings:

1.1. "**Affiliate**" means a corporation, partnership, trust or other entity that directly, or indirectly through one or more intermediates, controls, is controlled by or is under common control with a specified Party but only for so long as such relationship exists. For such purposes, "control", "controlled by", and "under common control with" shall mean the possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting equity, voting member or partnership interests, control of a majority of the board of directors or other similar body, by contract, or otherwise, including without limitation, in the case of a corporation, the direct or indirect ownership of fifty percent (50%) or more of its outstanding voting shares. Anything to the contrary in this paragraph notwithstanding, [*].

1.2. "Alpha-Synuclein" means the human protein designated by UniProt P37840, and [*].

1.3. "Antibody Product" means any product containing an Antibody.

1.4. "Antibody " means any antibody molecule, or a Related Antibody thereof.

1.5. "**Applicable Laws**" means all applicable laws, rules, and regulations, including without limitation any rules, regulations, guidelines or other requirements of the Regulatory Authorities, that may be in effect from time to time in any relevant legal jurisdiction.

1.6. "**BI**" means Boehringer Ingelheim Pharma GmbH.

1.7. "**BI Supply Agreement**" means the Master Process Development and Clinical Supply Agreement, by and among Prothena, ELAN Pharma International Limited, and BI, effective as of June 23, 2010, as amended.

1.8. "**Biosimilar Version**" means, with respect to a Licensed Product in a particular country, a therapeutic product that (a) [*], and (b) is [*].

1.9. "**BLA**" means a Biologics License Application for a Licensed Product under Section 351 of the Public Health Service Act, as may be amended, supplemented, or replaced, or any foreign equivalent thereto.

1.10. "**BPCIA**" means the Biologics Price Competition and Innovation Act of 2009, Section 351(k) of the Public Health Service Act, as may be amended, supplemented, or replaced.

1.11. "**Brain Shuttle Technology**" means Roche's proprietary technology designed to enhance delivery of molecules through the blood-brain barrier, consisting of (a) an Antibody [*], as disclosed in [*] (the "**Brain Shuttle Application**"), and [*] the invention described in such application, (b) methods of using the Antibody described in subsection (a) to [*], as disclosed in the Brain Shuttle Application, and [*] the invention described in the Brain Shuttle Application, and [*] the invention described in such application, and (c) [*], in a manner disclosed in the Brain Shuttle Application, and [*] the invention described in such application.

1.12. "Budgets" means the Research Budget, Development Budget, and Commercialization Budget.

1.13. "**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.

1.14. "**Calendar Year**" means each successive period of twelve (12) months commencing on January 1 and ending on December 31; *provided, however*, that (a) the first Calendar Year of the Term shall extend from the Effective Date to December 31, and (b) the last Calendar Year of the Term shall end upon the expiration or termination of this Agreement.

1.15. "**Chugai**" means Chugai Pharmaceutical Co., Ltd.

1.16. "**Clinical Trials**" means any and all human clinical studies of a therapeutic compound, including without limitation Phase I Clinical Trials, Phase II Clinical Trials, Phase III Clinical Trials, and Phase IV Clinical Trials.

1.17. "Combination Product" means a single pharmaceutical formulation containing as its active ingredients both a Licensed Compound and one or more other therapeutically or prophylactically active ingredients or a combination therapy comprised of a Licensed Compound and [*] products, [*]. All references to a Licensed Product in this Agreement shall be deemed to include a Combination Product.

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1.18. "**Commercialize**" or "**Commercialization**" means all activities undertaken relating to the commercial manufacture, Detailing, distribution, pricing, reimbursement, and/or sale of a Licensed Product, including without limitation advertising, education, planning, marketing, distribution, product support, and post-launch medical activities such as Phase IV Clinical Trials, but shall exclude all Development activities.

1.19. "**Commercially Reasonable Efforts**" means such level of efforts required to carry out such obligation in a sustained manner consistent with the efforts Roche or Prothena, as applicable, devotes at the same stage of development or commercialization, as applicable, for its own internally developed pharmaceutical products in a similar area with similar market potential, at a similar stage of their product life taking into account the existence of other competitive products in the market place or under development, the proprietary position of the product, the regulatory structure involved, the anticipated profitability of the product and other relevant factors [*]. It is understood that such product potential may change from time to time based upon changing scientific, business and marketing and return on investment considerations. The Parties acknowledge that Roche (and its Affiliates) does not always seek to market its own products in every country or seek to obtain regulatory approval in every country or for every potential indication.

1.20. "Committee " means the JSC, JRT, JDC, JFT, JCC, and any other subcommittees formed pursuant to <u>Section 4.2(b)(xii)</u>.

1.21. "**Compulsory Sublicense**" means a license or sublicense granted to a Third Party through the order, decree or grant of a governmental authority having competent jurisdiction, authorizing such Third Party (each, a "**Compulsory Sublicensee**") to manufacture, use, sell, offer for sale, import or export a Licensed Product in any country in the Territory.

1.22. "[*] **Notice** " means the notice Prothena provides to Roche [*].

1.23. "**Control**" or "**Controlled**" means, with respect to any item of Information, Patent, Patent Application, or other intellectual property right, the right to grant a license or sublicense with respect thereto, or access thereto, as provided for in this Agreement, without violating the terms of any agreement or other arrangement with, or any legal rights of, and without requiring the consent of any Third Party or, unless the Parties otherwise agree in writing, payment to any Third Party.

1.24. "**Cover**" means (as an adjective or as a verb including conjugations and variations such as "**Covered**", "**Coverage**", or "**Covering**") that the developing, making, using, offering for sale, promoting, selling, exporting or importing of a given compound, formulation or product would infringe a claim of a Patent or would fall within the scope of a claim of a Patent Application in the absence of a license under the Patent or Patent Application to which such claim pertains. The determination of whether a compound, formulation, process or product is Covered by a particular claim shall be made on a country-by-country basis.

1.25. "Data Package" means, with respect to a Termination Product, (a) all material Information in Roche's Control that [*], (b) other Information related to the Termination Product that [*], and (c) all Regulatory Filings and Regulatory Approvals for the Termination Product.

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1.26. "**Detail**" or "**Detailing**" means, with respect to a Licensed Product, the communication by a Sales Representative to a Prescriber during a sales call (a) involving face-to-face contact or, if permitted by the Co-Detailing Agreement, contact by means of an e-detail or video, (b) describing in a fair and balanced manner the FDA-approved indicated uses and other relevant characteristics of such Licensed Product, (c) using the Promotional Materials in an effort to inform Prescribers about a Licensed Product for its FDA-approved indicated uses, and (d) made at such Prescriber's office, at another appropriate alternate care setting, or in any other venue as described in the Co-Detailing Agreement and consistent with Applicable Law, the Co-Detailing Agreement and other industry standards. For the avoidance of doubt, discussions at conventions or other scientific meetings shall not constitute "Details" or "Detailing".

1.27. "**Develop**" or "**Development**" means all activities relating to obtaining Regulatory Approval of a Licensed Product and all manufacturing activities undertaken prior to commencement of supply for Commercialization, including without limitation (a) non-clinical testing in support of the applicable Licensed Product, toxicology, formulation, Clinical Trials, and regulatory affairs, including without limitation preparation of Regulatory Filings, and (b) manufacturing process development for the applicable Licensed Compound and/or Licensed Product, production of clinical supply of the applicable Licensed Compound and/or Licensed Product, and manufacturing and quality assurance technical support activities prior to the commencement of Commercialization, including without limitation those activities reasonably required for the scale up of manufacturing processes or equipment in preparation for commercial supply of the applicable Licensed Compound and/or Licensed Product. For clarity, "Development" does not include research activities intended to identify and optimize Antibodies that target Alpha-Synuclein.

1.28. "**Dispute**" means any dispute, controversy, or claim in connection with this Agreement and any other agreement entered into pursuant hereto, the construction hereof or thereof, or the rights, obligations, or liabilities of either Party hereunder or thereunder.

1.29. "**Dollar**" means a U.S. dollar, and "**\$**" shall be interpreted accordingly.

1.30. "**Effective Date**" means the later of (a) the Signing Date, or (b) if a HSR filing is made, the second business day immediately following the earlier of (i) the date upon which the waiting period under HSR expires or terminates early or (ii) the date upon which all requests to the Parties by the Federal Trade Commission or the Justice Department, as the case may be, with regard to the transaction contemplated by this Agreement, have been satisfactorily met and no objection on the part of the Federal Trade Commission or the Justice Department remains.

1.31. "**EMA Guideline**" means the European Medicines Agency's publication "*Guideline on Clinical Investigation of Medicinal Products in the Treatment of Parkinson's Disease*", Doc. Ref. CPMP/EWP/563/95 Rev. 1 (London, 24 July 2008).

1.32. "EU" means the European Union and all its present and future member countries.

1.33. "FDA" means the United States Food and Drug Administration, or any successor thereto, having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products, delivery systems and devices in the Shared Territory.

1.34. "Field " means all uses, including the prevention, diagnosis, treatment, supportive care or amelioration of diseases and conditions.

1.35. "Financial Appendix" means the financial appendix attached as <u>Exhibit 1.35</u>.

1.36. "**First Commercial Sale**" means, on a country-by-country basis, the first invoiced sale of a Licensed Product to a Third Party by the Roche Group, following the receipt of any Regulatory Approval required for the sale of such Licensed Product, or if no such Regulatory Approval is required, the date of the first invoiced sale of a Licensed Product to a Third Party by the Roche Group in such country.

1.37. "FTE Rate" means the amount of [*] per FTE, on a fully burdened cost basis.

1.38. "**FTE**" means a full-time equivalent person-year, based upon a total of no less than [*] hours per year, undertaken in connection with the conduct of research in the Research Collaboration or as otherwise agreed by the Parties. In no circumstances can the work of any given person exceed one (1) FTE.

1.39. "GAAP" means United States generally accepted accounting principles, consistently applied.

1.40. "Good Clinical Practices" or "GCP" means the standards, practices and procedures set forth in the guidelines entitled in "Good Clinical Practice: Consolidated Guidance", the related regulatory requirements imposed by the FDA, and, as applicable, any equivalent or similar standards in jurisdictions outside the Shared Territory.

1.41. "Good Laboratory Practices" or "GLP" means the regulations set forth in 21 C.F.R. Part 58, the requirements thereunder imposed by the FDA, and, as applicable, any equivalent or similar standards in jurisdictions outside the Shared Territory.

1.42. "Good Manufacturing Practices" or "GMP" means the regulations set forth in 21 C.F.R. Parts 210-211, 820 and 21 C.F.R. Subchapter C (Drugs), Quality System Regulations, the requirements thereunder imposed by the FDA, and, as applicable, any equivalent or similar standards in jurisdictions outside the Shared Territory.

1.43. "[*]" means [*].

1.44. "**HSR**" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as may be amended, supplemented, or replaced.

1.45. "**IFRS**" means International Financial Reporting Standards, consistently applied.

1.46. "**IND**" means an Investigational New Drug Application for a Licensed Product, which must be approved by the FDA (or foreign equivalent) before such Licensed Product can be administered to humans.

1.47. "**Information**" means ideas, inventions, discoveries, concepts, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology,

[*] 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 the omitted portions.

designs, drawings, computer programs, skill, experience, documents, results, clinical and regulatory strategies, data, including without limitation pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, Patent and legal data, market data, financial data or descriptions, assay protocols, specifications, and the like, in written, electronic or other form, now known or hereafter developed, whether or not patentable.

1.48. "**Inventions**" means any and all inventions conceived or reduced to practice by or on behalf of either Party or its Affiliates or Sublicensees in the course of [*] under this Agreement.

1.49. "Jointly Funded Product/Indication" means the first Licensed Product for the Parkinson's Disease Indication, unless Prothena exercises its Opt-Out with respect thereto pursuant to <u>Section 6.2</u>, as well as (a) the first Licensed Product for any other indication(s) for which Prothena exercises its Opt-In pursuant to <u>Section 6.1(b)</u> and (b) any other Licensed Products developed for indications for which Prothena exercises its Opt-In pursuant to <u>Section 6.1(b)</u> and (b) any other case (a) and (b) unless Prothena exercises its Opt-Out with respect thereto pursuant to <u>Section 6.2</u>.

1.50. "Lead Compound" means (a) the Antibody having the amino acid sequence set forth in Exhibit 1.50 ("PRX002"), and (b) any modifications to PRX002 that are[*].

1.51. "Lead Product" means a product incorporating the Lead Compound.

1.52. "Licensed Compounds" means (a) the Lead Compound, (b) any Licensed Prothena Compounds, (c) any Licensed Roche Compounds, and (d) any Research Collaboration Compounds. [*]

1.53. "Licensed Other Product" means any Licensed Product other than the Lead Product.

1.54. "**Licensed Product Trademarks**" means the Trademarks that pertain specifically to a Licensed Product.

1.55. "**Licensed Product**" means any product, including without limitation any Combination Product, incorporating a Licensed Compound as pharmaceutically active agent, regardless of its finished form or formulation or dosage.

1.56. "**Licensed Prothena Compound**" means any Antibody that binds to Alpha-Synuclein or fragments thereof and is listed on <u>Exhibit 1.56</u>, and any Related Antibodies thereof.

1.57. "Licensed Roche Compound" means any Antibody that binds to Alpha-Synuclein or fragments thereof and is listed on Exhibit 1.57, and any Related Antibodies thereof.

1.58. "Major Market Country" means [*].

1.59. "Parkinson's Disease" means [*].

1.60. "**Parkinson's Disease Indication**" means the treatment of patients for Parkinson's Disease.

1.61. "**Patent**" means (a) letters patent (or other equivalent legal instrument), including without limitation utility and design patents, extensions, substitutions, registrations, confirmations, reissues, re-examinations or renewals thereof, and (b) all foreign or international equivalents, including supplementary protection certificates, of any of the foregoing in any country.

1.62. "**Patent Application**" means (a) an application for letters patent, including without limitation a provisional application, a non-provisional application, a reissue application, a re-examination application, a continuation application, a continuation-in-part application, a divisional application or any equivalent thereof that is pending at any time during the Term before a government patent agency, and (b) all foreign or international equivalents of any of the foregoing in any country.

1.63. "**Pharmacovigilance Agreement**" means an agreement entered into by the Parties to set forth the protocols and procedures for reporting adverse events and complying with reporting requirements set forth by Regulatory Authorities.

1.64. "**Phase I Clinical Trial**" means any clinical study conducted on sufficient numbers of human subjects to establish that a pharmaceutical product is reasonably safe for continued testing and to support its continued testing in Phase II Clinical Trials as required by 21 C.F.R. § 312.21(a) or similar Applicable Law in a country other than the United States.

1.65. "**Phase II Clinical Trial**" means any clinical study conducted on sufficient numbers of human subjects that have the targeted disease of interest to investigate the safety and efficacy of a pharmaceutical product for its intended use and to define warnings, precautions, and adverse reactions that may be associated with such pharmaceutical product in the dosage range to be prescribed as required by 21 C.F.R. § 312.21(b) or similar Applicable Law in a country other than the United States.

1.66. "**Phase III Clinical Trial**" means any clinical study intended as a pivotal study for purposes of seeking Regulatory Approval that is conducted on sufficient numbers of human subjects to establish that a pharmaceutical product is safe and efficacious for its intended use, to define warnings, precautions, and adverse reactions that are associated with such pharmaceutical product in the dosage range to be prescribed, and to support Regulatory Approval of such pharmaceutical product or label expansion of such pharmaceutical product as required by 21 C.F.R. § 312.21(c) or similar Applicable Law in a country other than the United States..

1.67. "Phase IV Clinical Trial" means clinical study of a pharmaceutical product on human subjects commenced after receipt of Regulatory Approval of such pharmaceutical product for the purpose of satisfying a condition imposed by a Regulatory Authority to maintain or expand Regulatory Approval, or to support the marketing of such pharmaceutical product, and not for the purpose of obtaining initial Regulatory Approval of a pharmaceutical product.

[*] 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 the omitted portions.

1.68. "**Plans**" means the Research Plan, Development Plan, Commercialization Plan, and Co-Detailing Plan.

1.69. "[*]" means [*].

1.70. "**Prescribers**" means physicians and other health care professionals, including without limitation neurologists, who are permitted by Applicable Law to prescribe Licensed Products.

1.71. "**Promotional Materials**" means all Sales Representative training materials and all written, printed, graphic, electronic, audio or video matter, including without limitation journal advertisements, sales visual aids, leave-behind items, formulary binders, reprints, direct mail, direct-to-consumer advertising, internet postings and sites and broadcast advertisements intended for use or used by or on behalf of either Party or their respective Affiliates in connection with any promotion of a Licensed Product.

1.72. "**Prothena Know-How**" means all Information that is Controlled by Prothena as of the Effective Date or during the Term that is not publicly known, even though parts thereof may be publicly known, and is necessary or useful to Develop, make, use, sell, offer to sell, import or export a Licensed Compound or Licensed Product incorporating such Licensed Compound, except for any Information licensed to Prothena or its Affiliates under the UCSD License Agreement. Prothena Know-How does not include Prothena Patent Rights.

1.73. "**Prothena Patent Rights**" means (a) the Patents listed in <u>Exhibit 1.73</u>, (b) any Patents that issue from the Patent Applications listed in <u>Exhibit 1.73</u>, (c) any Patents and/or Patent Applications that claim priority to a Patent or Patent Application listed in <u>Exhibit 1.73</u>, and (d) any Patent and/or Patent Application Controlled by Prothena as of the Effective Date or during the Term that claims a product, method, apparatus, material, manufacturing process or other technology necessary or useful to Develop, make, use, sell, offer to sell, import or export a Licensed Compound or Licensed Product, except in each case (a) through (d) excluding any Patents and/or Patent Applications licensed to Prothena or its Affiliates under the UCSD License Agreement and jointly owned by Prothena. For the avoidance of doubt, to the extent included in the foregoing and Controlled by Prothena, "Prothena Patent Rights" shall [*]. Prothena Patent Rights do not include Prothena Know-How.

1.74. "**Prothena Technology**" means Prothena Patent Rights and Prothena Know-How.

1.75. "**Prothena Trademarks**" means the Trademarks Controlled by Prothena used in the Commercialization of a Licensed Product.

1.76. "**Regulatory Approval**" means (a) in the United States, approval by the FDA of a BLA or other applicable Regulatory Filing and satisfaction of related applicable FDA registration and notification requirements, if any, or (b) in any country other than the United States, approval by Regulatory Authorities having jurisdiction in such country of a single application or set of applications comparable to a BLA or other applicable Regulatory Filing and satisfaction and notification requirements, if any, is a satisfaction of related applications comparable to a BLA or other applicable Regulatory Filing and satisfaction and notification requirements, if any; in each case

(a) or (b) together with any other approvals necessary to manufacture and Commercialize a Licensed Product in such country. [*].

1.77. "Regulatory Authority" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities, including without limitation the FDA, regulating or otherwise exercising authority with respect to the Development or Commercialization of a Licensed Product.

1.78. "**Regulatory Exclusivity**" means any applicable exclusivity, including any extension thereto (including pediatric extension), granted by a Regulatory Authority for a pharmaceutical product, including without limitation orphan drug status or data exclusivity, in a country with respect to a product (such as those periods listed under the BPCIA or periods under national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83, and equivalents in other countries in the Territory). For the avoidance of doubt, "Regulatory Exclusivity" excludes patent term extensions, supplementary protection certificates, and international equivalents thereof.

1.79. "**Regulatory Filings**" means any and all regulatory applications, filings, approvals and associated correspondence required to Develop Licensed Products and for Regulatory Approval of a Licensed Product in each country in the Territory.

1.80. "**Related Antibodies**" means [*]. <u>Exhibit 1.80</u> sets forth examples of situations in which an antibody is intended to constitute a Related Antibody for a given antibody.

1.81. "**Research Collaboration Compound**" means any Antibody [*].

1.82. "**Roche Excluded Patent Rights** " means the Patents and Patent Applications listed in <u>Exhibit</u> <u>1.82</u>.

1.83. "Roche Group" means collectively Roche, its Affiliates and its Sublicensees.

1.84. "**Roche Know-How**" means all Information that is Controlled by Roche as of the Effective Date or during the Term that is not publicly known, even though parts thereof may be publicly known, and is necessary or useful to Develop, make, use, sell, offer to sell, import or export a Licensed Compound or Licensed Product incorporating such Licensed Compound. Roche Know-How does not include Roche Patent Rights.

1.85. "**Roche Patent Rights**" means (a) the Patents listed in <u>Exhibit 1.85</u>, (b) any Patents that issue from the Patent Applications listed in <u>Exhibit 1.85</u>, (c) any Patents and/or Patent Applications that claim priority to a Patent or Patent Application listed in <u>Exhibit 1.85</u>, and (d) any Patent and/or Patent Application Controlled by Roche as of the Effective Date or during the Term that claims a product, method, apparatus, material, manufacturing process or other technology necessary or useful to Develop, make, use, sell, offer to sell, import or export a Licensed Compound or Licensed Product incorporating such Licensed Compound, except for any Roche Excluded Patent Rights. Roche Patent Rights do not include Roche Know-How.

1.86. "**Roche Technology**" means Roche Patent Rights and Roche Know-How.

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1.87. "**Roche Trademarks**" means the Trademarks Controlled by Roche, other than Licensed Product Trademarks, used in the Commercialization of a Licensed Product.

1.88. "Royalty Net Sales" means, for a Licensed Product in a particular period, the amount calculated by subtracting from the Royalty Sales of such Licensed Product for such period: (a) a lump sum deduction of [*] in lieu of those deductions that are not accounted for on a Licensed Product-by-Licensed Product basis, including without limitation freight, postage charges, transportation insurance, packing materials for dispatch of goods, custom duties; (b) uncollectible amounts accrued during such period based on [*] in accordance with the then-currently used IFRS in the calculation of Royalty Sales of such Licensed Product for such period; and (c) government mandated fees and taxes (excluding income or franchise taxes) and [*] in accordance with the then-currently used IFRS in the calculation of Royalty Sales of such Licensed Product for such period, including, for example, any fees, taxes or other charges that become due in connection with [*]. For clarity, any given deduction shall be taken only under one of subsections (a) and (b), and only once in calculating Royalty Net Sales.

1.89. "**Royalty Sales**" means, for a Licensed Product in a particular period, the sum of (a) and (b) below:

(a) The amount [*] with respect to such Licensed Product for such period [*] in the Royalty Territory. This amount reflects [*], taken in accordance with the then-currently used IFRS. By way of example, the gross-to-net deductions taken in accordance with IFRS as of the Effective Date include the following: [*].

For clarity, any given deduction shall be taken only under one of subsections (i) through (v), and only once in calculating Royalty Sales. For purposes of clarity, sales by Roche and its Affiliates to any Sublicensees that are not Affiliates of Roche shall be excluded from "Royalty Sales", unless such Sublicensees are end users of such Licensed Product.

(b) For Sublicensees that are not Affiliates of Roche and not end users of such Licensed Product [*], the sales amounts in the Royalty Territory reported to Roche and its Affiliates in accordance with [*]. For purposes of clarity, [*].

1.90. "Royalty Territory" means, on a Licensed Product-by-Licensed Product and indication-byindication basis, (a) for Jointly Funded Product/Indications, worldwide except for the Shared Territory, and (b) for all Licensed Products that are not Jointly Funded Product/Indications, worldwide.

1.91. "**Sales Representative**" means a pharmaceutical sales representative who is trained with respect to the Licensed Product, including its labeling and Promotional Materials, engaged or employed by either Party (as permitted hereunder) to conduct Detailing with respect to the Licensed Products in accordance with the terms of this Agreement and the Co-Detailing Agreement.

1.92. "Shared Territory" means, for any Jointly Funded Product/Indication, the United States, [*].

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1.93. "**Sublicense Agreement**" means that certain sublicense agreement by and between the Parties which grants to Roche a sublicense under UCSD's joint interest in the UCSD/Prothena Patent Rights licensed to Prothena under the UCSD License Agreement and a license under Prothena's joint interest in the UCSD/Prothena Patent Rights.

1.94. "Sublicensee" means an entity to which a Party has granted a sublicense under <u>Section 2.3</u> (through one or multiple tiers), other than through a Compulsory Sublicense, pursuant to this Agreement.

1.95. "Territory" means worldwide.

1.96. "**Third Party**" means any person or entity other than Prothena, Roche, or an Affiliate of Party.

1.97. "**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof, whether registered or unregistered, including without limitation any trademark, trade dress, service mark, service name, brand mark, trade name, brand name, logo or business symbol.

1.98. "UCSD License Agreement" means that certain License Agreement by and between the Regents of the University of California ("UCSD") and Prothena Ireland, effective as of November 4, 2013, as may be amended, which grants to Prothena Ireland and its Affiliates a license under UCSD's interest in patent rights jointly owned with Prothena Ireland (the "UCSD/Prothena Patent Rights").

1.99. "Valid Claim" means, with respect to any country, a claim of (a) an unexpired issued Patent to the extent such claim has not been revoked or held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and which claim has not been admitted to be invalid or unenforceable through reissue, reexamination, disclaimer, or otherwise in the relevant country, or (b) a Patent Application pending for less than [*] from its earliest priority date in the relevant country, provided that, for clarity, any claim of a Patent Application that is pending for more than [*] after its earliest priority date, as applicable, shall become a Valid Claim if it later issues and otherwise falls within subsection (a).

1.100. Additional Definitions . Each of the following definitions is set forth in the section of this Agreement indicated below:

Definition	Section
AAA	17.3(b)
Accounting Period	9.9(a)
Alliance Manager	4.7
Allowable Expenses	Exhibit 1.35
Brain Shuttle Application	1.11
CDAs	11.1
Co-Detailed Product	7.1(b)

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Co-Detailing Agreement	7.1(d)
Co-Detailing Option	7.1(b)
Co-Detailing Plan	7.1(d)
Collaboration	Exhibit 1.35
Commercialization Budget	Exhibit 1.35
Commercialization Bluget	Exhibit 1.35
Confidential Information	11.1
Confidential information Cost of Goods Sold	Exhibit 1.35
CREATE Act	12.4(c)
Current Firewall	3.2
Damages	14.1
Development Budget	6.6(a)
Development Costs	Exhibit 1.35
Development Plan	6.6(a)
Enforcement Action	12.6(b)
EURIBOR	9.10
Executives	4.2(d)
Filing	9.4(b)
[*]	[*]
Handle	12.5(b)
Indemnification Claim	14.3
Indemnitee	14.3
Indemnitor	14.3
Indirect Taxes	9.15(a)
Infringement Claim	12.7(a)
Infringer	12.6(a)
Janssen	13.2(g)
JCC	4.1
JDC	4.1
JDC Chairperson	4.4(a)
JDC Members	4.4(a)
JFT	4.1
Joint Inventions	12.3(c)
Joint Patent Rights	12.3(c)
JRT	4.1
JRT Chairpersons	4.3(a)
JRT Members	4.3(a)
JSC	4.1
JSC Chairperson	4.2(a)
JSC Members	4.2(a)
Opt-In	6.1(b)
Opt-Out	6.2
Package	7.4
Parties	Preamble
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Party	Preamble
Payment Currency	9.11
Payments	9.15(b)
PhRMA	13.4
Press Release	11.6
Prothena	Preamble
Prothena Antibody Product	6.7(b)
Prothena Indemnitees	14.1
Prothena Inventions	12.3(b)
Prothena Ireland	Preamble
Prothena US	Preamble
Ramp-up Costs	6.7(a)
Region	16.4
Representing Party	13.1
Research Budget	5.2(a)
Research Collaboration	5.1
Research Plan	5.2(a)
Research Term	5.8
Roche	Preamble
Roche Basel	Preamble
Roche Indemnitees	14.2
Roche Inventions	12.3(a)
Roche Nutley	Preamble
Rules	17.3(b)
Samples	16.8(a)(v)(2)
Signing Date	Preamble
Tax	9.15(a)
Tax Authority	9.15(a)
Term	16.1
Termination Products	16.8(a)(v)
Third Party Royalties	Exhibit 1.35
UCSD	1.98
UCSD/Prothena Patent Rights	1.98
USPTO	12.4(c)

2. LICENSES .

2.1. License Grants to Roche . Subject to the terms and conditions of this Agreement, Prothena hereby grants to Roche (excluding [*]):

(a) under the Prothena Technology, an exclusive (subject to Prothena's and its Affiliates' retained rights to conduct Development activities under this Agreement), royalty-bearing license, with the right to grant sublicenses in accordance with <u>Section 2.3</u>, to Develop,

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make, have made, use, sell, offer to sell, import, and export Licensed Compounds and Licensed Products in the Field in the Royalty Territory.

(b) under the Prothena Technology, an exclusive (subject to Prothena's and its Affiliates' retained rights to conduct Development activities under this Agreement) license, subject to the sharing of Profit and Loss as set forth in <u>Section 9.3</u>, with the right to grant sublicenses in accordance with <u>Section 2.3</u>, to Develop, make, have made, use, sell, offer to sell, import, and export Licensed Compounds included in the Jointly Funded Product/Indications, and such Jointly Funded Product/Indications, in the Field in the Shared Territory; *provided, however*, that the foregoing license shall be co-exclusive (with Prothena and its Affiliates) with respect to co-Detailing, subject to Prothena exercising its Co-Detailing Option, during the time Prothena is co-Detailing in the Shared Territory. For clarity, the only Licensed Products in the Shared Territory are Jointly Funded Product/Indications.

(c) under the Prothena Trademarks, a non-exclusive, royalty-free license, with the right to grant sublicenses in accordance with <u>Section 2.3</u>, to use and display such Trademarks in connection with the Commercialization of Licensed Products in the Field in the Territory, as provided under and in accordance with <u>Section 7.6</u> and the Co-Detailing Agreement.

Notwithstanding the foregoing, the exclusive licenses granted by Prothena to Roche under this <u>Section</u> <u>2.1</u> shall be subject to any in-licenses to Prothena that may be nonexclusive.

2.2. License Grant to Prothena . Subject to the terms and conditions of this Agreement, Roche hereby grants to Prothena, under the Roche Technology, a non-exclusive, royalty-free license, with the right to grant sublicenses in accordance with <u>Section 2.3</u>, to conduct activities pursuant to this Agreement. Roche acknowledges that Prothena is not obligated to conduct activities that would require a license under any of the Roche Excluded Patent Rights, and that if it is determined during the Term that such a license will be necessary or useful for Prothena's conduct of activities pursuant to this Agreement, the Parties will discuss the terms of such license in good faith. Roche hereby confirms that the Roche Excluded Patent Rights do not claim inventions that are necessary for Prothena's performance of its obligations under any Co-Detailing Agreement.

2.3. Sublicense Rights .

(a) Roche shall have the right to grant sublicenses, through multiple tiers, under the licenses granted to it under Section 2.1, subject to Section 2.3(b) and Section 2.3(c), and shall provide written notice to Prothena within [*] of granting such sublicense. Prothena shall have the right to grant sublicenses under the licenses granted to it under Section 2.2 (i) to its Affiliates and (ii) upon the prior written consent of Roche, unless otherwise permitted under Section 5.3 or Section 6.8, to Third Parties.

(b) If Chugai does not become a Sublicensee of Roche for Japan, then either Party may propose a Sublicensee for Japan, and the JSC shall agree upon such a Sublicensee for Japan. Upon the determination of the JSC regarding the identity of such Sublicensee, Roche

[*] 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 the omitted portions.

shall negotiate the terms of and be a party to the sublicense agreement, which shall be on commercially reasonable terms and consistent with this Agreement.

(c) Roche shall not have the right to grant sublicenses under the license granted to it under <u>Section</u> 2.1 to [*] without the prior written consent of Prothena.

2.4. No Implied Rights or Licenses ; Certain Covenants. Neither Party grants to the other Party any rights or licenses in or to any Patent or other intellectual property right, whether by implication, estoppel or otherwise, except to the extent expressly provided for under this Agreement. The Parties acknowledge and agree that the Prothena Technology and Roche Technology may be useful for [*], and that no rights or licenses in or to any Patent or other intellectual property right are granted to the other Party for such products. Each Party covenants and agrees that it shall not, and it shall cause its Affiliates and Sublicensees not to, use or practice the intellectual property rights licensed under this Agreement, or use Information provided by the other Party to such Party, except as expressly permitted by this Agreement.

2.5. UCSD License Agreement .

(a) The Parties shall [*]. The Parties shall work in good faith to enter into the Sublicense Agreement on mutually acceptable terms within [*] following the amendment of the UCSD License Agreement. At any time prior to any amendment of the UCSD License Agreement, [*]. Roche shall have the right to [*] by Roche to Prothena under this Agreement.

(b) Upon [*], unless the [*], the Parties hereby agree that [*].

2.6. HSR Filings .

(a) General . Subject to the terms and conditions of this Agreement, each Party shall use all reasonable efforts to take, or cause to be taken, all reasonable actions and to do, or cause to be done, all things necessary and appropriate to consummate the transaction contemplated by this Agreement. Notwithstanding anything to the contrary contained in this Agreement, Roche shall have the sole and exclusive right to determine, at its option but without any obligation whatsoever, whether it shall have any obligation to take any actions in connection with, or agree to, any demands for the license, sale, divestiture or disposition of assets of Roche, its Affiliates or Prothena, asserted by the United States Federal Trade Commission, the Antitrust Division of the United States Department of Justice or any other Regulatory Authority in connection with antitrust matters or international competition laws, or to defend through litigation any proceeding commenced by the Federal Trade Commission, the Antitrust Division of the United States Department of Justice or other Governmental Authority in connection with the foregoing matters. Each Party shall cooperate with the other Party in the preparation, execution and filing of all documents that are required pursuant to the HSR Act. [*] with respect to preparing, executing and filing such documents, provided that, for clarity, [*] to the applicable Regulatory Authority.

(b) **Condition Subsequent**. If the HSR Act or any other applicable governmental law applies to the transactions contemplated by this Agreement, then the effectiveness of this Agreement and the transactions contemplated hereunder shall be subject to

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and contingent upon the satisfaction under the following condition subsequent to the execution of this Agreement. The condition subsequent shall be the earlier to occur of (i) approval of the transaction by the Federal Trade Commission or any other applicable governmental authority, or (ii) expiration or termination of all applicable waiting periods, and requests for information (and any extensions thereof) under the HSR Act or other applicable law. Subject to the terms and conditions of this Agreement, each Party shall use all reasonable efforts to take, or cause to be taken, all reasonable actions and to do, or cause to be done, all things necessary and appropriate to satisfy the condition subsequent and to consummate the transactions contemplated by this Agreement. Each Party shall cooperate with the other Party in the preparation, execution and filing of all documents that are required or permitted to be filed on or before the Closing Date for the purpose of consummating this transaction, including filings pursuant to the HSR Act or other governmental filing. [*] with respect to preparing, executing and filing such documents, provided that, for clarity, [*] to the applicable Regulatory Authority.

(c) **Termination no HSR clearance**. Either Party may terminate this Agreement in its entirety, upon [*] prior written notice to the other Party if the condition subsequent under this <u>Section 2.6</u> has not been fulfilled within [*] after the Signing Date, in which case, upon termination, there shall be [*] of this <u>Section 2.6</u>.

3. EXCLUSIVITY .

3.1. Antibody Products targeting Alpha-Synuclein . During the Term, except as otherwise provided below, each Party and its Affiliates[*] shall work exclusively with the other Party and its Affiliates to research and develop Antibody Products targeting Alpha-Synuclein. In particular, Prothena and its Affiliates will not conduct, participate in, or fund, directly or indirectly, alone or with a Third Party, research, development or commercialization activities specifically directed to any Antibody Products targeting Alpha-Synuclein except pursuant to this Agreement, and Roche and its Affiliates[*] will not conduct, participate in, or fund, directly or indirectly, alone or with a Third Party, research, development or commercialization activities specifically directed to any Antibody Product targeting Alpha-Synuclein except pursuant to this Agreement. [*]

3.2. [*]. [*]

 3.3. [*].

(a) The Parties agree and acknowledge that the licenses granted to Roche pursuant to <u>Section 2.1</u> do not include [*]. However, the Parties also acknowledge that [*]. If either Party in good faith believes that [*].

- (b) [*] Roche will make an election as set forth in subsection (i) or (ii) below, as applicable. [*]
 - (i) [*]
 - (ii) [*]

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4. GOVERNANCE .

4.1. General. Promptly after the Effective Date, but in no event more than [*] after the Effective Date, the Parties shall establish a joint steering committee (the "JSC") in accordance with <u>Section 4.2</u> to oversee and direct the Parties' conduct under this Agreement, and the following subcommittees and teams which shall report to the JSC: a joint research team (the "JRT") in accordance with <u>Section 4.3</u> to oversee the Research Collaboration, a joint development committee (the "JDC") in accordance with <u>Section 4.4</u> to oversee the Development of the Licensed Products, a joint finance team (the "JFT") in accordance with <u>Section 4.6</u>, a joint commercialization committee (the "JCC") to oversee the Co-Detailing of the Co-Detailed Products. Each of these committees and teams shall have the responsibilities and authority allocated to it in this <u>Article 4</u> and elsewhere in this Agreement. The JSC shall have the right to form additional subcommittees and teams as it deems appropriate for carrying out the purposes of this Agreement. Each of these committees and teams shall make decisions consistent with the goal of implementing the Plans for which it is responsible and conducting other activities under this Agreement in a manner consistent with the optimization of Development and Commercialization. In the event that any of the JRT, JFT, JDC, or JCC are dissolved or do not come into existence, as applicable, the JSC shall take on all of the responsibilities of such subcommittee or team.

4.2. Joint Steering Committee .

(a) Membership . The JSC shall be composed of three (3) representatives from each of Prothena and Roche (" JSC Members "), including the Alliance Managers who shall be non-voting JSC members. The Parties each shall appoint JSC Members with appropriate seniority and functional expertise. Each Party may replace any of its JSC Members and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a JSC Member shall notify the other Party at least [*] prior to the next scheduled meeting of the JSC. Both Parties shall use Commercially Reasonable Efforts to keep an appropriate level of continuity in representation on the JSC. Both Parties may invite a reasonable number of additional experts and/or advisors to attend part or the whole JSC meeting with prior notification to the JSC. JSC Members may be represented at any meeting by another person designated by the absent JSC Member. There shall be an annually rotating chairperson of the JSC (" JSC Chairperson "), with the first JSC Chairperson to be designated by [*].

(b) **Responsibilities**. The JSC shall oversee and monitor the direction and course of the activities to be conducted under this Agreement, and shall oversee the JRT, JDC, JFT, and JCC (to the extent each subcommittee or team exists). Without limiting the generality of the foregoing, the JSC shall:

(i) review the Research Collaboration and Development activities and obligations of the Parties under this Agreement throughout the Territory for each Licensed Product;

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(ii) approve each Research Plan and Research Budget, and updates thereto, no less frequently than once per year, and review and approve any substantive departure from each;

(iii) approve each Development Plan and Development Budget, and updates thereto, for each Jointly Funded Product/Indication no less frequently than once per year, and review and approve any substantive departure from each;

(iv) facilitate the flow of information between Parties to aid in performance against goals;

(v) review the Parties' strategy for scientific publications;

(vi) approve Regulatory Filings for Jointly Funded Product/Indications, including but not limited to INDs (except as expressly provided for in Section 6.1(a)), applications for Regulatory Approval, and supportive filings with Regulatory Authorities;

(vii) agree on timing of the transfer of IND for the Lead Product to Roche;

(viii) oversee allocation of supply of Licensed Compounds and Licensed Products in the case of a shortage of supply in accordance with <u>Section 8.7</u>;

(ix) discuss any issues elevated from any subcommittees or teams;

(x) resolve Disputes and, if applicable, submit unresolved Disputes to the process described in $\underline{Section 4.2(d)}$; and

(xi) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties, including without limitation forming additional subcommittees and periodic evaluation of performance against goals.

(c) Meetings, Agenda, and Minutes . The JSC shall meet at least one (1) time per Calendar Quarter or as otherwise mutually agreed upon by the Parties. At least two (2) such meetings per Calendar Year must be held in person, and all other such meetings may be held by teleconference or videoconference. The location of the meetings of the JSC to be held in person shall alternate between sites designated by each Party. Each Party shall bear all the expenses of its representatives on the JSC. The JSC Chairperson or his/her delegate shall be responsible for sending invitations and agendas for all JSC meetings to all JSC Members at least [*] before the next scheduled meeting of the JSC. The JSC Chairperson shall be responsible for designating a JSC Member, or an attending member of another committee or team, to record in reasonable detail and circulate draft minutes of JSC meetings to all JSC Members for comment and review within [*] after the relevant meeting. The JSC Members shall have [*] to provide comments. The JSC Members within [*] after the relevant meeting. The JSC Chairperson shall approve the finalized minutes to all JSC Members within [*] after the relevant meeting. The JSC Chairperson shall approve the final version of the minutes before its distribution.

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(d) Voting; Dispute Resolution . Each of Prothena and Roche shall have one (1) collective vote on the JSC, and any matter voted on shall require the unanimous vote of both Parties. The JSC shall have no power to amend or waive compliance with this Agreement. The Parties expressly agree that [*] shall be [*]. For all [*] within the JSC's jurisdiction under Section 4.2(b), if the JSC is unable to resolve any such Dispute within [*] after it first addresses such matter (or such longer period as the Parties may mutually agree upon), then such Dispute shall be referred to the [*] and the [*] (the "Executives"). In the event the Executives of each Party are unable to resolve the Dispute within [*] after receiving notice of the Dispute (or such longer period as the Parties may mutually agree upon), then such Dispute shall be [*].

(e) Lifetime . The JSC shall exist from the Effective Date until such time that the Parties mutually agree to dissolve the JSC [*], subject to Section 4.8.

4.3. Joint Research Team.

(a) Membership . The JRT shall be composed of two (2) representatives from each of Prothena and Roche ("JRT Members"). The Parties each shall appoint JRT Members with appropriate seniority and functional expertise. Each Party may replace any of its JRT Members and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a JRT Member shall notify the other Party at least [*] prior to the next scheduled meeting of the JRT. Both Parties shall use Commercially Reasonable Efforts to keep an appropriate level of continuity in representation on the JRT. Both Parties may invite a reasonable number of additional experts and/or advisors to attend part of or the whole JRT meeting with prior notification to the JRT. JRT Members may be represented at any meeting by another person designated by the absent JRT Member. The JRT shall be co-chaired by JRT Members from each Party ("JRT Chairpersons").

(b) **Responsibilities**. The JRT shall be responsible for overseeing the Research Collaboration. Specific responsibilities and authority of the JRT shall include:

(i) planning, allocating and coordinating all Research Collaboration activities;

(ii) establishing each Research Plan and Research Budget to be proposed to the JSC for approval, and monitoring timelines and budgets, including any updates and revisions thereto;

- (iii) reviewing data arising out of the Research Plan;
- (iv) making decisions on the Research Plan and Research Budget;
- (v) reviewing and approving any substantive scientific study plans under the Research Plan;

(vi) reviewing any deviations from the requirements for agreements with subcontractors as set forth in Section 5.3;

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- (vii) attempting to reach consensus on any issues or disputes on an informal basis; and
- (viii)

JSC.

periodic reporting of Research Collaboration activities and related matters to the

The JRT shall have no responsibility and authority other than that expressly set forth in this Section 4.3

<u>(b)</u>.

(c) Meetings, Agenda, and Minutes . The JRT shall meet at least one (1) time per Calendar Quarter, unless otherwise specified by the JSC, at times and in locations agreed upon by the JRT. At least one (1) such meeting per Calendar Year must be held in person, and all other such meetings may be held by teleconference or videoconference. Each Party shall bear all the expenses of its representatives on the JRT. The JRT Chairpersons or their delegates shall be responsible for sending invitations and agendas for all JRT meetings to all JRT Members at least [*] before the next scheduled meeting of the JRT. The JRT Chairpersons shall be responsible for designating a JRT Member to record in reasonable detail and circulate draft minutes of JRT meetings to all JRT Members for comment and review within [*] after the relevant meeting. JRT Members shall have [*] to provide comments. The JRT Members and JSC Members within [*] after the relevant meeting. The JRT Chairpersons shall approve the final version of the minutes before its distribution.

(d) Voting. The JRT shall decide matters within its responsibilities set forth in <u>Section 4.3(b)</u>. Each of Prothena and Roche shall have one (1) collective vote on the JRT. JRT Members shall act in good faith and seek agreement with respect to matters to be decided by the JRT. If the JRT is unable to decide a matter by consensus for more than [*] after the JRT first addresses such matter (or such longer period as the Parties may mutually agree upon), then such disagreement shall be submitted to the JSC for resolution. The JRT shall have no power to amend or waive compliance with this Agreement.

(e) Lifetime . The JRT shall exist during the Research Term, subject to <u>Section 4.8</u>.

4.4. Joint Development Committee .

(a) **Membership**. The JDC shall be composed of three (3) representatives from each of Prothena and Roche (" JDC Members"). The Parties each shall appoint JDC Members with appropriate seniority and functional expertise. Each Party may replace any of its JDC Members and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a JDC Member shall notify the other Party at least [*] prior to the next scheduled meeting of the JDC. Both Parties shall use Commercially Reasonable Efforts to keep an appropriate level of continuity in representation on the JDC. Both Parties may invite a reasonable number of additional experts and/or advisors to attend part of or the whole JDC meeting with prior notification to the JDC. JDC Members may be represented at any meeting by another person designated by the absent JDC Member. The JDC shall be [*] (" JDC Chairperson ").

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(b) **Responsibilities** . The JDC shall be responsible for overseeing the Development of Licensed Products throughout the Territory. Specific responsibilities and authority of the JDC shall include:

(i) reviewing Development activities and obligations of the Parties under this Agreement throughout the Territory for each Licensed Product;

(ii) planning, allocating and coordinating all Development activities for Jointly Funded Product/Indications;

(iii) reviewing and commenting on each Development Plan and Development Budget for Jointly Funded Products/Indications to be proposed to the JSC for approval, and monitoring timelines and budgets, including any updates and revisions thereto;

(iv) sharing information at a high level regarding Roche's development plans for Licensed Products that are not Jointly Funded Product/Indications;

(v) reviewing and approving any clinical protocols for each Jointly Funded Product/Indication;

(vi) overseeing the progress of the Clinical Trial(s) for Jointly Funded Product/Indications;

(vii) overseeing the manufacturing activities for Jointly Funded Product/Indications;

(viii) reviewing Regulatory Filings for Jointly Funded Product/Indications, including but not limited to INDs, applications for Regulatory Approval, and supportive filings with Regulatory Authorities;

(ix) overseeing pharmacovigilance efforts for Jointly Funded Product/Indications;

(x) reviewing any deviations from the requirements for agreements with subcontractors as set forth in Section 6.8;

(xi) attempting to reach consensus on any issues or disputes on an informal basis; and

(xii) periodic reporting of Development activities and related matters to the JSC.

The JDC shall have no responsibility and authority other than that expressly set forth in this Section 4.4(b).

(c) Meetings, Agenda, and Minutes . The JDC shall meet at least one (1) time per Calendar Quarter, unless otherwise specified by the JSC, at times and in locations

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agreed upon by the JDC. At least one (1) such meeting per Calendar Year must be held in person, and all other such meetings may be held by teleconference or videoconference. Each Party shall bear all the expenses of its representatives on the JDC. The JDC Chairperson or his/her delegate shall be responsible for sending invitations and agendas for all JDC meetings to all JDC Members at least [*] before the next scheduled meeting of the JDC. The JDC Chairperson shall be responsible for designating a JDC Member to record in reasonable detail and circulate draft minutes of JDC meetings to all JDC Members for comment and review within [*] after the relevant meeting. JDC Members shall have [*] to provide comments. The JDC Members and JSC Members within [*] after the relevant meeting. The JDC Chairperson shall approve the final version of the minutes before its distribution.

(d) Voting . The JDC shall decide matters within its responsibilities set forth in <u>Section 4.4(b)</u>. Each of Prothena and Roche shall have one (1) collective vote on the JDC. JDC Members shall act in good faith and seek agreement with respect to matters to be decided by the JDC. If the JDC is unable to decide a matter by consensus for more than [*] after the JDC first addresses such matter (or such longer period as the Parties may mutually agree upon), then such disagreement shall be submitted to the JSC for resolution. The JDC shall have no power to amend or waive compliance with this Agreement.

(e) Lifetime . The JDC shall exist during the period of time in which at least one (1) Jointly Funded Product/Indication is being Developed, subject to <u>Section 4.8</u>.

4.5. Joint Finance Team. The JFT shall have the membership, responsibilities, meetings, and lifetime as set forth in Section 6 of <u>Exhibit 1.35</u>.

4.6. Joint Commercialization Committee. If Prothena exercises its Co-Detailing Option in accordance with <u>Section 7.1(b)</u>, then upon [*], the Parties shall establish a JCC under the Co-Detailing Agreement to oversee the Co-Detailing of the Co-Detailed Products and Commercialization of the Jointly Funded Product/Indications, which shall include the responsibilities set forth in Sections 4.6(a) and (b). If the JCC does not come into existence, the JSC shall have the following additional responsibilities:

(a) reviewing and commenting on each Commercialization Plan and Commercialization Budget for each Jointly Funded Product/Indication in the Shared Territory no less frequently than once per Calendar Year, and monitoring timelines and budgets, including any updates and revisions thereto; and

(b) reviewing Commercialization activities in the Territory at a high level.

4.7. Alliance Managers . Promptly after the Effective Date, each Party shall appoint an individual to act as the alliance manager for such Party (each, an "Alliance Manager "). Each Alliance Manager shall be a non-voting JSC Member. The Alliance Managers will be responsible for the day-to-day coordination of the collaboration activities contemplated by this Agreement, will facilitate communication regarding all activities hereunder, and will be responsible for following-up on decisions made by the JSC. The name and contact information for such Alliance Manager, as well as any replacement(s) chosen by Prothena or Roche, in their

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sole discretion, from time to time, shall be promptly provided to the other Party in accordance with Section 18.5.

4.8. Membership in Committees. Prothena's membership in any Committee shall be at its sole discretion, as a matter of right and not obligation, for the sole purpose of participation in governance, decision-making, and information exchange with respect to activities within the jurisdiction of such Committee. Prothena shall have the right to withdraw from membership in any or all of the Committees upon [*].

5. **RESEARCH COLLABORATION**

5.1. General . Commencing on the Effective Date, the Parties shall collaborate on [*] (together, the "**Research Collaboration**").

5.2. Research Plan and Research Budget .

a. In General. The Research Collaboration shall be governed by a Research Collaboration plan (the "Research Plan"), and the costs and expenses relating to Research Collaboration shall be governed by a Research Collaboration budget (the "Research Budget"), the initial forms of which are attached as <u>Exhibit 5.2(a)(i)</u> and <u>Exhibit 5.2(a)(i)</u>, respectively. The Research Plan will set forth (i) the scope of the Research Collaboration and the resources that will be dedicated to the activities for the Research Collaboration, including the responsibilities of each Party, (ii) specific objectives for each Calendar Year, which objectives will be updated or amended, as appropriate, by the JRT as research progresses, (iii) Prothena and Roche personnel assigned to the team from specified functional areas, and (iv) any activities to be performed by Third Party contractors.

b. Research Plan Updates and Amendments. The JRT shall review the Research Plan on an ongoing basis and may amend the Research Plan. Any such changes shall be reflected in written amendments to the relevant Research Plan. The Research Plan and the Research Budget will be updated annually. The JRT will commence discussions of each Research Plan and Research Budget in [*] of the year preceding the year in which such Research Plan and Research Budget to the JSC for review and approval by [*] of each Calendar Year for the then-current Calendar Year. The JSC shall provide comments on each such updated Research Plan or Research Budget, as applicable, within [*] following their submission. Within [*] following such original submission, the JSC shall either approve the Research Plan and Research Budget or approve a modified Research Plan and Research Budget prepared by the JRT.

c. Funding; FTEs. Roche will be responsible for funding the Research Collaboration in accordance with the Research Budget. Prothena shall provide, and Roche shall fund, up to [*] Prothena FTEs at the FTE Rate for performance of the research and other activities for which Prothena is responsible under the Research Plan. Each individual included in the funded FTEs shall [*] by such individual under the Research Plan.

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5.3. Third Party Contractors . Roche shall be free to subcontract its activities under the Research Plan. If specified in the Research Plan, or agreed in writing by the JRT, Prothena may use Third Party contractors to perform its activities under the Research Plan. The subcontracting Party shall ensure that, unless otherwise agreed by the JRT, for each subcontractor under this <u>Section 5.3</u>: (a) such subcontractor has entered or shall enter into, prior to performing activities under this Agreement, an appropriate written agreement obligating such subcontractor to be bound by obligations of confidentiality that are no less restrictive than the obligations set forth in <u>Article 11</u>; (b) the subcontractor in performing such services; and (c) the subcontracting Party shall at all times be responsible for the performance of such subcontractor as if such activities were performed by the responsible Party.

5.4. Personnel; Efforts . The Prothena personnel assigned to work on the Research Collaboration shall comprise a core team for the research efforts. Prothena shall use the research funding it receives from Roche solely to carry out its activities under the Research Collaboration in accordance with this Agreement. Each Party shall use Commercially Reasonable Efforts to perform its respective tasks and obligations in conducting all activities ascribed to it in the then-current Research Plan.

5.5. Reports. Within [*] after the reasonable request of Roche during the Research Term for informal updates or within [*] after the completion of a study during the Research Term or expiration of the Research Term, as applicable, Prothena shall provide to Roche a written informal update or report summarizing its activities under the Research Collaboration, including any material data and information generated in the course of the Research Collaboration not previously provided to Roche.

5.6. Materials. During the Research Term, at a Party's request, the other Party will provide reasonable quantities of those materials generated pursuant to the Research Collaboration solely to allow each Party to conduct activities related to the Research Collaboration.

5.7. Rese a **rch Records**. Each Party shall maintain records of the Research Collaboration (or cause such records to be maintained) in sufficient detail and in good scientific manner to properly reflect all work done and results achieved by or on behalf of such Party in the performance of the Research Collaboration. All laboratory notebooks shall be maintained for no less than the term of any Patents issuing therefrom. To the extent practical, the notebooks of each Party for this Agreement shall be separate from notebooks documenting other research and Development of such Party.

5.8. Term and Termination . The Research Collaboration shall commence on the Effective Date and, unless earlier terminated, shall continue for a period of three (3) years, as may be extended for one or more additional one (1) year periods by written agreement of the Parties (the "**Research Term**"). Roche may terminate the Research Term at any time upon ninety (90) days' prior written notice to Prothena. On notice of such termination, Prothena will use Commercially Reasonable Efforts to wind down Prothena's continuing Research Collaboration activities and transition to

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Roche [*], in such a manner as not to impact negatively the further research, and return to Roche [*]. Roche will be responsible for [*].

6. DEVELOPMENT AND REGULATORY MATTERS

6.1. Lead Product and Initial Indication; Prothena's Opt-In to Co-Develop Licensed Products

(a) Lead Product and Initial Indication . The initial indication for the Lead Product shall be the Parkinson's Disease Indication and, subject to <u>Section 6.2</u>, such Lead Product for the Parkinson's Disease Indication shall be a Jointly Funded Product/Indication and will be Developed in accordance with the Development Plan. Prothena shall file the IND in the United States for the Lead Product, and shall be responsible for communications with Regulatory Authorities for such Lead Product, with reasonable review and input from Roche (for clarity, the submission of the first IND for the Lead Product shall not be subject to Roche's approval), until such time as Prothena transfers the IND to Roche, as agreed upon by the JSC. Thereafter, Roche shall be responsible for all interactions with Regulatory Authorities for the Lead Product.

(b) **Prothena's Opt-In to Co-Develop Licensed Products**. To the extent that Roche, in consultation with the JSC, decides to Develop the first Licensed Product for additional indications, or additional Licensed Products for one or more indications (including without limitation the Parkinson's Disease Indication), Prothena shall have the option to co-Develop such Licensed Product for such indication with Roche (each, an "Opt-In") upon written notice to Roche at any time prior to [*]. Following such Opt-In, such Licensed Product shall thereafter be a Jointly Funded Product/Indication, and the Parties shall thereafter share Profit and Loss, including Development Costs, pursuant to Exhibit 1.35 with respect thereto.

6.2. Prothena's Opt-Out Rights . Prothena may elect to opt out of sharing Profit and Loss, including Development Costs, in the Shared Territory for a Jointly Funded Product/Indication (each, an "**Opt-Out** ") upon written notice to Roche at any time after [*]. If Prothena exercises an Opt-Out under this <u>Section 6.2</u>, then:

(a) Prothena shall have no further responsibility for conducting new Development activities with respect to such Licensed Product for such indication, and Prothena will use Commercially Reasonable Efforts to wind down Prothena's continuing Development tasks for such Licensed Product for such indication and transition them to Roche in such a manner as not to impact negatively the Development of such Licensed Product for such indication. Roche shall [*].

(b) Such Licensed Product for such indication shall no longer be included as a Jointly Funded Product/Indication, and <u>Section 6.3</u> shall apply;

(c) Prothena shall not bear any further Development Costs incurred with respect to such Licensed Product for such indication after the wind down and transition as set forth in <u>Section 6.2</u> has been completed, and Prothena shall not thereafter be eligible to share Profit and Loss pursuant to <u>Exhibit 1.35</u> with respect to such Licensed Product for such indication but shall instead receive milestones and royalties with respect to such Licensed

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Product for such indication pursuant to <u>Section 9.4(d)</u> and <u>Section 9.5(c)</u>. The JFT will take necessary actions to equitably address Development Costs committed up to the effective date of Prothena's Opt-Out; and

(d) Prothena will retain its option to co-Detail such Licensed Product for such indication in the United States pursuant to <u>Section 7.1(b)</u>.

6.3. Allocation Mechanism . If a Licensed Product is Developed for indications other than the indications constituting a Jointly Funded Product/Indication (whether because Prothena has not Opted In to such other indication or has Opted Out of such other indication), then the Parties shall meet to establish, within [*] after Roche decides to Develop such Licensed Product for such other indication, a mechanism to allocate future Profit and Loss, including Development Costs (to the extent not specifically identifiable to a particular indication) and Royalty Net Sales for the relevant Licensed Products for the indications constituting the Jointly Funded Product/Indication and the other indications for which such Licensed Products are so Developed, to effect the economic intent of this Agreement.

6.4. Development Activities . Roche shall take the lead in the Development of Licensed Products, provided that, unless otherwise agreed by the JSC, Prothena shall be responsible for [*]. Each Party shall be responsible for conducting the activities assigned to it in the Development Plan under the direction and supervision of the JDC, with Development Costs for Jointly Funded Product/Indications shared by the Parties as set forth in <u>Section 6.7(a)</u>. Each Party shall be responsible for selection and supervision of its personnel assigned to tasks related to Development activities. Subject to <u>Section 6.1(a)</u> and the role of the JDC and JSC, Roche shall be responsible for making, and have authority to make, all decisions, and undertake any actions necessary as a result of such decisions, regarding Development (including additional preclinical and clinical development and testing), selecting drug candidates, and preparing and filing BLAs and any other applications for Regulatory Approval, all in a manner consistent with this Agreement.

6.5. Development Efforts . In the Shared Territory, each Party shall use Commercially Reasonable Efforts to Develop the Jointly Funded Product/Indications in accordance with the Development Plan and the terms of this Agreement. In the Royalty Territory, Roche shall use Commercially Reasonable Efforts to Develop at least one Licensed Product in accordance with the terms of this Agreement.

6.6. Development Plan and Development Budget.

(a) **Content**. The Development of Jointly Funded Product/Indications shall be governed by a global Development plan (the "**Development Plan**"), and the costs and expenses relating to the Development of Jointly Funded Product/Indications shall be governed by a Development budget (the "**Development Budget**"), the initial forms of which are attached as <u>Exhibit 6.6(a)(i)</u> and <u>Exhibit 6.6(a)(ii)</u>, respectively. The Development Plan and Development Budget shall be updated by the JDC at least annually and shall cover the following [*] period. Each Development Plan shall include without limitation (i) an overview of the Clinical Trials anticipated to be conducted by the Parties to support Regulatory Approval of the Jointly Funded Product/Indications in the Territory, and related timelines, (ii) other material activities necessary

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for Development of the Jointly Funded Product/Indications in the Territory, (iii) the proposed overall program of Development for the Licensed Products, and (iv) at an appropriate stage of Development, a publication strategy. The Development Budget shall specify that (1) unless Prothena has Opted Out in accordance with <u>Section 6.2</u>, Prothena may contribute up to [*] funded FTEs at the FTE Rate for Development activities up through and including the first Phase I Clinical Trial, (2) Roche shall [*], and (3) the Parties shall discuss [*].

(b) Updates . The JDC shall, on an annual basis, update the Development Plan and Development Budget for the [*] period. The JDC shall submit such updated Development Plans and Development Budgets for each Jointly Funded Product/Indication to the JSC for approval by [*] of each Calendar Year for the then-current Calendar Year. The JSC shall provide comments, if any, on each such updated Development Plan or Development Budget for each Jointly Funded Product/Indication, as applicable, within [*] following their submission. Within [*] following such original submission, the JSC shall either approve the Development Plan and Development Budget or approve a modified Development Plan and Development Budget prepared by the JDC for each Jointly Funded Product/Indication.

6.7. Development Costs for Jointly Funded Product/Indications .

(a) Sharing of Development Costs. The Parties shall share all Development Costs in the following ratio: Prothena shall bear thirty percent (30%) of Development Costs and Roche shall bear seventy percent (70%) of Development Costs, including all of Prothena's reasonable, out-of-pocket costs incurred in connection with preparation to conduct the Phase I Clinical Trial of Licensed Products ("Ramp-up Costs"), even if such costs were incurred prior to the Effective Date; *provided, however*, that in no event shall Roche be obligated to reimburse to Prothena more than [*] in Ramp-up Costs. Prothena shall invoice Roche after the Effective Date for the amounts incurred by Prothena prior to the Effective Date that are reimbursable Ramp-up Costs, and provide to Roche documentation of such reimbursable Ramp-up Costs. Roche shall pay all invoiced amounts within [*] after receiving such invoice.

(b) [*] **Development Costs**. For the first Jointly Funded Product/Indication that [*] (a "**Prothena Antibody Product**"), Roche shall provide Prothena by [*] of each Calendar Year with a budget detailing the estimated Development Costs for such Prothena Antibody Product for the [*]. The budget set forth for the [*] will be considered a firm estimate. If in any [*] the actual Development Costs for such Prothena Antibody Product exceed the costs set forth in the firm estimate for such [*], then [*]. For example, if the Development Costs for a Prothena Antibody Product exceed the costs that are set forth in the firm estimate for [*], then [*].

(c) Biomarkers and Companion Diagnostics . [*] shall be responsible for [*] activities associated with the research related to identification of biomarkers and companion diagnostics, prior to validation of such biomarkers and companion diagnostics. Any Development activities for biomarkers and companion diagnostics commencing with clinical studies intended to validate such biomarkers and companion diagnostics, in which such items are studied along with Licensed Products, will be agreed by the JDC, and costs thereof for use with Jointly Funded Product/Indications shall be included in Development Costs; otherwise, [*] shall solely bear all such costs.

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6.8. Development Subcontracting. Prothena may subcontract its material Development obligations to the Third Parties set forth in Exhibit 6.8 without the prior written consent of Roche, and may subcontract its other material Development obligations to any Third Party with the prior written consent of Roche. Roche may subcontract its Development obligations to any Third Party with the prior written consent of Prothena. The direct, out-of-pocket costs of engaging any such Third Party in the Shared Territory, to the extent related to the Jointly Funded Product/Indications, shall be included as Development Costs. The subcontracting Party shall ensure that, unless otherwise agreed by the JDC, for each subcontractor under this <u>Section 6.8</u>: (a) such subcontractor has entered or shall enter into, prior to performing activities under this Agreement, an appropriate written agreement obligations set forth in <u>Article 11</u>; (b) the subcontractor party shall retain or obtain ownership of any Inventions and all intellectual property rights therein made by such subcontractor in performing such services; and (c) the subcontracting Party shall at all times be responsible for the performance of such subcontractor as if such activities were performed by the responsible Party.

6.9. Cooperation. During the period of time in which at least one (1) Jointly Funded Product/Indication is being Developed, the Parties shall cooperate with each other to provide reasonable support in the conduct of all activities necessary or useful for the Development of Jointly Funded Product/Indications.

6.10. Licensed Products other than Jointly Funded Product/Indications . Except for those activities set forth in <u>Section 6.1(a)</u>, as between the Parties, Roche (and, if applicable, Roche's Sublicensees and/or Affiliates) has the sole right and responsibility for, and control over, all Development activities, including all regulatory activities, with respect to Licensed Compounds and Licensed Products that are not Jointly Funded Product/Indications. Unless Prothena exercises its Opt-In and as may be otherwise agreed by the Parties, Roche shall bear all costs and expenses associated with research, Development, manufacturing and Commercialization activities with respect to Licensed Compounds and Licensed Product/Indications.

6.11. R&D Technology Transfer. As agreed upon by the JRT or JDC, as applicable, Prothena shall provide reasonable assistance and technical expertise as necessary to transfer to Roche [*] to support Development of the Licensed Products.

6.12. Ownership of Regulatory Filings and Regulatory Approvals. Subject to <u>Section 6.1(a)</u>, Roche shall be the owner of all Regulatory Filings and Regulatory Approvals covering the Licensed Products in the Territory. Roche shall provide Prothena, through a shared file system that allows for secured access, with a copy of all Regulatory Filings and Regulatory Approvals. Roche shall list Prothena as the "collaborator" in each Regulatory Filing for Jointly Funded Product/Indications in the Shared Territory.

6.13. Interaction with Regulatory Authorities. Subject to <u>Section 6.1(a)</u>, Roche shall be responsible for all interactions with Regulatory Authorities relating to Development in the Territory. Roche shall update Prothena as to all material communications with Regulatory Authorities on matters related to the Licensed Products. Roche will provide to Prothena any copies of material written communications [*]. To the extent allowed by Applicable Law and as

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is reasonably practicable due to the nature and urgency of meetings with Regulatory Authorities, Prothena shall have the right to participate in meetings with Regulatory Authorities throughout the Territory [*]. Upon request by Roche, Prothena shall provide reasonable support for Roche's meetings with Regulatory Authorities in the Royalty Territory relating to the Licensed Products.

6.14. Scientific Record Keeping. Each Party shall record, and shall require its Affiliates, Sublicensees, and subcontractors to record, to the extent practical, all research and Development Information relating to this Agreement in accordance with its internal practices and industry standards. Such records shall be complete and accurate and shall fully and properly reflect all such work done and results achieved in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. To the extent practical, the notebooks of each Party for this Agreement shall be separate from notebooks documenting other research and Development of such Party.

6.15. Pharmacovigilance. Roche and Prothena shall execute a separate Pharmacovigilance Agreement when applicable, setting forth the procedures and timelines for compliance with Applicable Laws pertaining to safety reporting and their related activities with respect to Licensed Products in the Territory. Prior to the transfer of the IND to Roche in accordance with <u>Section 6.1(a)</u>, Prothena shall be responsible for safety data and maintaining the safety database for the Lead Product. Thereafter, Prothena shall transfer the safety database to Roche and Roche will be responsible for safety data and maintaining the safety database for all Licensed Products.

7. COMMERCIALIZATION .

7.1. Commercialization Activities .

(a) General . Subject to Prothena's Co-Detailing Option as set forth below, Roche shall be responsible for the Commercialization of the Licensed Products in the Territory, and all costs associated therewith. Throughout the Territory, Roche shall book all sales of the Licensed Products.

(b) Co-Detailing Option . Prothena shall have the option to co-Detail in the United States: (i) the first Licensed Product for the Parkinson's Disease Indication to obtain Regulatory Approval, whether or not such Licensed Product is a Jointly Funded Product/Indication, and (ii) if Prothena exercises such option for such first Licensed Product for the Parkinson's Disease Indication, then each subsequent Licensed Product to obtain Regulatory Approval for the Parkinson's Disease Indication [*] (each option, a "Co-Detailing Option ", and each product, a "Co-Detailed Product "). Each Co-Detailing Option shall be exercisable no later than [*] by providing written notice to Roche specifying that Prothena is electing to co-Detail such Licensed Product.

(c) Right to Use a Contract Sales Force . Prothena's Sales Representatives shall be its own employees, except that during the [*] following the First Commercial Sale of each Co-Detailed Product, Prothena may engage a contract sales organization or contract sales representatives approved by Roche, such approval not to be unreasonably withheld, to perform co-Detailing activities on a transitional basis. Such sales force must be in place no later than [*]

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prior to the estimated date of First Commercial Sale of the applicable Co-Detailed Product; otherwise, Prothena's right to co-Detail such Co-Detailed Product shall terminate.

(d) **Co-Detailing Plan; Co-Detailing Agreement**. Within [*] after Prothena's exercise of a Co-Detailing Option, the JSC shall meet and discuss (i) a co-Detailing plan prepared by Roche (the "**Co-Detailing Plan**"), (ii) Prothena's obligations under the Co-Detailing Plan, and (iii) compensation to be paid to Prothena for its co-Detailing efforts. Within [*] after Prothena's exercise of such Co-Detailing Option, the Parties shall negotiate in good faith and execute a co-Detailing agreement, which shall specify the terms of the co-Detailing arrangement between the Parties in the United States with respect to the applicable Licensed Product, and shall be consistent with the terms and conditions set forth in Exhibit 7.1(d) (the "Co-Detailing Agreement").

7.2. Commercialization Efforts . In the Shared Territory, Roche shall use Commercially Reasonable Efforts to Commercialize the Jointly Funded Product/Indications in accordance with the Commercialization Plan and the terms of this Agreement, and if applicable, Prothena shall use Commercially Reasonable Efforts to Detail each Co-Detailed Product and perform activities assigned to Prothena in the Co-Detailing Plan. In each Major Market Country in the Royalty Territory, Roche shall use Commercially Reasonable Efforts to Commercialize at least one Licensed Product.

7.3. Commercialization Plan and Commercialization Budget for the Shared Territory. A Commercialization Plan and Commercialization Budget for each Jointly Funded Product/Indication in the Shared Territory shall be prepared and updated in accordance with Section 3 of <u>Exhibit 1.35</u>.

7.4. Discounted Sales. It is possible that a Licensed Product could be included as part of a package of products offered to customers by Roche or its Affiliates or Sublicensees, and that discounts on packages including a Licensed Product (a "**Package**") may be offered independently in the Shared Territory and the Royalty Territory. Roche shall not discount the price of a Licensed Product sold as part of a Package unreasonably compared to the discount Roche offers on prices of the other products included in such Package.

7.5. Recalls. Roche shall provide prompt written notice to Prothena in the event of a recall of any Licensed Products in the Territory, and shall be solely responsible for handling such recall. For clarity, the expenses of a recall of Jointly Funded Product/Indications in the Shared Territory, including without limitation the expenses related to maintaining a call center and responding to consumer and physician inquiries, shall be included as an Allowable Expense.

7.6. Trademarks .

(a) Licensed Product Trademarks . Roche shall select and solely own the Licensed Product Trademarks.

(b) **Display of Trademarks**. To the extent allowed by Applicable Law, all Licensed Product labeling and packaging, including without limitation package inserts and any Promotional Materials associated with the Licensed Products, shall carry a Licensed Product

[*] 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 the omitted portions.

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Trademark and a Roche Trademark selected by Roche, and for Co-Detailed Products in the United States, a Prothena Trademark selected by Prothena.

(c) Use of Trademarks . Neither Party shall use any Trademark of the other Party outside the scope of this Agreement, or knowingly take any action that would materially adversely affect the value of any such Trademark. Each Party shall retain the right to monitor the quality of the goods on or with which its Trademark is used to the extent necessary to maintain its Trademark rights.

(d) **Prosecution and Maintenance**. Roche shall be responsible for filing, prosecuting and maintaining the Licensed Product Trademarks and Roche Trademarks, and conducting litigation with respect thereto, and Roche shall bear all costs and expenses associated therewith. To the extent a Prothena Trademark is used, Prothena shall bear all costs and expense of, and be responsible for filing, prosecuting and maintaining, any Prothena Trademarks.

8. MANUFACTURING AND SUPPLY OBLIGATIONS .

8.1. Process Transfer [*]. If Roche decides to develop or have developed the process of manufacturing the Lead Compound and Lead Product [*], then to the extent [*] with respect to technology transfer of the Lead Compound and Lead Product in its then-current formulation [*], and Roche shall [*].

8.2. Termination of [*]. Following the earlier of the completion of technology transfer [*] as set forth in <u>Section 8.1</u>, or the execution of a manufacturing and supply agreement [*], (a) Prothena shall [*] specific to the Lead Compound and (b) Roche shall [*].

8.3. Manufacturing Responsibility . Until the completion of technology transfer [*] as set forth in <u>Section 8.1</u>, or the execution of a manufacturing and supply agreement [*], but in no event longer than [*], Prothena shall be responsible for providing manufacturing-related services to Roche, including but not limited to the supply of quantities of Lead Compound and Lead Product manufactured under the BI Supply Agreement as requested by Roche for technical, non-clinical and clinical Development in the Territory. The costs related to such activities at BI as requested by Roche shall be shared as a Development Cost for the Shared Territory or borne for the Royalty Territory by Roche [*], as applicable. For purposes of clarity, all costs for clinical supply of Lead Compound and/or Lead Product already manufactured as of the Effective Date shall be borne by Prothena, as well as costs of stability testing incurred prior to the Effective Date, but costs incurred after the Effective Date for ongoing stability testing for such material will be shared as a Development Cost. After such date, Roche shall have sole responsibility for all manufacturing-related activities, including without limitation obtaining and making available adequate supplies of Licensed Compounds and Licensed Products for Development and Commercialization in the Territory.

8.4. Manufacturing Approvals. Prothena shall be responsible for obtaining Regulatory Approval for the manufacture of the Lead Product until the transfer of the IND as agreed by the JSC under <u>Section 6.1(a)</u>. Thereafter, Roche shall be responsible for obtaining Regulatory Approval for the manufacture of Licensed Products as part of the Regulatory Filings

[*] 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 the omitted portions.

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for such Licensed Products. Such filings shall include the filing and maintenance of a Drug Master File with the FDA and the equivalent thereof in the other countries in the Territory.

8.5. Compliance with Applicable Law. Each Party shall manufacture, or have a Third Party manufacture, Licensed Compounds and Licensed Products in full compliance with all aspects of Applicable Law, the applicable specifications, and all applicable FDA (or foreign equivalent) requirements, including without limitation thencurrent GMP, as applicable.

8.6. Supply Expenses . The Fully Burdened Manufacturing Cost of supplying Jointly Funded Product/Indications for use in Development in the Shared Territory shall be included in Development Costs. The Cost of Goods Sold for the manufacture and supply of Jointly Funded Product/Indications for Commercialization in the Shared Territory shall be included in Cost of Sales. Roche shall be responsible for the cost of manufacturing quantities of Licensed Products in the Royalty Territory in accordance with the terms of this Agreement.

8.7. Shortage of Supply. In the event that Roche is unable to manufacture sufficient quantities of a Licensed Product to satisfy worldwide demand, then the JSC shall (a) determine what quantity of such Licensed Product shall be allocated to the Clinical Trials then on-going to obtain Regulatory Approval and (b) allocate the remaining available Licensed Product [*], subject to any limitations imposed by regulatory requirements.

8.8. Capital Costs . Roche shall be responsible for all capital costs incurred in connection with the manufacture of each Licensed Compound and Licensed Product incorporating such Licensed Compound, including without limitation building out manufacturing capacity for such Licensed Compound and Licensed Product and final packaging of such Licensed Product. The [*] in accordance with Roche's internal accounting policies as consistently applied.

9. PAYMENT OBLIGATIONS .

9.1. Upfront Payment. In consideration for the rights granted to Roche under this Agreement, Roche Basel shall pay to Prothena Ireland a one-time, non-refundable, non-creditable payment of thirty million Dollars (\$30,000,000), within [*] of the Effective Date and receipt by Roche Basel of an invoice for such amount from Prothena Ireland, by wire transfer of immediately available funds into an account designated in writing by Prothena Ireland.

9.2. Research Collaboration Costs . Roche shall pay for the costs of conducting the Research Collaboration in accordance with the Research Plan and Research Budget.

9.3. Sharing of Profit and Loss . Roche Nutley and Prothena US shall share all Profit and Loss in the Shared Territory for all Jointly Funded Product/Indications. The ratio of such sharing shall be as follows: thirty percent (30%) of Profit and Loss to Prothena US and seventy percent (70%) of Profit and Loss to Roche Nutley. The method and timing for payment of Profit and Loss is set forth in Exhibit 1.35.

9.4. Milestone Payments .

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(a) **Clinical Milestones**. In consideration for the rights granted to Roche under this Agreement, Roche shall make the following one-time, non-refundable, non-creditable milestone payments to Prothena (up to a total of \$[*] per Licensed Product) within [*] after the achievement of the relevant milestone for each Licensed Product and receipt by Roche of an invoice for such amount from Prothena; [*]:

		Milestone Event	Payment
(i)	[*]		\$15,000,000
(ii)	[*]		\$[*]
(iii)	[*]		\$[*]
(iv)	[*]		\$[*]

Notwithstanding the foregoing, [*]. The following summarizes the percentage of the payments set forth above that are due with respect to various types of Licensed Compounds:

Type of Licensed Compound	Percentage of milestone amount due to Prothena (based on the table immediately above), if such Licensed Compound [*]	Percentage of milestone amount due to Prothena (based on the table immediately above), if such Licensed Compound [*]
[*]	[*]%	[*]%
[*]	[*]%	[*]%
[*]	[*]%	[*]%
[*]	[*]%	[*]%

The Parties will coordinate to have separate invoices with respect to each milestone payment so that accounting can be allocated appropriately (based on [*] or as otherwise mutually agreed by the JFT) to Roche Nutley and Prothena US for the portion of such milestone payment related to the United States and to Roche Basel and Prothena Ireland for the balance of such milestone payment.

(b) **Regulatory and Commercial Milestones**. In consideration for the rights granted to Roche under this Agreement, Roche shall make the following one-time, non-refundable, non-creditable milestone payments (up to \$[*] per Licensed Product) to Prothena within [*] after the achievement of the relevant milestone for each Licensed Product and receipt by Roche of an invoice for such amount from Prothena; [*]:

	Milestone Event	Payment
(i)	Filing of first BLA in [*]	\$[*]
(ii)	Filing of first BLA in [*]	\$[*]
(iii)	Filing of first BLA in [*]	\$[*]
(vii)	Filing of first BLA in [*]	\$[*]
(viii)	Filing of first BLA in [*]	\$[*]
(ix)	Filing of first BLA in [*]	\$[*]
(iv)	Upon First Commercial Sale in [*]	\$[*]
(v)	Upon First Commercial Sale in [*]	\$[*]
(vi)	Upon First Commercial Sale in [*]	\$[*]
(x)	Upon First Commercial Sale in [*]	\$[*]
(xi)	Upon First Commercial Sale in [*]	\$[*]
(xii)	Upon First Commercial Sale in [*]	\$[*]
[*]		
[]		

The Parties will coordinate to have separate invoices with respect to milestone payments so that accounting can be allocated appropriately to Roche Nutley and Prothena US for milestone payments related to the United States and to Roche Basel and Prothena Ireland for all other milestone payments.

(c) **Royalty Territory Sales Milestones**. In consideration for the rights granted to Roche under this Agreement, Roche Basel shall make the following one-time, non-refundable, non-creditable milestone payments (up to \$175,000,000 per Licensed Product) to Prothena Ireland within [*] after the achievement of the relevant milestone for each Licensed Product and receipt by Roche of an invoice for such amount from Prothena:

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	Milestone Event	Payment
(i)	Achievement of at least \$[*] in Royalty Net Sales within a single Calendar Year in [*]	\$[*]
(ii)	Achievement of at least \$[*] in Royalty Net Sales within a single Calendar Year in [*]	\$[*]
(iii)	Achievement of at least \$[*] in Royalty Net Sales within a single Calendar Year in [*]	\$[*]
(iv)	Achievement of at least \$[*] in Royalty Net Sales within a single Calendar Year in [*]	\$[*]
(v)	Achievement of at least \$[*] in Royalty Net Sales within a single Calendar Year in [*]	\$[*]
(vi)	Achievement of at least \$[*] in Royalty Net Sales within a single Calendar Year in [*]	\$[*]
(vii)	Achievement of at least \$[*] in Royalty Net Sales within a single Calendar Year in [*]	\$[*]
(viii)	Achievement of at least \$[*] in Royalty Net Sales within a single Calendar Year in [*]	\$[*]

(d) United States Sales Milestones (If no Opt-In or After Opt-Out). For any Licensed Products and indications for which Prothena US does not Opt In or for which Prothena US Opts Out, in consideration for the rights granted to Roche under this Agreement, Roche Nutley shall make the following one-time, non-refundable, non-creditable milestone payments (up to \$155,000,000) to Prothena US within [*] days after the achievement of the relevant milestone in United States [*] for each Licensed Product and receipt by Roche Nutley of an invoice for such amount from Prothena US:

	Milestone Event	Payment
(i)	Achievement of at least \$[*] in Royalty Net Sales within a single Calendar Year in the United States	\$[*]
(ii)	Achievement of at least \$[*] in Royalty Net Sales within a single Calendar Year in the United States	\$[*]
(iii)	Achievement of at least \$[*] in Royalty Net Sales within a single Calendar Year in the United States	\$[*]
(iv)	Achievement of at least \$[*] in Royalty Net Sales within a single Calendar Year in the United States	\$[*]

9.5. Royalties .

(a) **Royalty Territory Other than United States and** [*]. In consideration for the rights granted to Roche under this Agreement, including without limitation licenses under the Prothena Technology and other proprietary rights, Roche Basel shall pay Prothena Ireland royalties on a Licensed Product-by-Licensed Product basis in the Royalty Territory (other than the United States and [*]) as follows:

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	Royalty Rate		
Portion of Aggregate Royalty Net Sales for the Royalty Territory (other than the United States and [*]) in a Calendar Year	Lead Product	Each Licensed Other Product [*]	Each Licensed Other Product [*]
≤ \$[*] > \$[*] and	[*]%	[*]%	[*]%
\leq \$[*]	[*]%	[*]%	[*]%
> \$[*] and			
\leq \$[*]	[*]%	[*]%	[*]%
> \$[*] and	[]/0	[]/0	[]/0
\leq \$[*]	[*]0/	[*]0/	[*]0/
>\$[*]	[*]% [*]%	[*]% [*]%	[*]% [*]%

For example, if the aggregate Royalty Net Sales for the Lead Product in the Royalty Territory (other than the United States and [*]) in a Calendar Year are \$[*], then the royalty rate shall be [*]% for the first \$[*] in Royalty Net Sales (i.e., \$[*]) and [*]% for the next \$[*] in Royalty Net Sales (i.e., \$[*]), for a total royalty of \$[*].

(b) [*]. In consideration for the rights granted to Roche under this Agreement, including without limitation licenses under the Prothena Technology and other proprietary rights, Roche Basel shall pay Prothena Ireland royalties on a Licensed Product-by-Licensed Product basis in [*] as follows:

Portion of Aggregate Royalty Net Sales for [*] in a Calendar Year	Lead Product	Royalty Rate Each Licensed Other Product [*]	Each Licensed Other Product [*]
≤ \$[*] > \$[*] and	[*]%	[*]%	[*]%
≤ \$[*] > \$[*] and	[*]%	[*]%	[*]%
≤ \$[*] > \$[*]	[*]% [*]%	[*]% [*]%	[*]% [*]%

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For example, if the aggregate Royalty Net Sales for the Lead Product in [*] in a Calendar Year are [*], then the royalty rate shall be [*]% for the first [*] in Royalty Net Sales (i.e., [*]), [*]% for the next [*] in Royalty Net Sales (i.e., [*]), and [*]% for the next [*] in Royalty Net Sales (i.e., [*]), for a total royalty of [*].

(c) United States (If no Opt-In or After Opt-Out). For any Licensed Products and indications for which Prothena US does not Opt In under <u>Section 6.1(b)</u> or for which Prothena US Opts Out in accordance with <u>Section 6.2</u>, in consideration for the rights granted to Roche under this Agreement, including without limitation licenses under the Prothena Technology and other proprietary rights, Roche Nutley shall pay Prothena US royalties on a Licensed Product-by-Licensed Product basis in the United States [*] as follows:

	Royalty Rate			
Portion of Aggregate Royalty Net Sales for the United States in a Calendar Year	Lead Product	Each Licensed Other Product [*]	Each Licensed Other Product [*]	
≤ \$[*] > \$[*] and	[*]%	[*]%	[*]%	
\leq [*]	[*]%	[*]%	[*]%	
> \$[*] and				
\leq \$[*]	[*]%	[*]%	[*]%	
> \$[*] and				
$\leq $ [*]	54367	THE R	54367	
	[*]%	[*]%	[*]%	
>\$[*]	[*]%	[*]%	[*]%	

For example, if the aggregate Royalty Net Sales for the Lead Product in the United States [*] in a Calendar Year are [*], then the royalty rate shall be [*]% for the first [*] in Royalty Net Sales (i.e., [*]) and [*]% for the next [*] in Royalty Net Sales (i.e., [*]), for a total royalty of [*]. For the avoidance of doubt, any sales of or for Jointly Funded Product/Indications in the United States shall be excluded from the determination of royalties under this <u>Section 9.5(c)</u>.

9.6. Royalty Reductions .

(a) **Royalty Step-Down**. On a country-by-country and Licensed Product-by-Licensed Product basis, the royalties due under <u>Section 9.5</u> shall be reduced as follows:

- (i) by [*] at any time at which [*]; or
- (ii) by [*] at any time at which [*].

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(b) **Biosimilar Entry**. After the entry of a Biosimilar Version of a Licensed Product in a country in the Territory, the royalties due under <u>Section 9.5</u> for such Licensed Product in such country shall be reduced as follows:

- (i) by [*] in subsequent [*] if in [*]; and
- (ii) by [*] in subsequent [*] if in [*].

(c) **Royalty Floor**. Notwithstanding the foregoing, in no event shall the application of <u>Section 9.6</u> (a) and <u>Section 9.6(b)</u> reduce the royalties due under <u>Section 9.5</u> below [*] of Royalty Net Sales of a Licensed Product in any country; [*].

9.7. Royalty Term. The royalties due under <u>Section 9.5</u>, as may be adjusted under <u>Section 9.6(a)</u> and <u>Section 9.6(b)</u>, shall continue on a country-by-country and Licensed Product-by-Licensed Product basis for the period commencing upon the First Commercial Sale of a Licensed Product in the applicable country of sale and ending on the date that is the last to occur of:

- (a) expiration of [*];
- (**b**) expiration of [*]; or
- (c) [*].

9.8. Apportionment of Compulsory Sublicensee Consideration. In the event that there is a Compulsory Sublicensee of the Licensed Product, the Parties shall discuss how the consideration, if any, actually paid by such Compulsory Sublicensee shall be apportioned between the Parties based on an equivalent profit share percentage to effect the economic intent of this Agreement. For purposes of clarity, any payments by Third Parties under a Compulsory Sublicense shall [*].

9.9. Royalty Accounting and Reporting .

(a) **Timing of Payments**. Roche shall calculate royalties on Royalty Net Sales quarterly as of March 31, June 30, September 30 and December 31 (each being the last day of an "**Accounting Period**") and shall pay royalties on Royalty Net Sales to Prothena within [*] after the end of each Accounting Period in which such Royalty Net Sales occur.

(b) **Currency Conversion**. When calculating the Sales of any Licensed Product that occur in currencies other than the Payment Currency, Roche shall convert the amount of such Sales into Swiss Francs and then into the Payment Currency using Roche's then-current internal foreign currency translation method actually used on a consistent basis in preparing its audited financial statements (at the Effective Date, YTD average rate as reported by Reuters).

(c) **Royalty Reporting**. Within [*] after the end of each Accounting Period, Roche shall provide to Prothena for such Accounting Period, on a Licensed Product-by-Licensed Product and country-by-country basis, a written report with the following information, [*]:

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(i) the gross amount invoiced in Swiss Francs;

(ii) Royalty Sales in Swiss Francs, and the specific deductions applied in the calculation of Royalty Sales pursuant to <u>Section 1.88</u>;

(iii) Royalty Net Sales in Swiss Francs, and the specific deductions applied in the calculation of Royalty Net Sales pursuant to <u>Section 1.89</u>;

(iv) exchange rate used for the conversion of Royalty Net Sales from Swiss Francs to the Payment Currency pursuant to <u>Section 9.9(b)</u>;

- (v) Royalty Net Sales in the Payment Currency;
- (vi) royalty rate pursuant to <u>Section 9.5</u>;
- (vii) adjustments to the royalty rate made pursuant to <u>Section 9.6</u>; and
- (viii) total royalty payable in the Payment Currency.

[*] For illustrative purposes only, a sample royalty report template is attached as <u>Exhibit 9.9(c)</u>.

9.10. Late Payment . Any payment under this Agreement that is not paid on or before the date such payment is due shall bear interest, to the extent permitted by Applicable Law, at [*] percentage points above the average one-month Euro Interbank Offered Rate (" EURIBOR "), as reported by Reuters from time to time, calculated on the number of days such payment is overdue.

9.11. Currency and Method of Payment. Royalties on Royalty Net Sales and all other amounts payable by Roche under this Agreement shall be paid by Roche in Dollars (the "**Payment Currency**") to account(s) designated by Prothena.

9.12. Accounting; Non-Cash Consideration.

(a) Each Party shall determine Royalty Net Sales and Profit and Loss using its then-applicable standard accounting procedures, in accordance with GAAP or IFRS as consistently applied by the respective Party, as if the applicable Licensed Product were Developed solely by such Party. The Parties also recognize that such procedures may change from time to time and that any such changes may affect the definition of Royalty Net Sales or Profit and Loss. The Parties agree that, where such changes are economically material to either Party, adjustments shall be made to compensate the affected Party in order to preserve the same economics as reflected under this Agreement under such Party's accounting procedures in effect prior to such change.

(b) In the event of the payment or receipt of non-cash consideration in connection with the performance of activities under this Agreement, the Party engaging in such non-cash transaction shall advise the JFT of such transaction, including without limitation such Party's assessment of the fair market value of such non-cash consideration and the basis therefor.

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Such transaction shall be accounted for on a cash equivalent basis, as mutually agreed by the Parties in good faith.

9.13. Third Party License Payments .

(a) If either Party reasonably determines that certain Third Party intellectual property rights are necessary for the Development or Commercialization of a Jointly Funded Product/Indication in the Shared Territory, then [*] shall have the first right to obtain a license to such Third Party intellectual property, with the right to sublicense, in order to permit both Parties to conduct their obligations under this Agreement. If [*] chooses not to license or is unsuccessful in obtaining such rights, then [*] shall have the right, but not the obligation, to negotiate and obtain rights from such Third Party. Subject to the foregoing, the terms and conditions involved in obtaining such rights shall be determined by mutual written consent of the Parties. If the Parties disagree on whether rights in Third Party intellectual property are reasonably necessary for the Development or Commercialization of the Jointly Funded Product/Indication in the Shared Territory, patent counsel from both Parties will be responsible for determining whether rights in such Third Party intellectual property should be obtained. In the event of a disagreement, [*]. In the Royalty Territory, [*] shall have sole decision making authority with regard to taking a license to any Third Party intellectual property rights.

(b) To the extent that such license as set forth in <u>Section 9.13(a)</u> provides for Third Party Royalties, such Third Party Royalties, including any amounts due pursuant to the BI Supply Agreement and the UCSD License Agreement [*], will be included in Cost of Sales in the Shared Territory. For any Licensed Product in the Royalty Territory, the Parties shall each pay [*] of any royalties and other payments associated with any Third Party intellectual property rights that Roche determines are reasonably necessary for the Development or Commercialization of such Licensed Product, including any amounts due pursuant to the BI Supply Agreement and the UCSD License Agreement [*]; *provided, however*, that [*] shall bear [*] of any such payments related to Third Party intellectual property rights Covering [*]. If a license covers the entire Territory, then the JFT shall allocate the economic terms (that are not dependent on net sales of Licensed Products) between the Shared Territory and the Royalty Territory based on the relevance of such license in the respective portions of the Territory.

9.14. Sublicense Agreement . In accordance with <u>Section 2.5(a)</u>, Roche shall have the right to [*] by Roche to Prothena under this Agreement.

9.15. Taxes .

(a) For purposes of this <u>Section 9.15</u>, "**Tax**" means any form of tax or taxation, levy, duty, charge, social security charge, contribution or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a Tax Authority; "**Tax Authority**" means any government, state or municipality, or any local, state, federal or other fiscal, revenue, customs, or excise authority, body or official anywhere in the world, authorized to levy Tax; and "**Indirect Taxes**" means value added taxes, sales taxes, consumption taxes and other similar taxes.

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The royalties, milestones and other amounts payable by Roche to Prothena pursuant to this **(b)** Agreement (the "Payments") shall not be reduced on account of Taxes unless required by Applicable Laws. Roche shall deduct or withhold from the Payments any Taxes that it is required by Applicable Laws to deduct or withhold. Notwithstanding the foregoing, if Prothena is entitled (whether under any applicable tax treaty or otherwise under Applicable Laws) to a reduction in the rate of, or the elimination of, withholding Tax, it may deliver to Roche or the appropriate Taxing Authority (with the assistance of Roche to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Roche of its obligation to withhold Tax, and Roche shall apply the reduced rate of withholding, or dispense with withholding, as the case may be, provided that Roche has received evidence, in a form reasonably satisfactory to Roche, of Prothena's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [*] prior to the time that the Payments are due; provided, however, that if Prothena determines that it needs additional time to obtain such forms or authorization, Prothena may elect, by written notice to Roche, to delay the payment date for any applicable Payment in order to obtain such forms or governmental authorization. Any such delay in accordance with such notice shall not be considered a breach of this Agreement by Roche. If, in accordance with the foregoing, Roche withholds any Tax, it shall make timely payment to the proper Tax Authority of the withheld Tax, in accordance with Applicable Laws, and send to Prothena proof of such payment as soon as reasonably practicable following such payment. Roche agrees to take reasonable and lawful efforts to minimize such Taxes to Prothena. Roche shall cooperate with Prothena as reasonably requested in any claim for refund or application to any Tax Authority. If Roche intends to withhold Tax from any Payment, Roche shall inform Prothena reasonably in advance of making such Payment to permit Prothena an opportunity to provide any forms or information or obtain any Tax Authority approval as may be available to reduce or eliminate such withholding.

(c) Notwithstanding anything to the contrary contained in this <u>Section 9.15</u> or elsewhere in this Agreement, the following shall apply with respect to Indirect Taxes. All Payments are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any Payments, Roche shall pay such Indirect Taxes at the applicable rate in respect of any such Payments following the receipt, where applicable, of an Indirect Taxes invoice issued by Prothena in respect of those Payments, such Indirect Taxes to be payable on the due date of the payment of the Payments to which such Indirect Taxes relate or at the time such Indirect Taxes are required to be collected by Prothena, in the case of payment of Indirect Taxes to Prothena. The Parties shall issue invoices for all goods and services supplied under this Agreement consistent with Indirect Tax requirements, and to the extent any invoice is not initially issued in an appropriate form, the invoice issuing Party shall promptly inform the other Party and shall cooperate with such other Party to provide such information or assistance as may be necessary to enable the issuance of such invoice consistent with Indirect Tax requirements.

10. RECORD KEEPING, RETENTION AND AUDITS .

10.1. Financial Record Keeping; Record Retention. Each Party shall keep complete and accurate records pertaining to the Development and Commercialization related to Licensed Compounds, Licensed Products, and Profit and Loss, in sufficient detail to permit the other Party to confirm the accuracy of calculations of all payments made under this Agreement. The records

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to be maintained by each Party under this <u>Section 10.1</u> shall be maintained for a minimum of [*] following the year in which the corresponding efforts or payments, as the case may be, were made under this Agreement, or longer if required by Applicable Law.

10.2. Auditing.

Parties' Right to Audit . Each Party shall keep, and shall require its Affiliates and (a) Sublicensees to keep, full, true and accurate books of account containing all particulars that may be necessary for the purpose of calculating all amounts payable or allocable under this Agreement, including Royalty Net Sales and Profit and Loss. Such books of accounts shall be kept at their principal place of business. At the expense of the auditing Party, such Party has the right to engage an internationally recognized independent public accountant (which shall not be deemed to be limited to the "Big Four" accounting firms) reasonably acceptable to the Party being audited to perform, on behalf of the auditing Party, an audit of such books and records of the audited Party and its Affiliates, that are deemed necessary by the independent public accountant for the period or periods requested by the auditing Party and the correctness of any financial report or payments made under this Agreement. Upon timely request and at least [*] prior written notice from the auditing Party to the Party being audited, such audit shall be conducted during regular business hours in such a manner as to not unnecessarily interfere with the audited Party's normal business activities, and shall be limited to results in the [*] prior to audit notification. Such audit shall not be performed more frequently than [*]. All Information, data, documents and abstracts herein referred to shall be used only for the purpose of verifying reports and payments made, shall be treated as the audited Party's Confidential Information subject to the obligations of Article 11, and need neither be retained (i) more than [*] after completion of an audit hereof, if an audit has been requested nor (ii) more than [*] to which each shall pertain.

(b) Audit Reports . The auditors shall only state factual findings in the audit reports and shall not interpret this Agreement. The auditors shall share any draft audit reports with the audited Party before any final audit report is issued, and the final audit report, if any, shall be shared with the auditing Party at the same time it is shared with the audited Party.

(c) **Over- or Underpayment**. If the audit reveals an overpayment, the auditing Party shall reimburse the audited Party for the amount of the overpayment within [*]. If the audit reveals an underpayment, the audited Party shall make up such underpayment with the next royalty payment or Profit and Loss balancing payment or, if no further payments are owed by the audited Party, the audited Party shall reimburse the auditing Party for the amount of the underpayment within [*]. The audited Party shall pay for the audit costs if the underpayment of the audited Party exceeds [*] of the aggregate amount of payments owed with regard to the statements subject to the audit. Interest due pursuant to Section 9.10 shall apply to this Section 10.2(c).

(d) **Duration of Audit Rights**. If a Party does not request verification of any payment within the period during which corresponding records must be maintained under this <u>Article 10</u>, then such Party will be deemed to have accepted the payments and/or reports for the relevant periods.

10.3. Survival . This <u>Article 10</u> shall survive any termination or expiration of this Agreement for a period of [*] following the final payment made by either Party hereunder, or longer if required by Applicable Law.

11. CONFIDENTIALITY.

11.1. Confidential Information. During the Term and for [*] thereafter, each Party shall maintain in confidence all Information and materials of the other Party disclosed or provided to it by the other Party pursuant to this Agreement and/or the Non-Disclosure Agreements between Roche Nutley and Prothena US, effective as of [*], and the Secrecy Agreement among Roche Basel, Prothena Ireland, and BI, effective as of [*] (collectively, the "**CDAs**") and identified as confidential, either in writing or verbally (together with all embodiments thereof, the "**Confidential Information**"). Confidential Information also includes without limitation Information generated hereunder and Information regarding intellectual property and confidential or proprietary Information of Third Parties. The terms and conditions of this Agreement shall be deemed Confidential Information of both Parties.

11.2. Degree of Care; Permitted Use . Each Party shall take reasonable steps to maintain the confidentiality of the Confidential Information of the other Party, which steps shall be no less protective than those steps that such Party takes to protect its own Information and materials of a similar nature, but in no event less than a reasonable degree of care. Neither Party shall use or permit the use of any Confidential Information of the other Party except for the purposes of carrying out its obligations or exercising its rights under this Agreement, and neither Party shall copy any Confidential Information of the other Party except as may be reasonably useful or necessary for such purposes. All Confidential Information of a Party, including without limitation all copies and derivations thereof, is and shall remain the sole and exclusive property of the disclosing Party and subject to the restrictions provided for herein. Neither Party shall disclose any Confidential Information of the other Party other than to those of its Affiliates, directors, officers, employees, independent contractors, licensors, licensees, Sublicensees, assignees, agents, potential or actual investors, underwriters or acquirers, and external advisors [*] that are directly concerned with performance under this Agreement, on a strictly applied "need to know" basis; provided, however, that such Affiliates, directors, officers, employees, independent contractors, licensors, licensees, Sublicensees, assignees, agents, potential or actual investors, underwriters or acquirers, and external advisors are subject to confidentiality obligations at least as stringent as the confidentiality obligations provided for in this Article 11.

11.3. Exceptions to Confidentiality. The obligations set forth in <u>Section 11.2</u> shall not apply to that portion of Confidential Information that the receiving Party can demonstrate by contemporaneous tangible evidence was (a) known to the general public at the time of its disclosure to the receiving Party or its Affiliates, or thereafter became generally known to the general public, other than as a result of actions or omissions of the receiving Party or anyone to whom the receiving Party disclosed such Information; (b) known by the receiving Party or its Affiliates, without confidentiality restrictions, prior to the date of disclosure by the disclosing Party; (c) disclosed to the receiving Party or its Affiliates, without confidentiality restrictions, from a Third Party not under a duty of confidentiality to the disclosing Party; or (d) independently developed by the receiving Party or its Affiliates by personnel that did not have access to or use of Confidential Information of the disclosing Party; [*]. Any combination of

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features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or known to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation thereof are published or known to the general public or are in the rightful possession of the receiving Party.

11.4. Permitted Disclosures . The obligations set forth in <u>Section 11.2</u> shall not apply to the extent that the receiving Party is required to disclose Confidential Information pursuant to (a) an order of a court of competent jurisdiction, (b) Applicable Laws, (c) regulations or rules of a securities exchange, (d) requirements of a governmental agency for purposes of obtaining approval to test or market a Licensed Product, (e) disclosures of Information to a Patent office for the purposes of filing a Patent Application as permitted in this Agreement, or (f) the exercise by each Party of the rights granted to it under this Agreement or its retained rights; provided that in each case the receiving Party shall, where practicable, provide prior written notice thereof to the disclosure and request confidential treatment thereof or a protective order therefor. Each Party agrees to consider in good faith any requests by the other Party to disclose such Party's Confidential Information where the other Party has a reasonable need to do so in order to pursue patent protection on Inventions as permitted pursuant to <u>Article 12</u>.

11.5. Return of Confidential Information. Each Party shall return or destroy, at the other Party's instruction, all Confidential Information of the other Party in its possession upon termination or expiration of this Agreement, except for (a) one (1) archival copy of each item of Confidential Information kept solely for purposes of showing compliance with this Agreement and (b) any other Confidential Information that is necessary to allow such Party to perform or enjoy any of its rights or obligations that expressly survive the termination or expiration of this Agreement.

11.6. **Public Disclosure and Publications**. The Parties agree that the initial public announcement of the execution of this Agreement shall be in the form of a mutually agreed upon press release that describes the nature and scope of the collaboration, including its aggregate value, attached hereto as Exhibit 11.6 (the "Press Release"). During the Term, in all cases other than the announcement set forth in the Press Release, each Party shall submit to the other Party for review and approval (a) all proposed press releases relating to this Agreement, and (b) academic, scientific, and medical publications and public presentations relating to Licensed Compounds or Licensed Products that have not been previously publicly disclosed and that are not otherwise permitted under Section 11.4. For press releases, the other Party shall provide its approval, not to be unreasonably withheld, within [*] of its receipt. Written copies of proposed publications and presentations (other than press releases) shall be submitted to the other Party no later than [*] before submission for publication or presentation. The reviewing Party shall provide its comments, if any, and (if it so chooses) its approval, not to be unreasonably withheld, within [*] of its receipt of any written copy of such proposed publication or presentation; provided, however, that the reviewing Party may delay the date of publication or presentation by up to [*] in order to apply for patent protection thereon. For clarity, any publications required by Applicable Laws or regulations or rules of a securities exchange, and any subject matter previously approved by the other Party, shall not be subject to this Section 11.6.

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12. INVENTIONS AND PATENTS .

12.1. Existing Intellectual Property. Other than as expressly provided in this Agreement, neither Party grants any right, title, or interest in any Information, Patent, Patent Application, or other intellectual property right Controlled by such Party to the other Party.

12.2. Disclosure of Inventions. Each Party shall promptly disclose to the other Party any Inventions that it or its Affiliates or Sublicensees or their employees, independent contractors and their employees, or agents solely or jointly make, conceive, reduce to practice, or otherwise discover.

12.3. Ownership of Inventions .

(a) **Roche Inventions**. All Inventions that [*] (" **Roche Inventions** "), together with all intellectual property rights therein, shall be solely owned by Roche.

(b) **Prothena Inventions** . All Inventions that [*] (" **Prothena Inventions** "), together with all intellectual property rights therein, shall be solely owned by Prothena.

Other Inventions. Except as provided in Section 12.3(a) and Section 12.3(b), (i) (c) inventorship of all Inventions together with all intellectual property rights therein shall be determined in accordance with United States patent law, Title 35, United States Code, (ii) ownership shall follow inventorship, and (iii) with respect to each Invention made, conceived, reduced to practice, or otherwise discovered jointly by employees, independent contractors and their employees, or agents of each of Prothena and Roche, or their respective Affiliates or Sublicensees ("Joint Inventions"), each Party shall own an undivided interest in such Joint Inventions, together with all Patents and Patent Applications claiming each Joint Invention (" Joint Patent Rights "), and all other intellectual property rights therein, without a duty of accounting to the other Party and without an obligation to obtain consent of the other Party to grant licenses thereunder in countries in which such duty or obligation would otherwise apply. For the avoidance of doubt, subject to compliance with the exclusive licenses granted to Roche under Section 2.1, each Party (1) shall be free to practice any Joint Invention in any country of the world without the consent of or notice or accounting to the other Party, subject to its obligations of exclusivity to the other Party under <u>Article 3 and (2)</u> hereby consents to the licensing by the other Party, subject to such other Party's obligations of exclusivity under Article 3 to such Party, to an Affiliate or Third Party of any and all of the other Party's rights under any Joint Invention; provided, however, that during the Term, neither Party shall [*] except as expressly permitted under this Agreement.

(d) **Ownership Disputes**. Patent counsel from each Party shall attempt in good faith to resolve any Disputes arising hereunder regarding ownership of Inventions, Patents, Patent Applications, and any other intellectual property right.

12.4. Assignment and Assistance.

(a) Assignment of Inventions . Without additional consideration, each Party shall assign and hereby does assign to the other Party such of its right, title, and interest in and to any Inventions, together with all intellectual property rights therein (and shall require its

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Affiliates and Sublicensees, and all employees, independent contractors and their employees, and agents of such Party and its Affiliates and Sublicensees to so assign to the other Party such of their right, title, and interest) as is necessary to effectuate the allocation of right, title, and interest as set forth in <u>Section 12.3</u>.

(b) Assistance . Each Party shall (and shall cause its Affiliates and Sublicensees, and all employees, independent contractors and their employees, and agents of such Party and its Affiliates and Sublicensees to) cooperate with the other Party and take all reasonable additional actions and execute such agreements, instruments, and documents as may be reasonably required to perfect the other Party's right, title, and interest in and to Inventions, and Patents and Patent Applications claiming such Inventions, and all other intellectual property rights therein. If a Party is unwilling or unable to execute any such agreements, instruments, and documents, it hereby appoints the other Party as its attorney-in-fact, which shall be coupled with an interest, to execute the same on its behalf. Each Party shall also include provisions in its relevant agreements with Third Parties that effect the intent of this Section 12.4.

CREATE Act . Each Party acknowledges and agrees that this Agreement is a "joint research (c) agreement" as contemplated by 35 U.S.C. § 102(c), and that all Inventions are intended to have the benefit of the rights and protections conferred by the Cooperative Research and Enhancement Act of 2004 (the "CREATE Act "). In the event that a Party seeks to rely on the foregoing and to invoke the CREATE Act with respect to any Invention, such Party will give prior written notice to the other Party of its intent to invoke the CREATE Act and of each submission or disclosure such Party intends to make to the United States Patent and Trademark Office (the "USPTO") pursuant to the CREATE Act, including: (i) any disclosure of the existence or contents of this Agreement to the USPTO, (ii) the disclosure of any "subject matter developed by the other Party" (as such term is used in the CREATE Act) in an information disclosure statement or otherwise, or (iii) the filing of any terminal disclaimer over the intellectual property of the other Party, it being agreed that no such submission, disclosure or filing shall be made by such Party without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, except that no such consent shall be required to disclose to the USPTO, through an information disclosure statement or otherwise, any "subject matter developed by the other Party" that was previously published or included in a Patent Application by the other Party. The other Party will provide reasonable cooperation to such Party in connection with such Party's efforts to invoke and rely on the CREATE Act.

12.5. Patent Filings, Prosecution, and Maintenance .

(a) General . Each Party and its patent counsel shall, to the maximum extent practicable, strive to separate the Patents and Patent Applications that claim Inventions into separate Patents and Patent Applications that claim Inventions solely owned by Prothena, Inventions solely owned by Roche, or solely Joint Inventions.

(b) Solely Owned Patents . Prothena shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain, including interferences, reissue, re-examination and opposition proceedings (collectively "Handle"), all Patents and

Patent Applications solely claiming Inventions solely owned by Prothena and all other Patents and

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Patent Applications within the Prothena Patent Rights. Roche shall have the first right, but not the obligation, to Handle all Patents and Patent Applications solely claiming Inventions solely owned by Roche and all other Patents and Patent Applications within the Roche Patent Rights. The Parties shall file each such Patent Application prior to any oral, written, or electronic disclosure of the Inventions claimed therein to maintain the validity of such Patent Applications and Patents issuing thereon. To the extent practicable, at least [*] prior to the contemplated filing date of any Patent Application in the Territory claiming [*], each Party shall submit to the other Party a substantially completed draft thereof, confer with the other Party thereon, and make every reasonable effort to adopt the other Party's commercially reasonable suggestions regarding the preparation and prosecution of such Patent Application. Each Party shall copy the other Party on all official actions and submissions with respect to such Patent Application.

(c) Patent Opt-In Rights . If Prothena elects, in any country, not to file or not to continue to prosecute and thereby abandon a Patent or Patent Application licensed to Roche under this Agreement in the Territory, or not to maintain and thereby abandon such a Patent or Patent Application, without the intent to pursue substantially similar subject matter in a continuation or divisional filing or an equivalent thereof, and not for the purpose of avoiding prosecution history estoppel, then Prothena shall notify Roche not less than [*] before any relevant submission date, and thereafter Roche shall have the right, but not the obligation, to Handle such Patent or Patent Application. If Roche elects, in any country, not to file or not to continue to prosecute and thereby abandon a Patent or Patent Application, without the intent to pursue substantially similar subject matter in a continuation or divisional filing or an equivalent thereof, and not for the purpose of avoiding prosecution history estoppel, then Roche shall notify Prothena not less than [*] before any relevant submission date, and thereby abandon such a Patent or Patent Application, without the intent to pursue substantially similar subject matter in a continuation or divisional filing or an equivalent thereof, and not for the purpose of avoiding prosecution history estoppel, then Roche shall notify Prothena not less than [*] before any relevant submission date, and thereafter Prothena shall have the right, but not the obligation, to Handle such Patent or Patent Application [*] before any relevant submission date, and thereafter Prothena shall have the right, but not the obligation, to Handle such Patent or Patent Application.

(d) Joint Patent Filings . Notwithstanding anything in this <u>Section 12.5</u> to the contrary, on a Joint Invention-by-Joint Invention basis, the Parties shall mutually agree on independent patent counsel to Handle each Joint Patent Right with respect to such Joint Invention. Such patent counsel shall be instructed by the Parties to keep each Party informed of the status of all pending Patent Applications in the Joint Patent Rights which it Handles, and to consider in good faith each Party's comments regarding any aspect of such patent Handling, giving greater deference to the comments from a Party regarding a Joint Patent Right claiming subject matter directly relating to the claimed subject matter of such Party's Solely Owned Patents. Neither Party may instruct such patent counsel to discontinue Handling any Joint Patent Right (including but not limited to selection of countries for foreign filing or entry into the PCT National Stage) without at least [*] prior written notice to the other Party's sole expense, and in such case, [*].

(e) **Patent Term Extensions**. In the event that Applicable Law in any country in the Territory provides for the extension of the term of any Patent or Patent Application licensed under this Agreement, including under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of the Member States of the European Union, and other similar measures in any other country, patent counsel from both Parties shall discuss the strategy for obtaining such available patent term

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extensions. If the patent counsel do not agree on a strategy, then [*] regarding which Patent or Patent Application owned or licensed under this Agreement shall be selected for such extension(s). The Party responsible for prosecuting such Patent or Patent Application under this <u>Section 12.5</u> shall apply for and use its reasonable efforts to obtain such extension(s), and the other Party shall cooperate with the prosecuting Party in obtaining such extension(s).

(f) Costs . All costs and expenses incurred by a Party for Handling Patents and Patent Applications shall borne solely by the Party Handling such Patents or Patent Applications; *provided, however*, that [*] the costs and expenses of independent patent counsel Handling any Joint Patent Rights under <u>Section 12.5(d)</u>.

(g) Upstream Licenses . Notwithstanding the foregoing, this <u>Section 12.5</u> shall be subject to the terms of any in-licenses to Prothena with respect to the rights of a Third Party as to the Handling of Patents and Patent Applications.

12.6. Enforcement Against Infringement by Third Parties.

(a) Notice . If either Party learns of any alleged or threatened infringement or misappropriation of the Prothena Technology and/or Roche Technology by a Third Party (an "Infringer"), such Party shall promptly notify the other Party in writing and shall promptly provide the other Party with available evidence of the infringement, misappropriation, or other claim.

(b) Shared Territory. Except as set forth in <u>Section 12.6(f)</u>, Roche shall determine which Party shall institute an infringement suit or take other appropriate action to enforce the Prothena Technology and/or Roche Technology arising by reason of [*] (an "Enforcement Action ") against an Infringer in the Shared Territory. The costs and expenses of any Enforcement Action in the Shared Territory, including without limitation fees of attorneys and other professionals, shall be shared in the following ratio: [*]. Any award paid by Third Parties as a result of an Enforcement Action in the Shared Territory, whether by way of settlement or otherwise, shall be shared in the following ratio: [*].

(c) Royalty Territory . Roche shall have the first right, but not the obligation, to institute an Enforcement Action against an Infringer in the Royalty Territory. If Roche does not institute an Enforcement Action (which may include sending a cease and desist letter if appropriate) against such Infringer, Roche shall notify Prothena of such as soon as reasonably practicable but in any event no later than [*] of learning of such Infringer. Upon receipt of such notice, or absent an Enforcement Action within such [*], Prothena shall have the right at its sole discretion to institute an Enforcement Action against such Infringer in the name of either or both Parties. The costs and expenses of any Enforcement Action in the Royalty Territory, including without limitation fees of attorneys and other professionals, shall be borne by the Party instituting the Enforcement Action. Any award paid by Third Parties as a result of an Enforcement Action in the Royalty Territory, whether by way of settlement or otherwise, shall be applied first to reimburse enforcing Party for all costs and expenses incurred with respect to such Enforcement Action, and, if after such reimbursement any amounts remain from such award, they shall be shall be shared as follows: (i) if Prothena is the enforcing Party, then [*]; and (ii) if Roche is the enforcing Party, then [*].

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(d) Assistance . Each Party shall execute all necessary and proper documents and take such actions as shall be appropriate to allow the other Party to institute an Enforcement Action in accordance with this <u>Section 12.6</u>, and shall otherwise cooperate in the institution and prosecution of such Enforcement Action, including without limitation consenting to being joined in such Enforcement Action as a party plaintiff.

(e) Infringement Outside the Field . Prothena shall retain any and all rights to pursue an action against, and control all proceedings relating to, an infringement by a Third Party of the Prothena Technology that is not an Enforcement Action. Roche shall retain any and all rights to pursue an action against, and control all proceedings relating to, an infringement by a Third Party of the Roche Technology that is not an Enforcement Action.

Biologics Price Competition and Innovation Act . To the extent permissible under the (**f**) BPCIA or as may be agreed between Roche and an applicant submitting a Section 351(k) application under the BPCIA relating to a Licensed Product (a "Section 351(k) applicant"), Roche shall promptly notify Prothena upon the receipt of a copy of a Section 351(k) application under the BPCIA relating to a Licensed Product. Subject to the preceding sentence, provided that (i) Prothena has informed the Section 351(k) applicant of Prothena's agreement to be subject to the confidentiality provisions set forth in Section 351(1)(1) of the BPCIA and (ii) Prothena has obtained the Section 351(k) applicant's agreement that the confidential information (as defined in the BPCIA) provided to Roche by such applicant may be shared with Prothena and has so notified Roche, the Parties shall cooperate to exercise any rights that may be exercisable by Roche as the reference product sponsor under the BPCIA, including: (i) engaging in the information exchange provisions of the BPCIA, including providing a list of patents that relate to the relevant Licensed Compound and/or Licensed Product incorporating such Licensed Compound, (ii) engaging in the patent resolution provisions of the BPCIA, and (iii) determining which patents will be the subject of immediate patent infringement action under Section 351(1)(6) of the BPCIA. In the event that the Parties do not agree with respect to the exercise of any such rights, Roche shall make the determination with respect thereto, including without limitation with respect to (i), (ii) and (iii), above. Roche shall have the first right, but not the obligation, to bring an action for patent infringement under Section 351(1) of the BPCIA against a Section 351(k) applicant relating to a Licensed Product. If Roche elects not to bring an action for patent infringement against a Section 351(k) applicant, Roche shall notify Prothena of such as soon as reasonably practicable but in any event no later than [*] after agreement on the patents in suit in accordance with Section 351(1)(4) (A) of the BPCIA or the exchange of lists pursuant to Section 351(1)(5)(B) of the BPCIA. Upon receipt of such notice or absent an action for patent infringement within such [*], then to the extent permitted under Applicable Law, Prothena shall have the right at its sole discretion to institute an action for patent infringement against the Section 351(k) applicant in its own name and, unless expressly agreed otherwise by Roche, Prothena may not assert any patent comprising the Roche Patent Rights. The costs and expenses of any action under this Section 12.6(f), and any award paid by Third Parties as a result, shall be allocated as set forth in Section 12.6(b).

(g) Upstream Licenses . Notwithstanding the foregoing, this <u>Section 12.6</u> shall be subject to the terms of any in-licenses to Prothena with respect to the rights of a Third Party as to the enforcement of the Prothena Technology.

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12.7. Defense of Infringement Claims by Third Parties .

(a) Notice . If the Development, Commercialization, manufacture, sale, or use of Licensed Compounds or Licensed Products pursuant to this Agreement results in a claim, action, suit, or proceeding that such activity infringes or misappropriates the Patents or other intellectual property rights of a Third Party (an "Infringement Claim"), the Party to this Agreement first having notice of such shall promptly notify the other Party in writing. The notice shall set forth the facts of the Infringement Claim in reasonable detail.

(b) Shared Territory . Patent counsel for each Party shall discuss and determine how best to control the defense of an Infringement Claim in the Shared Territory. In the event the Parties cannot agree on the defense of any Infringement Claim, such defense shall be controlled by [*], provided that [*] shall have the right to participate in such defense and to be represented in any such action by counsel of its selection at its sole discretion and sole cost. The entity that controls the defense of the Infringement Claim shall also have the right to control settlement of such Infringement Claim; *provided, however*, that no settlement shall be entered into without the other Party's prior written consent, which shall not be unreasonably withheld, delayed, or conditioned. The expenses of defense, settlement, and judgments pursuant to this Section 12.7(b) shall be shared in the following ratio: [*].

(c) Royalty Territory . Roche shall defend against an Infringement Claim in the Royalty Territory at its own expense, and shall be responsible for all damages incurred as a result thereof. Prothena shall assist and cooperate with Roche, at Roche's reasonable request, and Roche shall reimburse Prothena any reasonable, documented, out-of-pocket costs incurred in connection therewith. Roche shall control the defense of the Infringement Claim, provided that Prothena shall have the right to participate in such defense and to be represented in any such action by counsel of its selection at its sole discretion and sole cost. Roche shall also have the right to control settlement of such Infringement Claim; *provided, however*, that no settlement that could adversely affect Prothena's rights or interests shall be entered into without Prothena's prior written consent, which shall not be unreasonably withheld, delayed, or conditioned.

13. REPRESENTATIONS, WARRANTIES AND COVENANTS .

13.1. Representations and Warranties of the Parties. Prothena and Roche (each, a " **Representing Party** ") each hereby represents and warrants to each other, as of the Effective Date, as set forth below:

(a) Such Representing Party is a corporation duly organized and subsisting under the laws of its jurisdiction of organization.

(b) Such Representing Party has the power, authority, and legal right, and is free, to enter into this Agreement and, in so doing, shall not violate any other agreement to which it is a party as of the Effective Date.

(c) Such Representing Party has the power, authority, and legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement

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(d) This Agreement has been duly executed and delivered on behalf of such Representing Party, and all necessary consents, approvals and authorizations of all Regulatory Authorities and other Third Parties required to be obtained by such Representing Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

(e) This Agreement constitutes a legal, valid, and binding obligation of such Representing Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

(f) The execution and delivery of this Agreement and the performance of such Representing Party's obligations hereunder (i) do not conflict with or violate any requirement of Applicable Laws or any provision of the articles of incorporation, bylaws, or any similar instrument of such Representing Party, as applicable, in any material way, and (ii) do not conflict with, violate, or breach or constitute a default or require any consent under, any Applicable Laws or any contractual obligation or court or administrative order by which such Representing Party is bound.

(g) There are no claims or investigations (other than with respect to the Parties' HSR filings), pending or threatened against the Representing Party or any of its Affiliates, at law or in equity, or before or by any governmental authority relating to the matters contemplated under this Agreement or that would materially adversely affect such Representing Party's ability to perform its obligations hereunder.

(h) To such Representing Party's knowledge, all of its employees, independent contractors and their employees, and agents have executed agreements requiring assignment to such Representing Party of all Inventions made during the course of and as a result of their association with such Representing Party and obligating each such employee, independent contractor and its employees, and agent to maintain as confidential the Confidential Information of such Representing Party.

(i) Neither such Representing Party, nor any of its employees, officers, subcontractors or consultants who have rendered or shall render services relating to a Licensed Product (i) has ever been debarred or is subject to debarment or convicted of a crime for which an entity or person could be debarred under 21 U.S.C. Section 335a or (ii) has ever been under indictment for a crime for which a person or entity could be debarred under said Section 335a.

13.2. Additional Representations, Warranties, and Covenants of Prothena . Prothena hereby represents, warrants, and covenants to Roche that:

(a) As of the Effective Date, Prothena is entitled to grant the rights and licenses granted to Roche under this Agreement, and is not currently bound by any agreement with any Third Party, or by any outstanding order, judgment, or decree of any court or administrative agency, that restricts it from granting to Roche the rights and licenses as set forth in this Agreement.

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(b) As of the Effective Date, the Prothena Patent Rights and Prothena Know-How are Controlled by Prothena.

(c) Prothena has not granted as of the Effective Date, and shall not grant during the Term, any right, option, license or interest in or to any of the Prothena Patent Rights or Prothena Know-How that is in conflict with the rights or licenses granted to Roche under this Agreement.

(d) <u>Exhibit 1.73</u> contains a complete and accurate list of all Prothena Patent Rights existing as of the Signing Date that claim inventions that are necessary or useful to Develop, make, use, sell, offer to sell, import or export the Lead Compound.

(e) As of the Effective Date, the inventors of the Inventions disclosed and/or claimed in the Prothena Patent Rights have transferred or are under a contractual obligation to transfer to Prothena full ownership of the Patents and Patent Applications licensed to Roche under this Agreement, [*], to the extent any employee or contractor of such entities is an inventor of the claimed subject matter of such Patents and Patent Applications.

(f) As of the Effective Date, Prothena is not in possession of information that would, in its reasonable opinion and to its knowledge, render invalid and/or unenforceable any claims that are in any of the Prothena Patent Rights, and Prothena has no knowledge of any inventorship disputes concerning any Prothena Patent Rights.

(g) As of the Effective Date, except with respect to [*], Prothena has not received any notice of infringement of, or an invitation to obtain a license under, any Patent or Patent Application owned by any Third Party that could prevent Roche from making, having made, using, offering for sale, selling or importing the Lead Compound in the Territory.

(h) In the event that [*] under the terms of [*].

(i) If, during the Term, Prothena has reason to believe that it or any of its employees, officers, subcontractors, or consultants rendering services relating to a Licensed Product (i) is or shall be debarred or convicted of a crime under 21 U.S.C. Section 335a, or (ii) is or shall be under indictment under said Section 335a, then Prothena shall immediately notify the other Party in writing.

13.3. Additional Representations, Warranties, and Covenants of Roche . Roche hereby represents, warrants, and covenants to Prothena that:

(a) As of the Effective Date, Roche is entitled to grant the rights and licenses granted to Prothena under this Agreement, and is not currently bound by any agreement with any Third Party, or by any outstanding order, judgment, or decree of any court or administrative agency, that restricts it from granting to Prothena the rights and licenses as set forth in this Agreement.

(b) As of the Effective Date, the Roche Patent Rights and Roche Know-How are solely Controlled by Roche free and clear of any liens, charges, encumbrances, or judgments.

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(c) Roche has not granted as of the Effective Date, and shall not grant during the Term, any right, option, license or interest in or to any of the Roche Patent Rights or Roche Know-How that is in conflict with the rights or licenses granted to Prothena under this Agreement.

(d) Roche has not received any notice of infringement of, or an invitation to obtain a license under, any Patent or Patent Application owned by any Third Party that could prevent Roche from making, having made, using, offering for sale, selling or importing a Licensed Roche Compound listed on <u>Exhibit 1.57</u>.

(e) As of the Effective Date, [*].

(f) If, during the Term, Roche has reason to believe that it or any of its employees, officers, subcontractors, or consultants rendering services relating to a Licensed Product (i) is or shall be debarred or convicted of a crime under 21 U.S.C. Section 335a, or (ii) is or shall be under indictment under said Section 335a, then Roche shall immediately notify Prothena in writing.

13.4. Compliance with Applicable Laws. Each Party, in performing its activities in connection with this Agreement, shall comply with all Applicable Laws within the Territory. including without limitation then-current GCP, GLP, and GMP, and all Applicable Laws regarding Detailing to be conducted by such Party. Neither Party shall cause the other Party to perform any activity in violation of any Applicable Laws or the Pharmaceutical Research and Manufacturers of America ("**PhRMA**") Code on Interactions with Healthcare Professionals.

13.5. Characterization of Agreement. Roche and Prothena agree and acknowledge that (i) each of Roche and Prothena will operate their own business as independent contractors pursuant to the terms of this Agreement, (ii) neither Roche nor Prothena intends that the terms of this Agreement would create or give rise, in whole or in part, to a partnership for tax reporting or any other purposes, and (iii) neither Roche nor Prothena shall take any position or cause their Affiliates to take any position inconsistent with such intention for tax purposes (including with respect to filing U.S. federal income Tax Returns and in the course of any audit, review or litigation), unless otherwise required by Applicable Laws or unless the other Party consents thereto, which consent shall not be unreasonably withheld, delayed or conditioned.

14. INDEMNIFICATIONS AND INSURANCE .

14.1. Prothena's Right to Indemnification. Roche shall indemnify, defend, and hold harmless Prothena, its Affiliates, and their respective officers, directors, employees, independent contractors, and agents, and their respective successors, heirs, assigns, and representatives (the "Prothena Indemnitees") from and against any and all damages, losses, suits, proceedings, liabilities, costs (including without limitation reasonable legal expenses, costs of litigation and reasonable attorney's fees), or judgments, whether for money or equitable relief, of any kind ("Damages ") resulting from any Third Party claim or action arising out of or relating to, directly or indirectly: (i) any breach by Roche of any obligation, representation, warranty, or covenant in this Agreement, (ii) the negligence, recklessness, or wrongful intentional acts or omissions of the Roche Indemnitees, or (iii) the Development, Commercialization, storage, transportation,

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handling, manufacturing, formulation, or other attribute of the Licensed Compounds or Licensed Products by or for Roche, its Affiliates, and their Sublicensees, independent contractors, or distributors; except in each case (i) through (iii) for Damages to the extent subject to indemnification by Prothena under Section 14.2.

14.2. Roche's Right to Indemnification. Prothena shall indemnify, defend, and hold harmless Roche, its Affiliates, and their respective officers, directors, employees, independent contractors, and agents, and their respective successors, heirs, assigns, and representatives (the "**Roche Indemnitees**") from and against any and all Damages resulting from any Third Party claim or action arising out of or relating to, directly or indirectly: (i) any breach by Prothena of any obligation, representation, warranty, or covenant in this Agreement, or (ii) the negligence, recklessness, or wrongful intentional acts or omissions of the Prothena Indemnitees; except in each case of (i) and (ii) for Damages to the extent subject to indemnification by Roche under <u>Section 14.1</u>.

14.3. **Process for Indemnification**. A claim to which indemnification applies under Section 14.1 or Section 14.2 shall be referred to herein as an "Indemnification Claim". If a Party (the "Indemnitee") intends to claim indemnification under Section 14.1 or Section 14.2, the Indemnitee shall notify the other Party (the "Indemnitor ") in writing promptly upon becoming aware of any claim that may be an Indemnification Claim (it being understood and agreed, however, that the failure by an Indemnitee to give such notice shall not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). The Indemnitor shall have the right to assume and control the defense of the Indemnification Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee; provided, however, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other party represented by such counsel in such proceedings. If the Indemnitor does not assume the defense of the Indemnification Claim as described above in this Section 14.3, the Indemnitee may defend the Indemnification Claim but shall have no obligation to do so. The Indemnitee shall not settle or compromise the Indemnification Claim without the prior written consent of the Indemnitor, and the Indemnitor shall not settle or compromise the Indemnification Claim in any manner which would have an adverse effect on the Indemnitee's interests, without the prior written consent of the Indemnitee, which consent, in each case, shall not be unreasonably withheld, delayed, or conditioned. The Indemnitee shall reasonably cooperate with the Indemnitor at the Indemnitor's expense and shall make available to the Indemnitor all pertinent Information under the control of the Indemnitee, which Information shall be subject to Article 11.

14.4. Insurance . Each Party shall maintain, at its sole expense, product liability insurance and general liability insurance (including contractual liability insurance) in amounts appropriate and customary in the pharmaceutical industry in light of the nature of the activities to be performed by each Party hereunder. Notwithstanding the foregoing, Roche shall have the right to self-insure.

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15. LIMITATION OF LIABILITY; DISCLAIMER OF WARRANTY.

15.1. LIMITATION OF LIABILITY . EXCEPT IN THE CASE OF A BREACH OF <u>ARTICLE 11</u>, AND WITHOUT LIMITING THE PARTIES' OBLIGATIONS UNDER <u>ARTICLE 14</u>, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS, OR OTHER ECONOMIC LOSS) ARISING OUT OF THIS AGREEMENT OR WITH RESPECT TO A PARTY'S PERFORMANCE OR NON-PERFORMANCE HEREUNDER.

15.2. DISCLAIMER OF WARRANTY . EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY PROVIDES ANY WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, REGARDING THE LICENSED PRODUCTS USED IN CLINICAL TRIALS OR FOR COMMERCIAL USE, AND EACH PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND FREEDOM FROM INFRINGEMENT OF THIRD PARTY RIGHTS.

16. TERM AND TERMINATION .

16.1. Term. The Term shall commence on the Effective Date and, unless sooner terminated as specifically provided in this Agreement, shall continue in effect on a country-by-country basis until the expiration of all payment obligations under this Agreement (the "**Term**"). Upon expiration of this Agreement with respect to a Licensed Product in a country in the Territory, Roche shall have a non-exclusive, royalty-free, fully paid-up license to make, have made, use, sell, offer to sell, have sold, import, and export such Licensed Product in the Field in such country.

16.2. Termination by Roche at Will. After the first anniversary of the Effective Date, Roche shall have the right to terminate this Agreement at will, either in its entirety or on a Licensed Product-by-Licensed Product basis, upon (a) ninety (90) days' prior written notice to Prothena prior to First Commercial Sale and (b) one hundred eighty (180) days' prior written notice to Prothena after First Commercial Sale. Additionally, if Roche decides to cease Development and Commercialization of all Licensed Compounds and Licensed Products, or to place the Licensed Compounds and Licensed Products on a prolonged hold primarily for business reasons not anticipated according to the Development program, Roche shall provide written notice of such decision to Prothena. In such event, Roche shall, within thirty (30) days after such notice is received, be deemed to have exercised its right to terminate this Agreement in its entirety pursuant to this <u>Section 16.2</u>, unless within such time period Roche either commences the Development and Commercialization of the Licensed Compounds and Licensed Products or adopts a written plan to do so.

16.3. Termination of Patent License for Patent Challenge. To the extent permissible under Applicable Laws, if a Party or any of its Affiliates or Sublicensees challenges in a court of competent jurisdiction, the validity, scope or enforceability of, or otherwise opposes, any claim

of any Patent included in the Prothena Patent Rights or Roche Patent Rights under which such Party has been granted a license under this Agreement, then Prothena or Roche, as applicable, can terminate all licenses with respect to such Patent in the country in which such Patent is being so challenged or so opposed, upon thirty (30) days' prior written notice. If the Party that causes such challenge or opposition terminates such challenge or opposition within the thirty (30) day period, then the termination of licenses with respect to such Patent shall not come into effect. Notwithstanding the preceding sentences of this <u>Section 16.3</u>, a Party may challenge any Patent of the other Party to defend itself or to assert or protect its rights in any legal action or proceeding brought by the other Party in connection with this Agreement or with any Patent subject to this Agreement.

16.4. Termination for Material Breach. If either Party believes the other is in material breach of an obligation under this Agreement, it may give notice of such breach to the other Party, which other Party shall have ninety (90) days in which to remedy such breach. If such alleged breach is not remedied in the time period set forth above, the non-breaching Party shall be entitled, without prejudice to any other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement, either in its entirety or on a Licensed Product-by-Licensed Product or Region-by-Region basis, upon further written notice to the other Party. For purposes of this <u>Article 16</u>, "**Region**" shall mean [*].

16.5. Termination upon Insolvency. To the extent permitted under Applicable Law, either Party may terminate this Agreement if the other Party (a) files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency, for reorganization, or for an arrangement or appointment of a receiver or trustee of such other Party or of its assets; (b) is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within forty-five (45) days after the filing thereof; (c) proposes or is a party to any dissolution or liquidation; or (d) makes an assignment for the benefit of its creditors.

16.6. Termination of Prothena's Co-Development Opt In. Prothena's Opt-In as set forth in <u>Section 6.1(b)</u>, any then on-going active Development by Prothena, and Prothena's right to participate on the JDC and JSC (and to otherwise receive Information regarding Development beyond Information necessary for purposes of sharing Profit and Loss), in each case with respect to the Parkinson's Disease Indication or any other Indication for which Prothena exercised its Opt-In for a Licensed Product pursuant to <u>Section 6.1(b)</u>, shall terminate upon written notice by Roche if Prothena commences a Clinical Trial designed to [*] (by itself or in collaboration with an Affiliate or Third Party) outside the scope of this Agreement for a product that [*]. In the event of a termination of certain of Prothena's rights under this <u>Section 16.6</u>, Prothena will use Commercially Reasonable Efforts to wind down Prothena's continuing Development tasks for each Jointly Funded Product/Indication for the Parkinson's Disease Indication or such other applicable Indication and transition them to Roche in such a manner as not to impact negatively the Development of each Jointly Funded Product/Indication for the Parkinson's Disease Indication or such other applicable Indication. Except as set forth in this <u>Section 16.6</u>, all other rights and obligations of the Parties under this Agreement shall survive, including without limitation Prothena's right to share Profit and Loss for each Jointly Funded Product/Indication.

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16.7. Termination of Prothena's Co-Detailing Option. Prothena's Co-Detailing Option as set forth in <u>Section 7.1(b)</u>, the Co-Detailing Agreement and any then on-going active Detailing by Prothena, and Prothena's right to participate on the JCC shall terminate upon written notice by Roche if Prothena commences a Phase III Clinical Trial (by itself or in collaboration with an Affiliate or Third Party) outside the scope of this Agreement for a product that [*]. In the event of a termination of certain of Prothena's rights under this <u>Section 16.7</u>, Prothena will use Commercially Reasonable Efforts to wind down Prothena's continuing Detailing tasks for each Co-Detailed Product and transition them to Roche in such a manner as not to impact negatively the Commercialization of each Co-Detailed Product. Except as set forth in this <u>Section 16.7</u>, all other rights and obligations of the Parties under this Agreement shall survive, including without limitation Prothena's right to share Profit and Loss for each Co-Detailed Product that is a Jointly Funded Product/Indication.

16.8. Consequences of Termination of this Agreement .

(a) **Termination by Roche at Will or by Prothena for Breach by Roche or Roche's Insolvency**. Upon termination by Roche at will under <u>Section 16.2</u>, or termination by Prothena for breach by Roche under <u>Section 16.4</u> or for Roche's insolvency under <u>Section 16.5</u>, the following shall apply:

(i) All rights and licenses granted by Prothena to Roche under this Agreement shall terminate in their entirety, on a Region-by-Region basis, or a Licensed Product-by-Licensed Product basis, as applicable, on the effective date of termination.

(ii) Roche shall cease any ongoing Research Collaboration, Development, or Commercialization activities related to the subject matter of such termination.

(iii) Only in the event of termination by Roche at will under <u>Section 16.2</u>, [*].

(iv) Only in the event of termination by Prothena for breach by Roche under <u>Section 16.4</u> or for Roche's insolvency under <u>Section 16.5</u>, any existing sublicense granted by Roche under <u>Section 2.3</u> shall continue in full force and effect, provided that (1) the Sublicensee did not cause the breach that gave rise to a termination under <u>Section 16.4</u>, (2) no default exists under the sublicense agreement with such Sublicensee, (3) such Sublicensee agrees to be bound by all the terms and conditions of this Agreement that are applicable to such Sublicensee, including rendering directly to Prothena all payments and other obligations due to Prothena related to such sublicense (including without limitation all milestone and royalty payments), and (4) Prothena is not bound by any obligations under the sublicense agreement more onerous than its obligations under this Agreement.

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(v) If Prothena desires to continue Development and/or Commercialization of the Licensed Product(s) in the Region(s) that are the subject of the termination (the "**Termination Products**"), then [*]:

(1) From the date of notice of termination until the effective date of termination, Roche shall continue activities under this Agreement, including preparatory activities, ongoing as of the date of notice of termination. However, Roche shall not be obliged to initiate any new activities not ongoing at the date of notice of termination.

(2) After the effective date of termination, Roche shall, to the extent Roche has the right to do so, assign and transfer to Prothena, [*] the Data Package for the Termination Products within [*] after the effective date of termination. All documents shall be transferred in the form and format in which such materials are maintained by Roche. Original paper copies shall only be transferred if required by Applicable Laws. Roche shall not be required to [*]. In connection with research studies or Clinical Trials, Roche may have collected human samples and related clinical information for additional limited research and development programs (" **Samples** "). Legal and contractual restrictions may apply to such Samples, and in particular, Samples that may qualify as personal identifiable information. Prothena acknowledges and accepts that notwithstanding anything herein, [*].

(3) Prothena shall, upon transfer, have the right to disclose the Data Package to (i) Regulatory Authorities to the extent required or desirable to secure Regulatory Approval for the Development, manufacturing or sale of Termination Product(s) in the applicable country, (ii) Third Parties acting on behalf of Prothena, its Affiliates or licensees, to the extent reasonably necessary for the Development, manufacture, or sale of Termination Product(s) in the applicable country(ies), and (iii) Third Parties to the extent reasonably necessary to continue to Develop and/or Commercialize Termination Product(s) in the applicable country(ies).

(4) At Prothena's request, Roche shall assign any clinical trial agreements between Roche and Third Parties, to the extent such agreements (i) have not been cancelled and are assignable without Roche having to pay additional consideration or commencing litigation in order to effect an assignment of any such agreement and (ii) relate solely to the Development of the Termination Product(s) and/or the management and continued performance of any Clinical Trials for such Termination Product(s) ongoing as of the effective date of such termination, provided that Prothena assumes all of Roche's obligations (including payment obligations) following the effective date of such assignment under such assigned agreement and pays any fees payable to such Third Party in connection with such assignment.

(5) Roche hereby grants to Prothena, effective as of the effective date of termination, (i) a [*] license under the Roche Technology,

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including Roche's interest in the Joint Patent Rights, [*] the Termination Product(s) in the applicable country(ies) and (ii) a [*] license under the Roche Technology, including Roche's interest in the Joint Patent Rights, [*] the Termination Product(s) in the applicable country(ies), provided that in each case (i) and (ii), with respect to any Roche Technology obtained pursuant to an agreement with a Third Party, Prothena assumes all of Roche's obligations (including payment obligations) under such agreement to the extent applicable to the Termination Product(s) in the applicable country(ies).

(6) Notwithstanding the foregoing, all licenses under this <u>Section 16.8(a)</u> shall exclude (i) [*] and (ii) [*].

(7) Roche shall assign or license to Prothena the Licensed Product Trademarks with respect to the Termination Product(s) on [*] the Termination Product(s) for which such Licensed Product Trademarks are used.

(8) Roche shall provide reasonable assistance and technical expertise, [*] in a technology transfer from Roche to a Third Party designated by Prothena with respect to the manufacturing of the Termination Products, including the transfer of chemistry, manufacturing and controls processes with respect thereto.

(9) Roche shall cooperate in any audits of Roche's books and records related to the Termination Products that are required by any Regulatory Authority;

(10) Roche shall transfer all existing and available clinical supplies of the Termination Products, and components thereof, to Prothena [*] within [*] after the effective date of termination. Roche shall have no obligation to perform any additional activities concerning such clinical supplies (e.g., retesting, analyses), and Prothena shall assume all liability for the use of such material.

(11) If a Licensed Product is marketed in any country of the Territory on the date of the notice of termination, Roche shall manufacture and supply commercial supplies of the Termination Products to Prothena for a period that shall not exceed [*]. Prothena shall use Commercially Reasonable Efforts to take over the manufacturing of the Termination Products.

(12) Prothena's obligations of exclusivity set forth in <u>Article 3</u> shall terminate in their entirety, on a Region-by-Region basis, or a Licensed Product-by-Licensed Product basis, as applicable, on the effective date of termination. Roche's obligations of exclusivity set forth in <u>Article 3</u> shall continue on a Region-by-Region basis, or a Licensed Product-by-Licensed Product basis, as applicable, for [*].

[*]

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(b) **Termination by Roche for Breach by Prothena**. Upon any termination by Roche for breach by Prothena under <u>Section 16.4</u> (but not for Prothena's insolvency under <u>Section 16.5</u>), the following shall apply:

(i) All rights and licenses granted by Roche to Prothena under this Agreement shall terminate in their entirety, on a Region-by-Region basis, or a Licensed Product-by-Licensed Product basis, as applicable, on the effective date of termination.

(ii) All rights and licenses granted to Roche under <u>Section 2.1</u> shall survive termination and become perpetual and irrevocable in their entirety, on a Region-by-Region basis, or a Licensed Product-by-Licensed Product basis, as applicable. <u>Article 9</u> shall survive termination; *provided, however*, that (1) all payments required to be paid for the Licensed Product(s) in the Region(s) that are the subject of the termination shall [*], and (2) any Termination Products that are Jointly Funded Product/Indications shall no longer be eligible for Profit and Loss sharing but shall instead be subject to the payment of milestone payments and royalties pursuant to <u>Section 9.4(d)</u> and <u>Section 9.5(c)</u>, with the Shared Territory becoming part of the Royalty Territory.

(iii) Prothena shall cease any ongoing Research Collaboration, Development, or Commercialization activities related to the subject matter of such termination.

(iv) Roche's obligations of exclusivity set forth in <u>Article 3</u> shall terminate in their entirety, on a Region-by-Region basis, or a Licensed Product-by-Licensed Product basis, as applicable, on the effective date of termination. Prothena's obligations of exclusivity set forth in <u>Article 3</u> shall continue on a Region-by-Region basis, or a Licensed Product-by-Licensed Product basis, as applicable, for [*].

(v) Prothena shall cooperate in any audits of Prothena's books and records related to the Termination Products that are required by any Regulatory Authority..

(vi) To the extent that Prothena remains responsible for manufacture of a Termination Product under <u>Section 8.3</u>, Prothena will continue to provide manufacturing-related services to Roche at a commercially reasonable price for such Termination Product until up to [*].

(c) Termination by Roche for Prothena's Insolvency . In the event that Roche would have the right to terminate this Agreement for Prothena's insolvency under <u>Section 16.5</u>, Roche may elect to retain its licenses under this Agreement, provided that [*].

(d) Ancillary Agreements . Unless otherwise agreed by the Parties, the termination of this Agreement in its entirety shall cause the automatic termination of the Pharmacovigilance Agreement, to the extent allowable under Applicable Laws and industry

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practices, and the Co-Detailing Agreement, if such agreements have been entered into by the Parties.

16.9. Surviving Obligations .

(a) **Ongoing Clinical Activities**. In case of any termination, upon the request of the Party taking responsibility for a Termination Product, if the other Party is conducting a Clinical Trial for such Termination Product, then the other Party shall complete any Clinical Trial related to the Termination Product that is being conducted under the IND for the Termination Product and is ongoing as of the effective date of termination; *provided, however*, that:

(i) both Prothena and Roche in their reasonable judgment have concluded that completing any such Clinical Trial does not present an unreasonable risk to patient safety;

(ii) neither Party shall have any obligation to recruit or enroll any additional patients after the date of termination; and

(iii) the Party taking responsibility for the Termination Product agrees to reimburse the other Party for all of its Development costs that arise after the effective date of termination in completing such Clinical Trial.

(b) **Royalty and Payment Obligations**. Termination of this Agreement by a Party, for any reason, shall not release Roche from any obligation to pay royalties or make any payments to Prothena that were due and payable prior to the effective date of termination, but unless otherwise expressly provided for herein, will release Roche from any obligation to pay royalties or make any payments to Prothena that would otherwise become due or payable after the effective date of termination.

(c) Other Surviving Obligations . The rights and obligations set forth in this Agreement shall extend beyond the expiration or termination of this Agreement only to the extent expressly provided for herein, or to the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge. In the event of expiration or termination of this Agreement for any reason, the following provisions shall survive in addition to others specified in this Agreement to survive in such event: Sections 16.8 and 16.9(c), and Articles 1, 10 (for the period set forth therein), 11 (for the period set forth therein), 12, 14, 15, 17, and 18.

16.10. Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Prothena to Roche are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Shared Territory Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the Shared Territory Bankruptcy Code. The Parties agree that Roche, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Shared Territory Bankruptcy Code.

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17. DISPUTE RESOLUTION.

17.1. Exclusive Dispute Resolution Mechanism. Except as otherwise provided in this Agreement, the procedures set forth in this <u>Article 17</u> shall be the exclusive mechanism for resolving any Dispute between the Parties that may arise from time to time that cannot be resolved through good faith negotiation between the Parties.

17.2. Resolution by Executives. In the event of any Dispute not subject to resolution pursuant to <u>Section</u> 4.2(d), either Party may, by written notice to the other Party, refer such Dispute for attempted resolution by the Executives of each Party. In the event the Executives of each Party are unable to resolve the Dispute within [*] after receiving notice of the Dispute (or such longer period as the Parties may mutually agree upon), then each Party may, at its sole discretion, seek resolution of such Dispute in accordance with <u>Section 17.3</u>.

17.3. Arbitration .

(a) Except as set forth in <u>Section 17.4</u> or <u>Section 17.5</u>, any Dispute that is not resolved pursuant to <u>Section 17.2</u> shall be exclusively and finally settled by binding arbitration pursuant to this <u>Section 17.3</u>.

(b) Any such arbitration shall be conducted in San Francisco, CA, unless otherwise agreed by the Parties in writing. Each arbitration shall be administered by the American Arbitration Association (the "AAA"), and shall be conducted in accordance with the then applicable Commercial Arbitration Rules of the AAA, as such Rules may be amended from time to time, or modified by this <u>Section 17.3</u> or by agreement of the Parties (the "**Rules**"). At any applicable hearing, the Parties may present testimony (either by live witness or deposition) and documentary evidence and have the right to be represented by counsel. The U.S. Federal Rules of Evidence shall apply to any and all matters submitted to final and binding arbitration under this Agreement. To the extent they are permissible under Applicable Laws, any deposition or document production sought in the course of an arbitration shall be governed by the U.S. Federal Rules of Civil Procedure.

(c) Within [*] after receipt of an arbitration notice from a Party, the Parties shall attempt in good faith to agree on a single neutral arbitrator with relevant industry experience to conduct such arbitration. For the purposes of this Section 17.3, "relevant industry experience" shall mean that such person(s) shall [*]. If the Parties do not agree on a single neutral arbitrator within [*] after receipt of an arbitration notice, each Party shall select one (1) arbitrator with relevant industry experience and the two (2) Party-selected arbitrators shall select a third arbitrator with relevant industry experience to constitute a panel of three (3) arbitrators to conduct the arbitration in accordance with the Rules. In the event that only one of the Parties selects an arbitrator, then such arbitrator shall be entitled to act as the sole arbitrator to resolve the Dispute and all unresolved issues subject to such arbitration. Each and every arbitrator of the arbitration panel conducting the arbitration must and shall agree to render an opinion within [*] after the final hearing before the panel.

(d) The decision or award of the arbitrator(s) shall be final, binding, and incontestable and may be used as a basis for judgment thereon in any jurisdiction. The

arbitrator(s) shall, upon the request of any Party, issue a written opinion of the findings of fact and conclusions of law and shall deliver a copy to each of the Parties. Each Party shall bear its own costs and attorney's fees, and the Parties shall equally bear the fees, costs, and expenses of the arbitrator(s) and the arbitration proceedings; *provided, however*, that the arbitrator(s) may exercise discretion to award costs, including without limitation attorney's fees, to the prevailing Party. Without limiting any other remedies that may be available under Applicable Laws, the arbitrator(s) shall have no authority to award provisional remedies of any nature whatsoever, or special, punitive, indirect, incidental, consequential, or any other similar form of damages (including without limitation damages resulting from loss of use, loss of profits, interruption or loss of business).

(e) The Parties undertake to keep confidential all awards in their arbitration, together with all materials in the proceedings created for the purpose of the arbitration and all other documents produced by another Party in the proceedings not otherwise in the public domain, save and to the extent that disclosure may be required of a Party by legal duty, the rules and regulations of any stock exchange or quotation services on which such Party's stock is traded or quoted, to protect or pursue a legal right or to enforce or challenge an award in legal proceedings before a court or other judicial authority.

(f) Unless otherwise agreed in writing, the Parties will continue to perform their respective obligations under this Agreement during any arbitration or court proceeding seeking enforcement of an arbitral decision or award, and, unless this Agreement is in its entirety deemed null and void or is otherwise revoked or rescinded in its entirely, the Parties shall continue to perform their respective remaining obligations under this Agreement, and may continue to exercise their respective remaining rights and remedies thereunder, following any arbitration.

17.4. 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.

17.5. Patent Disputes. Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the scope, construction, validity, and enforceability of any Patent or Patent Application in a country within the Territory shall be determined in a court or other governmental authority of competent jurisdiction under the applicable patent laws of such country.

18. MISCELLANEOUS.

18.1. Agency. Neither Party is, nor shall be deemed to be, an employee, agent, co-venturer or legal representative of the other Party for any purpose. Neither Party shall be entitled to enter into any contracts in the name of, or on behalf of the other Party, nor shall either Party be entitled to pledge the credit of the other Party in any way or hold itself out as having the authority to do so.

18.2. Assignment .

(a) Neither this Agreement nor any interest hereunder may be assigned, nor any obligation hereunder delegated, by either Party without the prior written consent of the other Party; *provided, however*, that upon prior written notice to the other Party, a Party may assign this Agreement or any interest hereunder, or may delegate any obligation hereunder, without consent to (i) an Affiliate [*] or (ii) any successor in interest by operation of law, merger, consolidation, or other business reorganization, or the sale of all or substantially all of its assets to which this Agreement relates; *provided further*, in each case (i) and (ii), that such assignment could not reasonably be expected to subject the other Party to any adverse Tax consequences with regard to any payments under this Agreement (including any increase in withholding Taxes in respect of any payment pursuant to <u>Section 9.15(b)</u>). Any assignment not in accordance with this <u>Section 18.2(a)</u> shall be void.

(b) This Agreement shall be binding upon and inure to the successors and permitted assignees of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successor's and permitted assigns to the extent necessary to carry out the intent of this Agreement.

18.3. Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

18.4. Force Majeure . Neither Party shall be liable or responsible to the other Party for loss or damages, nor shall it have any right to terminate this Agreement for any default or delay attributable to any event beyond its reasonable control and without its fault or negligence, including without limitation acts of God, acts of government (including injunctions), fire, flood, earthquake, strike, lockout, labor dispute, breakdown of plant, shortage of critical equipment, loss or unavailability of manufacturing facilities or material, casualty or accident, civil commotion, acts of public enemies, acts of terrorism or threat of terrorist acts, blockage or embargo and the like; *provided, however*, that in each such case the Party affected shall (i) use reasonable efforts to avoid such occurrence and to remedy it promptly and (ii) give prompt notice of any such cause to the other Party. The Party giving such notice shall thereupon be excused from such of its obligations hereunder as it is thereby disabled from performing for so long as it is so disabled and for [*] thereafter, and the Party receiving notice shall be similarly excused from its respective obligations which it is thereby disabled from performing; *provided, however*, that such affected Party commences and continues to take reasonable and diligent actions to cure such cause. Notwithstanding the foregoing, nothing in this <u>Section 18.4</u> shall excuse or suspend the obligation to make any payment due hereunder in the manner and at the time provided.

18.5. Notices . All notices and other communications hereunder shall be in writing and shall be deemed given (a) if delivered personally or by facsimile transmission (receipt verified), (b) three (3) business days after mailed by registered or certified mail (return receipt requested), postage prepaid, or (c) one (1) business day after sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice, provided that notices of a change of address shall be effective only upon receipt thereof):

If to Prothena:	Neotope Biosciences Limited 25-28 North Wall Quay Dublin 1, Ireland Attention: Director Facsimile: +353 1 902 3510		
	and		
	Prothena Biosciences Inc 650 Gateway Boulevard South San Francisco, CA 94080, U.S.A. Attention: Secretary Facsimile: +1 650 837 8560		
With a copy to:	Latham & Watkins LLP 140 Scott Drive Menlo Park, CA 94025, U.S.A. Attention: Alan Mendelson and Judith Hasko Facsimile: +1 650 463 2600		
If to Roche:	F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 CH-4070 Basel, Switzerland Attention: Legal Department Facsimile: +41 61 688 13 96		
	and		
	Hoffmann-La Roche Inc. 340 Kingsland Street Nutley, New Jersey 07110, U.S.A. Attention: Corporate Secretary Facsimile: +1 973 235-3500		

18.6. Governing Law . This Agreement shall be governed by and interpreted in accordance with the substantive laws of the state of New York, U.S.A., without regard to its or any other jurisdiction's choice of law rules.
 18.7. Amendment . No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

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18.8. Waiver. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

18.9. Severability . Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Applicable Laws, but if any provision of this Agreement is held to be prohibited by or invalid under Applicable Laws, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. In the event of such invalidity, the Parties shall seek to agree on an alternative enforceable provision that preserves the original purpose of this Agreement.

18.10. Construction. The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement. Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders. 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.

18.11. Entire Agreement; Conflicts. This Agreement, including the exhibits attached hereto, constitutes and contains the complete, final and exclusive understanding and agreement of the Parties, and cancels and supersedes any and all prior or contemporaneous negotiations, correspondence, understandings, and agreements, whether oral or written, between the Parties respecting the subject matter hereof, including without limitation the CDAs, and neither Party shall be liable or bound to the other Party with respect to the subject matter of this Agreement in any manner by any representations, warranties, covenants, or agreements except as specifically set forth herein. To the extent that anything set forth in an exhibit attached hereto conflicts with the terms of this Agreement, the terms of this Agreement shall prevail.

18.12. Counterparts; Electronic Delivery. This Agreement may be executed simultaneously in two counterparts, either one of which need not contain the signature of more than one Party, but both of which taken together shall constitute one and the same agreement. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement, shall have the same effect as physical delivery of the paper document bearing original signature.

[Signature Page Follows]

[*] 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 the omitted portions.

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In Witness Whereof, the Parties have caused this Agreement to be executed as of the Signing Date by their duly authorized representatives as set forth below.

Neotope Biosciences Limited		F. Hoffmann-La Roche Ltd	
By:	<u>/s/ Shane Cook</u>	By:	/s/ Christophe Carissimo
Name:	Shane Cook	Name:	Christophe Carissimo
Title:	Director	Title:	Global Head Transaction Excellence
Prothena Biosciences Inc		By:	/s/ Stefan Arnold
By:	/s/ Dale B. Shenk	Name:	Stefan Arnold
Name:	Dale B. Shenk	Title:	Head Legal Pharma
Title:	President and Chief Executive Officer		
		Hoffma	ann-La Roche Inc.
		By:	/s/ John P. Parise
		Name:	John P. Parise
		Title:	Authorized Signatory

FINANCIAL APPENDIX

For purposes of this Exhibit only, the consolidated accounting of operations for the collaboration in the Shared Territory shall be referred to as the "**Collaboration**". The Collaboration is not a legal entity, or a partnership within the meaning of any tax laws, and has been defined for identification purposes only.

This Financial Appendix addresses the financial planning, accounting policies and procedures to be followed in determining Profits and Losses, and related sharing of revenue and expenses, in the Shared Territory between Roche Nutley and Prothena US (for purposes of this Exhibit 1.35 only, the "**Collaboration Parties**"). Terms not defined in this Exhibit shall have the meanings set forth in <u>Article 1 of the body of this Agreement</u>.

This Exhibit sets forth the principles for reporting actual results and budgeted plans of the combined operations by the Collaboration Parties in the Shared Territory, the frequency of reporting, the use of a single functional currency for reporting, and the methods of determining payments to the Collaboration Parties and auditing of accounts.

1. Principles of Reporting

The budget, forecast, and quarterly actuals and estimates for Jointly Funded Product/Indications in the Shared Territory will be presented in the following format (as to all Jointly Funded Product/Indications and also on a Jointly Funded Product/Indication-by-Jointly Funded Product/Indication basis), with the categories as defined in Section 4 below:

Income Statement

Reporting Item	
[*]	

It is the intention of the Collaboration Parties that the interpretation of these definitions will be consistent with GAAP or IFRS as consistently applied by the respective Collaboration Party.

2. Frequency of Reporting

The fiscal year of the Collaboration will be a Calendar Year.

Reporting by each Collaboration Party for Collaboration revenues and expenses will be performed as follows (with copies provided to the JFT and to the other Collaboration Party):

Reporting Event Timing and Frequency of Submission

[*]

[*]

Reports of actual results compared to budget (as to all Jointly Funded Product/Indications and also on a Jointly Funded Product/Indication-by-Jointly Funded Product/Indication basis) will be [*].

3. Commercialization Plan and Commercialization Budget in the Shared Territory.

(a) **Content**. At least [*], [*] shall develop and submit to the JCC (or JSC if no JCC exists) for review and approval, a Commercialization plan (the "**Commercialization Plan**") and a Commercialization budget (the "**Commercialization Budget**") for the applicable Jointly Funded Product/Indication in the Shared Territory, which shall be updated at least annually and shall cover [*]. The Commercialization Plan with respect to each Jointly Funded Product/Indication in the Shared Territory will include: [*]. The Commercialization Budget will include [*]. The Commercialization Budget, [*].

(b) Updates . [*] shall, on an annual basis, update the Commercialization Plan and Commercialization Budget for each Jointly Funded Product/Indication for [*]. [*] shall submit such updated Commercialization Plans and Commercialization Budgets for each Jointly Funded Product/Indication to [*]. The [*] within [*] following their submission. Within [*] following such original submission, [*].

(c) Launch Plan and Launch Budget . The Commercialization Plan and Commercialization Budget for each Jointly Funded Product/Indication shall be [*] at least [*] of such Jointly Funded Product/Indication in the Shared Territory, to include without limitation a launch plan and launch budget covering the period through the [*] following the First Commercial Sale in the Shared Territory. The launch plan and launch budget shall be [*]. The launch plan shall include without limitation [*]. The launch budget shall include without limitation [*]. The launch budget shall include without limitation a breakdown of individual Allowable Expense items expected to be incurred in connection with performing the applicable launch plan, detailed sufficiently to meet the requirements of the Collaboration Parties' respective management for reporting and controlling purposes.

4. Definitions

"Administration Costs " means, [*].

"Allocable Overhead " means [*].

"Allocable Manufacturing Overhead " means, [*].

"Allowable Expenses" means the following items: Cost of Sales, Marketing Costs, Sales Costs, Development Costs, Other Operating Income/Expense, Distribution/Warehousing Costs and Administration Costs, for a given period.

"Cost of Goods Sold "means, [*].

"Cost of Sales" means, [*].

- "Development Costs " means, [*].
- "Distribution/Warehousing Costs" means [*].
- "Fully Burdened Manufacturing Costs " means, [*].
- "Marketing Costs" means, [*].
- "Outbound Freight " means [*].
- "Other Operating Income/Expense" means [*].

"**Profit and Loss**" means, as to all Jointly Funded Product/Indications (or, where applicable, on a Jointly Funded Product/Indication-by-Jointly Funded Product/Indication basis), Sales of such Jointly Funded Product/Indication, plus Sublicense Revenues, less Allowable Expenses.

"Sales" means, for a Jointly Funded Product/Indication in a particular period, the sum of (a) and (b)

below:

- (a) The amount [*] with respect to such Jointly Funded Product/Indication for such period [*] in the Shared Territory. This amount reflects the [*], taken in accordance with the then-currently used IFRS. By way of example, the gross-to-net deductions taken in accordance with IFRS as of the Effective Date include the following: [*]
 For clarity, any given deduction shall be taken only under one of subsections (i) through (v), and only once in calculating Sales. For purposes of clarity, sales by Roche and its Affiliates to any Sublicensees that are not Affiliates of Roche shall be excluded from "Sales", unless such Sublicensees are end users of such Jointly Funded Product/Indication.
- (b) For Sublicensees that are not Affiliates of Roche and not end users of such Jointly Funded Product/Indication [*], the sales amounts in the Shared Territory reported to Roche and its Affiliates in accordance with [*]. For purposes of clarity, [*].

"Sales Costs "means, [*].

"Sublicense Revenues" means all revenues or other consideration received from a Sublicensee as consideration for the grant of a sublicense under the licenses granted to Roche pursuant to <u>Section 2.1</u> in the Shared Territory.

"Third Party Royalties" means [*].

5. Foreign Exchange

The functional currency for accounting for Profit and Loss will be Dollars. The statement of operations will be translated into Dollars using the then-current internal foreign currency translation method actually used on a consistent basis in preparing audited financial statements by the respective Collaboration Party.

6. Joint Finance Team

(a) Membership. The JFT shall be composed of one (1) representative from each of Prothena US and Roche Nutley (" JFT Members "). The Collaboration Parties each shall appoint JFT Members with appropriate seniority and functional expertise. Each Collaboration Party may replace any of its JFT Members and appoint a person to fill the vacancy arising from each such replacement. A Collaboration Party that replaces a JFT Member shall notify the other Collaboration Party at least [*] prior to the next scheduled meeting of the JFT. Both Collaboration Parties shall use Commercially Reasonable Efforts to keep an appropriate level of continuity in representation on the JFT. Both Collaboration Parties may invite a reasonable number of additional experts and/or advisors to attend part or the whole JFT meeting with prior notification to the JFT. JFT Members may be represented at any meeting by another person designated by the absent JFT Member.

(b) **Responsibilities**. The JFT shall be responsible for addressing accounting and financial determinations relating to sharing of Profit and Loss and other financial matters under this Agreement. Specific responsibilities and authority of the JFT shall include:

(i) supporting the JDC, JCC, and JSC with respect to accounting and financial determinations relating to Profit and Loss sharing and other financial matters under this Agreement;

- (ii) reviewing and administering operations under the Financial Appendix;
- (iii) being a resource for the preparation of Budgets for Jointly Funded Product/Indications; and
- (iv) establishing mechanisms for reconciliation of costs and payments.

The JFT shall have no responsibility and authority other than that expressly set forth in this section.

(c) Meetings . The JFT shall meet as often as it deems necessary. Each Collaboration Party shall bear all the expenses of its representatives on the JFT.

(d) Lifetime . The JFT shall exist during the period of time in which at least one (1) Jointly Funded Product/Indication is being Developed or Commercialized, subject to <u>Section 4.8</u> of the body of this Agreement.

7. Method and Timing for Profit and Loss Payments between the Collaboration Parties

Balancing payments between the Collaboration Parties will be [*]. The Parties will work to ensure that there will be [*]. Payments will be made quarterly based on actual results within [*] after the end of each Calendar Quarter to effect the Collaboration Parties' sharing of Profit and Loss.

LEAD COMPOUND

LICENSED PROTHENA COMPOUNDS

[*] Two pages have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

LICENSED ROCHE COMPOUNDS

[*]

PROTHENA PATENT RIGHTS

[*] Five pages have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

RELATED ANTIBODY EXAMPLES

[*]

ROCHE EXCLUDED PATENT RIGHTS

[*] Two pages have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

ROCHE PATENT RIGHTS

[*]

EXHIBIT 2.5(a)(i)

EXHIBIT 2.5(a)(ii)

[*]

[*] Twenty-two pages have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 5.2(a)(i)

RESEARCH PLAN

[*] Four pages have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 5.2(a)(ii)

RESEARCH BUDGET

[*] Two pages have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 6.6(a)(i)

DEVELOPMENT PLAN

[*]

EXHIBIT 6.6(a)(ii)

DEVELOPMENT BUDGET

[*]

EXHIBIT 6.8

PROTHENA DEVELOPMENT SUBCONTRACTORS

EXHIBIT 7.1(d)

CO-DETAILING AGREEMENT TERM SHEET

Co-Detailing Agreement:

The Co-Detailing Agreement shall be a master agreement covering the first Licensed Product for the Parkinson's Disease Indication to be co-Detailed in the Shared Territory by Roche Nutley and Prothena US (for purposes of this Exhibit 7.1(d) only, the "**Co-Detailing Parties**"), with a provision permitting the Co-Detailing Parties to execute one or more addendums to add additional Co-Detailed Products.

Rights and Responsibilities:

JCC: The Co-Detailing Agreement shall provide for a JCC to oversee the Commercialization Plan activities and the co-Detailing activities of the Co-Detailing Parties. The JCC will strive to reach consensus on any matters within the JCC's authority. Any dispute at the JCC not resolved within [*] will be escalated to the JSC. Specific responsibilities and authority of the JCC shall include:

(i) reviewing and commenting on each Commercialization Plan and Commercialization Budget for each Jointly Funded Product/Indication no less frequently than once per year, and monitoring timelines and budgets, including any updates and revisions thereto; and

(ii) reviewing Commercialization activities in the Territory at a high-level;

(iii) reviewing and commenting on a Co-Detailing Plan governing the Co-Detailing Parties' Detailing activities with respect to each Co-Detailed Product;

(iv) coordinating activities designed to create, provide training for, deploy, and manage a sales force for each Co-Detailed Product;

(v) coordinating sales force responsibilities, and communicating adjustments in sizing of such sales force for each Co-Detailed Product as appropriate;

(vi) establishing [*];

(vii) performing such other functions as appropriate to further the purposes of this Agreement as directed by the JSC.

The JCC shall have no responsibility and authority other than those expressly set forth above.

[*] regarding design and implementation of all [*].

Prothena US: For each Co-Detailed Product, Prothena US shall have the right to deploy a sales force of up to [*] of the total Sales Representatives in the Shared Territory at full capacity, subject to fluctuations in the ordinary course of business. Prothena US shall engage its own employees to conduct co-Detailing activities, except that during the [*] following the First Commercial Sale of each Co-Detailed Product, Prothena US may engage a contract sales

organization or contract sales representatives to perform such co-Detailing activities on a transitional basis. Prothena US shall provide periodic reporting of its co-Detailing activities and related matters to the JCC.

Roche Nutley: [*] Co-Detailing Plan for the Shared Territory, and shall provide reasonable guidance on anticipated co-Detailing activities to the JCC within [*] after the establishment of the JCC. [*] shall have the right to determine the composition of the [*].

Licenses:

Each Co-Detailing Party shall grant to the other Co-Detailing Party appropriate licenses to carry out the co-Detailing activities in the Shared Territory, including, to the extent required, the non-exclusive right to use the other Co-Detailing Parties' Trademarks to Detail Co-Detailed Products in the Shared Territory.

Compensation to Prothena US:

Roche Nutley shall compensate Prothena US for Prothena US's sales efforts under the Co-Detailing Agreement [*]. Such compensation shall reflect the [*] but such compensation will not be greater than [*]. [*] of Prothena US's co-Detailing activities relating to Promotional Materials and samples, with the exception of [*]. To the extent that such Co-Detailed Product is a Jointly Funded Product/Indication under the License Agreement, all such costs shall be included in the calculation of Profit and Loss under the License Agreement. The compensation provided in the foregoing sentences shall be the only compensation to Prothena US for its co-Detailing activities.

Non-Solicitation:

Neither Co-Detailing Party shall, without the express written consent of the other Co-Detailing Party, recruit or solicit any employee of the other Co-Detailing Party involved in Detailing the Co-Detailed Products to terminate his or her employment with such other Co-Detailing Party. The foregoing provision shall not, however, restrict either Co-Detailing Party or its Affiliates from advertising employment opportunities in any manner that does not directly target the other Co-Detailing Party or its Affiliates or from hiring any persons who respond to such generalized public advertisements.

Term:

Any time period during the term of the Co-Detailing Agreement during which Prothena US is co-Detailing a given Co-Detailed Product shall be the "**Co-Detailing Term**" for such Co-Detailed Product. If [*] then the Co-Detailing Term for such Co-Detailed Product shall begin within [*] prior to the date of First Commercial Sale of such Co-Detailed Product in the Shared Territory to conduct training and other pre-launch activities and shall end [*].

Termination:

Neither Co-Detailing Party may terminate the Co-Detailing Agreement without cause prior to the [*] of the First Commercial Sale of the applicable Co-Detailed Product. Subsequently, Prothena US may terminate the Co-Detailing Agreement at will by giving one hundred eighty (180) days' prior written notice to Roche Nutley. Either Co-Detailing Party may terminate the Co-Detailing Agreement, either in its entirety or on a Co-Detailed Product-by-Co-Detailed Product basis, at any time upon material breach of the Co-Detailing Agreement by the other Co-Detailing Party, if

the other Co-Detailing Party fails to cure such breach within ninety (90) days of receiving notice of such breach by the non-breaching Co-Detailing Party. The Co-Detailing Agreement shall provide for reasonable transition and wind-down provisions following termination of Prothena US's co-Detailing right under such agreement. The Co-Detailing Parties shall jointly establish standards and consequences for material breach of the co-Detailing obligations, [*]. Breach by Prothena US of the Co-Detailing Agreement shall not be deemed a breach of the License Agreement.

The consequences of termination will be reasonably negotiated and detailed in the Co-Detailing Agreement, which will contain additional customary provisions governing any such termination.

EXHIBIT 8.1

SECTION 11.5.3 OF BI AGREEMENT

[*] Two pages have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 9.9(c)

SAMPLE ROYALTY REPORT TEMPLATE

EXHIBIT 9.13(b)

PRESS RELEASE

Basel, Switzerland and Dublin, Ireland - 11 December 2013

Roche and Prothena enter into worldwide collaboration to co-develop and co-promote antibodies for treatment of Parkinson's disease

Roche (SIX: RO, ROG; OTCQX: RHHBY) and Prothena Corporation plc (NASDAQ:PRTA), announced today that they have entered into a worldwide collaboration to develop and commercialize antibodies that target alpha-synuclein, including PRX002, Prothena's monoclonal antibody for the treatment of Parkinson's disease, which is currently in preclinical development and is expected to enter Phase 1 clinical trials in patients with Parkinson's disease in 2014.

Synuclein proteins are a family of charged proteins found throughout the body. One protein from this family, alphasynuclein, is found extensively in neurons and is a major component of pathological inclusions that characterize several neurodegenerative disorders, including Parkinson's disease, dementia with Lewy bodies, neurodegeneration with brain iron accumulation type 1, and multiple system atrophy, which collectively are termed synucleinopathies.

"Parkinson's is a severely debilitating and progressive neurodegenerative disease that leads to both a gradual worsening of motor function and cognitive and behavioral alterations," said Luca Santarelli, Head of Neuroscience and Small Molecules Research at Roche. "Currently, there is no treatment that modifies its course, and by targeting one of Parkinson's key molecular determinants, PRX002 has the potential to slowdown or reduce its progression. This approach is consistent with our strategy in other neurodegenerative diseases, such as Alzheimer's, Huntington, Multiple Sclerosis or Spinal Muscular Atrophy, where we target the molecular pathophysiology and intervene early with the objective to slowdown or halt the progression of disease."

"We are excited to be working with Roche to develop PRX002 as a disease modifying treatment for Parkinson's disease and potentially other synucleinopathies. Roche is a

global leader in drug development with significant experience in developing drugs to treat neurological diseases," said Dale Schenk, PhD, President and Chief Executive Officer of Prothena. "By combining Roche's expertise with our own, this collaboration will greatly enhance our development efforts with PRX002 and allow us to move forward in a more comprehensive manner. This collaboration also represents an important milestone in our growth as we continue to execute on our corporate strategy to be a leading fully-integrated biotechnology company."

Roche and Prothena will collaborate on the development of PRX002 for Parkinson's disease and potentially other synucleinopathies. Prothena also has an option to co-promote PRX002 in the U.S. In the U.S., the companies will share all development and commercialization costs, as well as profits, on a 70/30 basis (70% Roche and 30% Prothena). Outside the U.S., Roche will have sole responsibility for developing and commercializing PRX002 and will pay Prothena up to double-digit royalties on net sales.

Under the terms of the agreement, Prothena will receive an upfront payment and near-term clinical milestone totaling USD45 million. Prothena is also eligible to receive additional payments of up to USD380 million upon the achievement of development, regulatory and first commercial sales milestones plus up to an additional USD175 million in ex-U.S. commercial milestone payments. The total worldwide upfront and milestone payments may amount up to USD600 million.

Also as part of the agreement, Roche and Prothena will initiate a research collaboration focused on optimizing early stage antibodies targeting alpha-synuclein including incorporation of Roche's proprietary Brain Shuttle[™] technology to increase delivery of therapeutic antibodies to the brain.

- ### -

About Parkinson's disease

Parkinson's disease is the second most common neurodegenerative disorder after Alzheimer's disease. There are an estimated seven to ten million patients with Parkinson's disease worldwide. Current treatments for Parkinson's disease are effective at managing the early motor symptoms of the disease, mainly through the use of levodopa and

dopamine agonists. As the disease progresses and dopaminergic neurons continue to be lost, these drugs eventually become less effective at treating the symptoms.

About PRX002

PRX002, a monoclonal antibody targeting alpha-synuclein, has been tested in various cellular and animal models of synuclein-related disease and has shown in multiple transgenic mouse models of Parkinson's disease, that passive immunization with 9E4, the murine version of PRX002, reduced the appearance of synuclein pathology, protected synaptic connections and improved performance by the mice in behavioral testing. PRX002 may slow or reduce the neurodegeneration associated with synuclein misfolding and/or cell-to-cell transmission of pathogenic forms of synuclein.

About Prothena

Prothena Corporation plc is a clinical stage biotechnology company focused on the discovery, development and commercialization of novel antibodies for the potential treatment of a broad range of diseases that involve protein misfolding and cell adhesion, particularly on the discovery, development and commercialization of potential therapeutic monoclonal antibodies directed specifically to disease-causing proteins. These potential therapies have a broad range of indications, including AL and AA forms of amyloidosis (NEOD001), Parkinson's disease and related synucleinopathies (PRX002), and novel cell adhesion targets involved in inflammatory disease and metastatic cancers (PRX003). Prothena conducts its operations through its wholly owned subsidiaries, Neotope Biosciences Limited, Onclave Therapeutic Limited and Prothena Biosciences Inc. For more information, please visit www.prothena.com.

About Roche Neuroscience

Roche is working on new molecular entities in neuroscience that could become the next generation of medicines for a range of diseases including schizophrenia, multiple sclerosis, depression, neurodevelopmental disorders, Parkinson's disease and Alzheimer's disease. With one of the strongest neuroscience pipelines in the industry, and by working closely with academic institutions, biotech companies, and forming public-private partnerships, Roche's focus is on expanding its neuroscience franchise to better serve patients.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, infectious diseases, inflammation, metabolism and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit <u>www.roche.com</u>.

The transaction is subject to customary regulatory clearances including expiration of the applicable Hart-Scott-Rodino waiting period. Prothena's legal and financial advisers on the transaction were Latham & Watkins LLP and BioAsset Advisors, respectively.

For further information:

Roche Partnering

Emilie Vincent, Head of Roche Partnering Communications, emilie.vincent@roche.com

Prothena

Investors: Tran Nguyen, CFO, +1 650-837-8535, <u>IR@prothena.com</u> Media: Anita Kawatra, +1 646-256-5116, <u>anita.kawatra@prothena.com</u>

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

I, Dale B. Schenk, certify that:

- 1. I have reviewed this Amendment No. 1 to Annual Report on Form 10-K of Prothena Corporation plc;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 6, 2014

/s/ Dale B. Schenk

Dale B. Schenk President and Chief Executive Officer (Principal Executive Officer)

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

I, Tran B. Nguyen, certify that:

- 1. I have reviewed this Amendment No. 1 to Annual Report on Form 10-K of Prothena Corporation plc;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 6, 2014

/s/ Tran B. Nguyen

Tran B. Nguyen Chief Financial Officer (Principal Financial Officer)

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Dale B. Schenk, President and Chief Executive Officer of Prothena Corporation plc (the "Company") and Tran B. Nguyen, Chief Financial Officer of the Company, each hereby certify that, to the best of his knowledge:

- 1. The Company's Amendment No. 1 to Annual Report on Form 10-K for the fiscal year ended December 31, 2013, to which this Certification is attached as Exhibit 32.2 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- 2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: June 6, 2014

/s/ Dale B. Schenk

Dale B. Schenk President and Chief Executive Officer (Principal Executive Officer)

/s/ Tran B. Nguyen

Tran B. Nguyen Chief Financial Officer (Principal Financial Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.