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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 10-K/A  
(Amendment No. 2)**

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(Mark One)

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

For the fiscal year ended December 31, 2015

OR

**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: 001-37471

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**PIERIS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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**Nevada**  
(State or other jurisdiction of  
incorporation or organization)

**EIN 30-0784346**  
(I.R.S. Employer  
Identification No.)

**255 State Street, 9th Floor**  
**Boston, MA**  
**United States**  
(Address of principal executive offices)

**02109**  
(Zip Code)

**Registrant's telephone number, including area code**  
**857-246-8998**

**Securities registered pursuant to Section 12(b) of the Exchange Act:**

Title of each class  
Common Stock, par value \$0.001 per share

Name of each exchange on which registered  
The NASDAQ Stock Market LLC

**Securities registered pursuant to Section 12(g) of the Exchange Act:**

**None**  
(Title of class)

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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 Exchange Act. Yes  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  No

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer  [Do not check if a smaller reporting company]

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of Common Stock held by non-affiliates of the registrant on June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, based on the adjusted closing price on that date of \$2.75, was \$62,342,231.

As of March 20, 2016, the registrant had 39,833,023 shares of common stock outstanding.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

None.

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## EXPLANATORY NOTE

This Amendment No. 2 (“Amendment No. 2”) to the Annual Report on Form 10-K of Pieris Pharmaceuticals Inc. (the “Company”) for the fiscal year ended December 31, 2015 (the “Form 10-K”), originally filed with the Securities and Exchange Commission (the “SEC”) on March 23, 2016 and amended on April 29, 2016 (as amended, the “Original Report”) is being filed in response to comments from the SEC and for the purpose of re-filing the agreement filed as Exhibit 10.11 to the Original Report in order to restore certain redacted information that was subject to a confidential treatment request by the Company.

This Amendment No. 2 consists of a cover page, this explanatory note, a revised list of exhibits (Item 15 of Part IV), a signature page, CEO and CFO certifications pursuant to Section 302 of the Sarbanes Oxley Act of 2002 and Exhibit 10.11. Because no financial statements have been included in this Amendment No. 2 and this Amendment No. 2 does not contain or amend any disclosure with respect to Items 307 and 308 of Regulation S-K, paragraphs 3, 4 and 5 of the CEO and CFO certifications have been omitted.

This Amendment No. 2 speaks as of the initial filing date of the Original Report. Other than as expressly set forth above, no part of the Original Report is being amended. Accordingly, other than as discussed above, this Amendment No. 2 does not purport to amend, update or restate any other information or disclosure included in the Original Report or reflect any events that have occurred after the initial filing date of the Original Report. As a result, the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2015 continues to speak as of March 23, 2016 or, to the extent applicable, such other date as may be indicated in the Original Report. This Amendment No. 2 should be read in conjunction with the Company’s filings made with the Securities and Exchange Commission subsequent to the filing of the Original Filing, as information in such filings may update or supersede certain information contained in this Amendment No. 2.

**PART IV**

**Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

**(b) Exhibits**

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File / Registration Number</u>
2.1	Acquisition Agreement, dated as of December 17, 2014, by and among the Registrant, Pieris AG and the former stockholders of Pieris AG named therein	Form 8-K (Exhibit 2.1)	December 18, 2014	333-190728
3.1	Amended and Restated Articles of Incorporation of the Registrant	Form 8-K (Exhibit 3.1)	December 18, 2014	333-190728
3.2	Amended and Restated Bylaws of the Registrant	Form 8-K (Exhibit 3.2)	December 18, 2014	333-190728
4.1	Form of Common Stock certificate	Form 8-K (Exhibit 4.1)	December 18, 2014	333-190728
4.2	Form of Common Stock certificate	Form 10-K (Exhibit 4.2)	March 23, 2016	001-37471
10.1	2014 Employee, Director and Consultant Equity Incentive Plan	# Form 8-K (Exhibit 10.1)	December 18, 2014	333-190728
10.2	Form of Stock Option Award Agreement under the Registrant's 2014 Employee, Director and Consultant Equity Incentive Plan	# Form 8-K (Exhibit 10.2)	December 18, 2014	333-190728
10.3	Collaboration Agreement by and between Pieris AG and Allergan Sales, LLC, dated as of August 21, 2009	± Form 8-K (Exhibit 10.3)	December 18, 2014	333-190728
10.4	Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur SA, dated as of September 24, 2010	± Form 10-K (Exhibit 10.4)	March 30, 2014	333-190728
10.5	First Letter Agreement to Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur SA, dated as of February 20, 2013	± Form 8-K (Exhibit 10.5)	December 18, 2014	333-190728
10.6	Side Agreement to the Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur Inc., dated as of January 19, 2015	± Form S-1 (Exhibit 10.6)	February 2, 2015	333-202123
10.7	Collaboration Research and Technology Licensing Agreement by and between Pieris AG and Daiichi Sankyo Company Limited, dated as of May 31, 2011	± Form 10-K (Exhibit 10.7)	March 30, 2014	333-190728
10.8	Development and License Agreement by and between Pieris AG and Cadila Healthcare Limited, dated as of October 7, 2013	± Form 10-K (Exhibit 10.8)	March 30, 2014	333-190728

<u>Exhibit Number</u>	<u>Exhibit Description</u>		<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File / Registration Number</u>
10.9	Joint Development and License Agreement by and between Pieris AG and Stelis BioPharma Private Limited, dated as of November 21, 2013	±	Form 10-K (Exhibit 10.9)	March 30, 2014	333-190728
10.10	Research and Licensing Agreement by and between Pieris AG and Technische Universität München, dated as of July 26, 2007	±	Form 10-K (Exhibit 10.10)	March 30, 2014	333-190728
10.11	Research Collaboration and License Agreement by and among the Registrant, Pieris GmbH, Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd., dated as of December 8, 2015	*@			
10.12	Form of Indemnification Agreement by and between the Registrant and each of its current directors and executive officers	#	Form 8-K (Exhibit 10.10)	December 18, 2014	333-190728
10.13	Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of August 30, 2009	#	Form 8-K (Exhibit 10.11)	December 18, 2014	333-190728
10.14	Amendment to Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of March 12, 2012	#	Form 8-K (Exhibit 10.12)	December 18, 2014	333-190728
10.15	Amended and Restated Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of December 17, 2014	#	Form 8-K (Exhibit 10.13)	December 18, 2014	333-190728
10.16	Acknowledgement and Waiver Agreement by and between Pieris AG and Stephen S. Yoder, dated as of December 12, 2014	#	Form 8-K (Exhibit 10.14)	December 18, 2014	333-190728
10.17	Employment Agreement by and between the Registrant and Stephen S. Yoder, dated as of December 17, 2014	#	Form 8-K (Exhibit 10.15)	December 18, 2014	333-190728
10.18	Management Agreement by and between Pieris AG and Claus Schalper, dated as of February 6, 2008	#	Form 8-K (Exhibit 10.16)	December 18, 2014	333-190728
10.19	Consulting Agreement by and between Pieris AG and Claus Schalper, dated as of July 9, 2013	#	Form 8-K (Exhibit 10.17)	December 18, 2014	333-190728
10.20	Employment Agreement by and between Pieris AG and Dr. Ulrich Moebius, dated as of June 26, 2013	#	Form 8-K (Exhibit 10.18)	December 18, 2014	333-190728
10.21	Amendment to Employment Agreement by and between Pieris AG and Dr. Ulrich Moebius, dated as of January 28, 2014	#	Form 8-K (Exhibit 10.19)	December 18, 2014	333-190728
10.22	Amendment to Employment Agreement by and between Pieris AG and Dr. Ulrich Moebius, dated as of October 21, 2014	#	Form 8-K (Exhibit 10.20)	December 18, 2014	333-190728

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File / Registration Number</u>
10.23	Management Agreement by and between Pieris AG and Dr. Laurent Audoly, dated as of May 18, 2010	# Form 8-K (Exhibit 10.20)	December 18, 2014	333-190728
10.24	Consulting Agreement by and between Pieris AG and Danforth Advisors, LLC, effective as of November 19, 2014	# Form 8-K (Exhibit 10.22)	December 18, 2014	333-190728
10.25	Employment Agreement by and between the Registrant and Darlene Deptula-Hicks, dated as of August 27, 2015	# Form 10-Q (Exhibit 10.2)	November 11, 2015	001-37471
10.26	Employment Agreement by and between the Registrant and Louis A. Matis, M.D., dated as of July 20, 2015	# Form 10-Q (Exhibit 10.1)	November 11, 2015	001-37471
10.27	Lease Agreement by and between Pieris AG and Födergesellschaft IZB mbH, dated as of May 4, 2011	Form 8-K (Exhibit 10.23)	December 18, 2014	333-190728
10.28	Agreement of Sublease by and between Berenberg Capital Markets LLC and the Registrant, dated as of August 27, 2015	Form 10-Q (Exhibit 10.3)	November 11, 2015	001-37471
10.29	Convertible Bridge Loan Agreement by and among Pieris AG and the Stockholder parties listed therein, dated as of November 12, 2012	Form 8-K (Exhibit 10.24)	December 18, 2014	333-190728
10.30	Amendment to Convertible Bridge Loan Agreement by and among Pieris AG and the Stockholders listed therein, dated as of March 4, 2014	Form 8-K (Exhibit 10.25)	December 18, 2014	333-190728
10.31	Participation Agreement (silent partnership agreement) between Pieris AG and tbg Technologie-Beteiligungs-Gesellschaft mbH, dated May 13, 2003	Form 8-K (Exhibit 10.26)	December 18, 2014	333-190728
10.32	Repayment Agreement by and between Pieris AG and tbg Technologie-Beteiligungs-Gesellschaft mbH, dated as of April 3, 2014	Form 8-K (Exhibit 10.27)	December 18, 2014	333-190728
10.33	Settlement Agreement (Accelerated Repayment Agreement) by and between Pieris AG and tbg Technologie-Beteiligungs-Gesellschaft mbH, dated as of December 11, 2014	Form 8-K (Exhibit 10.28)	December 18, 2014	333-190728
10.34	Convertible Bridge Loan Agreement by and among Pieris AG and the Stockholders listed on Exhibit A thereto, dated as of April 14, 2014	Form 8-K (Exhibit 10.29)	December 18, 2014	333-190728
10.35	Consolidated Shareholders' Agreement 2014, Pieris AG, Freising, Germany, by and among Pieris AG and the Stockholders party thereto, dated October 10, 2014	Form 8-K (Exhibit 10.30)	December 18, 2014	333-190728

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File / Registration Number</u>
10.36	Investment Agreement, Pieris AG, Freising, Germany, by and among Pieris AG, Stephen Yoder and the Existing Shareholders party thereto, dated October 10, 2014	Form 8-K (Exhibit 10.31)	December 18, 2014	333-190728
10.37	Agreement, by and among Pieris AG and the Stockholders party thereto, dated December 5, 2014	Form 8-K (Exhibit 10.32)	December 18, 2014	333-190728
10.38	Split-Off Agreement, by and among the Registrant, Marika Enterprises Inc. and Aleksandrs Sviks, dated December 17, 2014	Form 8-K (Exhibit 10.33)	December 18, 2014	333-190728
10.39	General Release Agreement, by and among the Registrant, Marika Enterprises Inc. and Aleksandrs Sviks, dated December 17, 2014	Form 8-K (Exhibit 10.34)	December 18, 2014	333-190728
10.40	Form of Securities Purchase Agreement, dated December 17, 2014, by and among Pieris Pharmaceuticals, Inc. and the Purchasers	Form 8-K (Exhibit 10.1)	December 23, 2014	333-190728
10.41	Form of Registration Rights Agreement, dated December 17, 2014, by and among Pieris Pharmaceuticals, Inc. and the investors party thereto	Form 8-K (Exhibit 10.2)	December 23, 2014	333-190728
10.42	Form of Warrant to Purchase Common Stock, dated December 17, 2014, issued by Pieris Pharmaceuticals, Inc.	Form 8-K (Exhibit 10.3)	December 23, 2014	333-190728
14.1	Corporate Code of Ethics and Conduct and Whistleblower Policy	Form 10-K (Exhibit 14.1)	March 30, 2014	333-190728
21.1	List of Subsidiaries	Form 10-K (Exhibit 21.1)	March 23, 2016	001-37471
31.1	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 302 of the Sarbanes—Oxley Act of 2002	Form 10-K (Exhibit 31.1)	March 23, 2016	001-37471
31.2	Certification of Darlene Deptula-Hicks, Acting Chief Financial Officer, pursuant to Section 302 of the Sarbanes—Oxley Act of 2002	Form 10-K (Exhibit 31.2)	March 23, 2016	001-37471
31.3	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 302 of the Sarbanes—Oxley Act of 2002	Form 10-K/A (Exhibit 31.3)	April 29, 2016	001-37471
31.4	Certification of Darlene Deptula-Hicks, Acting Chief Financial Officer, pursuant to Section 302 of the Sarbanes—Oxley Act of 2002	Form 10-K/A (Exhibit 31.4)	April 29, 2016	001-37471
31.5	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 302 of the Sarbanes—Oxley Act of 2002	*		

<u>Exhibit Number</u>	<u>Exhibit Description</u>		<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File / Registration Number</u>
31.6	Certification of Darlene Deptula-Hicks, Acting Chief Financial Officer, pursuant to Section 302 of the Sarbanes—Oxley Act of 2002	*			
32.1	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 906 of the Sarbanes—Oxley Act of 2002, 18 U.S.C. Section 1350		Form 10-K (Exhibit 31.1)	March 23, 2016	001-37471
32.2	Certification of Darlene Deptula-Hicks, Acting Chief Financial Officer, pursuant to Section 906 of the Sarbanes—Oxley Act of 2002, 18 U.S.C. Section 1350		Form 10-K (Exhibit 31.2)	March 23, 2016	001-37471
32.3	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 906 of the Sarbanes—Oxley Act of 2002, 18 U.S.C. Section 1350		Form 10-K/A (Exhibit 31.3)	April 29, 2016	001-37471
32.4	Certification of Darlene Deptula-Hicks, Acting Chief Financial Officer, pursuant to Section 906 of the Sarbanes—Oxley Act of 2002, 18 U.S.C. Section 1350		Form 10-K/A (Exhibit 31.4)	April 29, 2016	001-37471
101.INS	XBRL Instance Document		Form 10-K	March 23, 2016	001-37471
101.SCH	XBRL Taxonomy Extension Schema Document		Form 10-K	March 23, 2016	001-37471
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document		Form 10-K	March 23, 2016	001-37471
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document		Form 10-K	March 23, 2016	001-37471
101.LAB	XBRL Taxonomy Extension Label Linkbase Document		Form 10-K	March 23, 2016	001-37471
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document		Form 10-K	March 23, 2016	001-37471

\* Filed herewith

± Confidential treatment received as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC.

@ Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC

# Indicates a management contract or compensatory plan



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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**PIERIS PHARMACEUTICALS, INC.**

Date: July 20, 2016

By: /s/ Stephen S. Yoder

Stephen S. Yoder

Chief Executive Officer and President

**CONFIDENTIAL TREATMENT REQUESTED**

**Research Collaboration and License Agreement**

This Agreement is entered into with effect as of the Effective Date (as defined below)

by and between

**F. Hoffmann-La Roche Ltd**

with an office and place of business at Grenzacherstrasse 124, 4070 Basel, Switzerland (“**Roche Basel**”)

and

**Hoffmann-La Roche Inc.**

with an office and place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424, U.S.A. (“**Roche US**”; Roche Basel and Roche US together referred to as “**Roche**”)

on the one hand

and

**Pieris Pharmaceuticals GmbH**

with an office and place of business at Lise-Meitner-Str. 30, 83534 Freising, Germany (“**Pieris Freising**”)

and

**Pieris Pharmaceuticals, Inc.**

with an office and place of business at 255 State Street, 9<sup>th</sup> Floor, Boston, MA 02109, USA (“**Pieris US**”; Pieris Freising and Pieris US together referred to as “**Pieris**”)

on the other hand.

*Portions of the exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

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*Portions of the exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

**Research Collaboration and License Agreement**

WHEREAS, Pieris has access to a proprietary Anticalin® (lipocalin derived) discovery and manufacturing platform and possesses proprietary technology and intellectual property rights relating thereto; and

WHEREAS, Roche has access to the [\*\*\*] and [\*\*\*] target protein and other tools and to [\*\*\*] for [\*\*\*] as well as expertise in the research, development, manufacture and commercialization of pharmaceutical and diagnostic products, in particular in the field of cancer immunotherapy; and

WHEREAS, the Parties wish to combine their respective expertise to develop binders that [\*\*\*] or specifically bind to [\*\*\*] using Pieris Technology and Roche's [\*\*\*] for application in particular in cancer, and the Parties will collaborate from the beginning of lead identification through a mutually agreeable preclinical research stage set forth in the Research Plan.

WHEREAS, Roche wishes to develop for commercialization such binders and explore their potential applications in various indications; and

WHEREAS, Pieris is willing to grant to Roche rights to use certain of its intellectual property rights to make, use, offer for sale, sell and import and export such binders (including Products containing such binders) in the Territory for use in the Field (as such terms are respectively defined below), as contemplated herein; and

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

**1. Definitions**

As used in this Agreement, the following terms, whether used in the singular or plural, shall have the following meanings:

**1.1 Affiliate**

The term "Affiliate" shall mean any individual, corporation, association or other business entity that directly or indirectly controls, is controlled by, or is under common control with the Party in question. As used in this definition of "Affiliate," the term "control" shall mean the direct or indirect ownership of more than fifty percent (>50%) of the stock having the right to vote for directors thereof or the ability to otherwise control the management of the corporation or other business entity whether through the ownership of voting securities, by contract, resolution, regulation or otherwise. Anything to the contrary in this paragraph notwithstanding, Chugai Pharmaceutical Co., Ltd, a Japanese corporation ("**Chugai**") and Foundation Medicine, Inc., an American corporation ("**Foundation**") and their subsidiaries, shall not be deemed an Affiliate of Roche unless Roche provides written notice to Pieris of its desire to include Chugai and/or Foundation as an Affiliate of Roche.

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*Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

**1.2 Agreement**

The term “Agreement” shall mean this document including any and all appendices and amendments to it as may be added and/or amended from time to time in accordance with the provisions of this Agreement.

**1.3 Agreement Term**

The term “Agreement Term” shall mean the period of time commencing on the Effective Date and, unless this Agreement is terminated sooner as provided in Article 19, expiring on the date when no royalty or other payment obligations under this Agreement are or will become due.

**1.4 Anticalin®**

The term “Anticalin®” shall mean, whether in nucleic acid or protein form, (i) any lipocalin mutein isolated from the Anticalin Libraries, or (ii) any lipocalin mutein that, in each case, has been derived (either physically, intellectually or by reverse engineering, in one (1) or more steps) from any lipocalin mutein referred to in Section (i) of this definition. For the sake of this Section, mutein shall mean a protein arising as a result of a mutation or a recombinant DNA procedure.

**1.5 Anticalin Affinity Maturation**

The term “Anticalin Affinity Maturation” shall mean the process of engineering for an Anticalin to enhance its developability profile, such as increasing binding activities and specificity by introducing, e.g., one or more amino acid mutations.

**1.6 Anticalin Expression**

The term “Anticalin Expression” shall mean heterologous expression of an Anticalin in E. coli or other hosts as may be mutually agreed between the Parties.

**1.7 Anticalin Libraries**

The term “Anticalin Libraries” shall mean any phage display library based on (i) the human [\*\*\*] lipocalin (Uniprot [\*\*\*]), (ii) the human [\*\*\*] lipocalin (Uniprot [\*\*\*]), or (iii) [\*\*\*], if applicable. For clarity, as of the Effective Date, Pieris [\*\*\*] referred to in Section (iii) of this definition and this Section (iii) only becomes relevant if and when Pieris [\*\*\*] or [\*\*\*] such [\*\*\*] during the Agreement Term. For further clarity, notwithstanding anything to the contrary in this Agreement, Pieris has no obligation to [\*\*\*] or [\*\*\*] such [\*\*\*] during the Term.

**1.8 Anticalin Selection**

The term “Anticalin Selection” shall mean the process of screening an Anticalin Library with a defined target through the process of phage display, within a solution, and physically separating the target, containing binding Anticalins, from the solution containing non-binding Anticalins.

**1.9 Applicable Law**

The term “Applicable Law” shall mean any law, statute, ordinance, code, rule or regulation that has been enacted by a government authority (including without limitation, any Regulatory Authority and the United States Securities and Exchange Commission (“SEC”)) and is in force as of the Effective Date or come into force during the Agreement Term, in each case to the extent that the same are applicable to the performance by the Parties of their respective obligations under this Agreement.

**1.10 Binder**

The term “Binder” shall mean an Anticalin® discovered under the Research Plan that specifically binds to or inhibits the Target.



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**1.11 Biosimilar Product**

The term “Biosimilar Product” shall mean a product that is not produced, licensed or owned by the Roche Group and is, according to the relevant Regulatory Authority for the given country or jurisdiction, highly similar with respect to a given Product, notwithstanding minor differences in clinically inactive components, and with no clinically meaningful differences between the Biosimilar Product and the given Product in terms of the safety, purity and potency of the product.

For countries or jurisdictions where no explicit biosimilar regulations exist, Biosimilar Product includes products which (i) have been deemed to be a Biosimilar Product by a Regulatory Authority in another country or jurisdiction or (ii) have the identical amino acid sequence.

**1.12 Calendar Quarter**

The term “Calendar Quarter” shall mean each period of three (3) consecutive calendar months, ending March 31, June 30, September 30, and December 31.

**1.13 Calendar Year**

The term “Calendar Year” shall mean the period of time beginning on January 1 and ending December 31, except for the first year which shall begin on the Effective Date and end on December 31.

**1.14 Change of Control**

The term “Change of Control” shall mean, with respect to a Party: (a) the acquisition by any Third Party of beneficial ownership of fifty percent (50%) or more of the then outstanding common shares or voting power of such Party, other than acquisitions by employee benefit plans sponsored or maintained by such Party; (b) the consummation of a business combination involving such Party, unless, following such business combination, the stockholders of such Party immediately prior to such business combination beneficially own directly or indirectly more than fifty percent (50%) of the then outstanding common shares or voting power of the entity resulting from such business combination; or (c) the sale of all or substantially all of such Party’s assets or business relating to the subject matter of the Agreement.

**1.15 Change of Control Group**

The term “Change of Control Group” shall mean with respect to a Party, the person or entity, or group of persons or entities, that is the acquirer of, or a successor to, a Party in connection with a Change of Control, together with affiliates of such persons or entities that are not Affiliates of such Party immediately prior to the completion of such Change of Control of such Party.

**1.16 Clinical Study**

The term “Clinical Study” shall mean a Phase I Study, Phase II Study, Phase III Study, as applicable.

**1.17 Combination Product**

The term “Combination Product” shall mean

- a) a single pharmaceutical formulation containing as its active ingredients either (i) a Selected Binder or (ii) a Modified Binder, in each case together with one or more other therapeutically or prophylactically active ingredients targeting an antigen other than the Target. For clarity, Combination Product in this Subsection a) also includes a [\*\*\*] comprised of a Selected Binder or Modified Binder [\*\*\*] or [\*\*\*] to [\*\*\*] an[\*\*\*],
- b) a combination therapy comprised of a Selected Binder or Modified Binder alone (or combined as described in a) above) and one or more other therapeutically or prophylactically active products, priced and sold in a single package containing such multiple products or packaged separately but sold together for a single price, or

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- c) a combination therapy comprised of a Selected Binder alone (or combined as described in a) above) and a Companion Diagnostic, priced and sold in a single package containing such multiple products or packaged separately but sold together for a single price, in each case, including all dosage forms, formulations, presentations, line extensions, and package configurations.

### **1.18 Commercially Reasonable Efforts**

The term “Commercially Reasonable Efforts” shall mean such level of efforts required to carry out such obligation in a sustained manner consistent with the efforts Roche or Pieris, 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.

However, 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. As a result, the exercise of diligence by Roche is to be determined by judging Roche’s commercially reasonable efforts, taken as a whole.

### **1.19 Companion Diagnostic**

The term “Companion Diagnostic” shall mean any product that is used for predicting and/or monitoring the response of a human being to treatment with a Product (e.g. device, compound, kit, biomarker or service that contains a component that is used to detect or quantify the presence or amount of an analyte in body or tissue that affects the pathogens of the disease).

### **1.20 Composition of Matter Claim**

The term “Composition of Matter Claim” shall mean, for a given Product in a given country of the Territory, a Valid Claim of a Patent Right that Covers the active ingredient of a Product as a composition of matter.

### **1.21 Compulsory Sublicense**

The term “Compulsory Sublicense” shall mean a license or sublicense granted to a Third Party (a “**Compulsory Sublicensee**”), through the order, decree or grant of a governmental authority having competent jurisdiction, authorizing such Third Party to manufacture, use, sell, offer for sale, import or export a Product in any country in the Territory.

### **1.22 Confidential Information**

The term “Confidential Information” shall mean any and all information, data or know-how (including Know-How), whether technical or non-technical, oral or written, that is disclosed by one Party or its Affiliates (“**Disclosing Party**”) to the other Party or its Affiliates (“**Receiving Party**”). Confidential Information shall not include any information, data or know-how that:

- (i) was generally available to the public at the time of disclosure, or information that becomes available to the public after disclosure by the Disclosing Party other than through fault (whether by action or inaction) of the Receiving Party or its Affiliates,
- (ii) can be evidenced by written records to have been already known to the Receiving Party or its Affiliates prior to its receipt from the Disclosing Party,
- (iii) is obtained at any time lawfully from a Third Party under circumstances permitting its use or disclosure,

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- (iv) is developed independently by the Receiving Party or its Affiliates as evidenced by written records other than through knowledge of Confidential Information,
- (v) is required to be disclosed by the Receiving Party or its Affiliates to comply with a court or administrative order, provided that the Receiving Party or its Affiliates furnishes prompt notice (in no event less than three (3) days prior to such required disclosure) to the Disclosing Party to enable it to contest such disclosure, or
- (vi) is approved in writing by the Disclosing Party for release by the Receiving Party.

The terms of this Agreement shall be considered Confidential Information of the Parties.

**1.23 Continuation Election Notice**

The term “Continuation Election Notice” shall mean the notice Pieris may provide to Roche under Section 19.3.4.

**1.24 Control**

The term “Control” shall mean (as an adjective or as a verb including conjugations and variations such as “Controls” “Controlled” or “Controlling”) (a) with respect to Patent Rights and/or Know-How, the possession by a Party of the ability to grant a license or sublicense of such Patent Rights and/or Know-How without violating the terms of any agreement or arrangement between such Party and any other party and (b) with respect to proprietary materials, the possession by a Party of the ability to supply such proprietary materials to the other Party as provided herein without violating the terms of any agreement or arrangement between such Party and any other party.

**1.25 Cover**

The term “Cover” shall mean (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 Valid Claim in the absence of a license under the Patent Rights to which such Valid Claim pertains. The determination of whether a compound, formulation, process or product is Covered by a particular Valid Claim shall be made on a country-by-country basis.

**1.26 Effective Date**

The term “Effective Date” shall mean December 8, 2015.

**1.27 Entry into Portfolio**

The term “Entry into Portfolio” shall mean, with regard to a Product, in the case of Roche, the decision by [\*\*\*] to enter [\*\*\*], and in the case of Pieris, with regards to a [\*\*\*], the decision by its [\*\*\*] to further develop such [\*\*\*] following confirmation of functionality in vitro.

**1.28 EU**

The term “EU” shall mean the European Union and all its then-current member countries.

**1.29 Event**

The term “Event” shall designate a Product and a certain Indication for such Product. Each subsequent Event differentiates itself from the prior Event by either having a different Indication for the same Product, or by being a different Product with the same or a different Indication.

**1.30 Expert**

The term “Expert” shall mean a person with no less than fifteen (15) years of pharmaceutical industry experience and expertise having occupied at least one senior position within a large pharmaceutical company relating to product development and/or licensing but excluding any current or former employee or current consultant of either Party. Such person shall be fluent in the English language.

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**1.31 FDA**

The term “FDA” shall mean the Food and Drug Administration of the United States of America.

**1.32 FDCA**

The term “FDCA” shall mean the Food, Drug and Cosmetics Act.

**1.33 Field**

The term “Field” shall mean all biopharmaceutical, biomedical and diagnostic uses, including all therapeutic and prophylactic uses.

**1.34 Filing**

The term “Filing” shall mean the filing of an application by the FDA as defined in the FDCA and applicable regulations, or the equivalent application to the equivalent agency in any other country or group of countries, the official approval of which is required before any lawful commercial sale or marketing of Products.

**1.35 First Commercial Sale**

The term “First Commercial Sale” shall mean, on a country-by-country basis, the first invoiced sale of a Product to a Third Party by the Roche Group following the receipt of any Regulatory Approval required for the sale of such Product, or if no such Regulatory Approval is required, the date of the first invoiced sale of a Product to a Third Party by the Roche Group in such country.

**1.36 FTE**

The term “FTE” shall mean a full-time equivalent person-year, taking into consideration statutory holidays and paid annual leave. In no circumstance can the work of any given person exceed one (1) FTE.

**1.37 FTE Rate**

The term “FTE Rate” shall mean the amount of EUR [\*\*\*] ([\*\*\*] Euros) per FTE, on a fully burdened cost basis. Notwithstanding the foregoing, such FTE Rate shall include the costs for [\*\*\*] not to exceed EUR [\*\*\*] ([\*\*\*] Euros) during the Research Term.

**1.38 Generated**

The term “Generated” means, with respect to a Product, that a plasmid construct was created and expressed in eukaryotic or bacterial cells.

**1.39 GLP Tox Study**

The term “GLP Tox Study” shall mean a study in accordance with the Good Laboratory Practice (GLP) to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for a product.

**1.40 Handle**

The term “Handle” shall mean preparing, filing, prosecuting (including interference and opposition proceedings) and maintaining (including interferences, reissue, re-examination, post-grant reviews, inter-parties reviews, derivation proceedings and opposition proceedings).

**1.41 HSR**

The term “HSR” shall mean the Hart-Scott-Rodino Antitrust Improvements Act.

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**1.42 ICD**

The term “ICD” shall mean the Tenth Revision of the International Classifications of Diseases and Related Health Problems of 2010.

**1.43 IFRS**

The term “IFRS” shall mean International Financial Reporting Standards.

**1.44 Indication**

The term “Indication” shall mean a distinct type of disease or medical condition in humans to which a Product is directed and eventually approved. To distinguish one Indication from another Indication, the two Indications have to be (i) listed in two different blocks of the ICD (as a way of example, any neoplasm under C15 is in a different block from any neoplasm under block C16, whereas C15.0 and C15.1 belong to the same block) and (ii) developed by Roche under separate Clinical Studies. Notwithstanding the foregoing, [\*\*\*] and [\*\*\*] shall be deemed to be two distinct Indications.

**1.45 Initiation**

The term “Initiation” or “Initiated” shall mean, with respect to Clinical Studies, the date that a human is first dosed with the Product in a Clinical Study approved by (or allowed by) the respective Regulatory Authority, or, with respect to GLP Tox Studies, the date an animal is first dosed with the Product in a GLP Tox Study approved by (or allowed by) the respective Regulatory Authority.

**1.46 Insolvency Event**

The term “Insolvency Event” shall mean circumstances under which a Party (i) has a receiver or similar officer appointed over all or a material part of its assets or undertaking; (ii) passes a resolution for winding-up (other than a winding-up for the purpose of, or in connection with, any solvent amalgamation or reconstruction) or a court makes an order to that effect or a court makes an order for administration (or any equivalent order in any jurisdiction); (iii) enters into any composition or arrangement with its creditors (other than relating to a solvent restructuring); (iv) ceases to carry on business; (v) is unable to pay its debts as they become due in the ordinary course of business.

**1.47 Invention**

The term “Invention” shall mean an invention that is conceived or reduced to practice in connection with any activity carried out pursuant to this Agreement. Under this definition, an Invention may be made (including conceived) by employees of Pieris solely or jointly with a Third Party (a “**Pieris Invention**”), by employees of Roche solely or jointly with a Third Party (a “**Roche Invention**”), or jointly by employees of Pieris and employees of Roche with or without a Third Party (a “**Joint Invention**”). Inventorship shall be determined in accordance with US patent laws.

**1.48 JP**

The term “JP” shall mean Japan.

**1.49 JRC**

The term “JRC” shall mean the joint research committee described in Section 6.

**1.50 Know-How**

The term “Know-How” shall mean data, knowledge and information, including materials, samples, chemical manufacturing data, toxicological data, pharmacological data, preclinical data, assays, platforms, formulations, specifications, quality control testing data, that are necessary or useful for the discovery, manufacture, development or commercialization of Products.

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**1.51 Modified Binder**

The term “Modified Binder” shall mean a) a single Selected Binder alone or b) multiple Selected Binders conjugated and/or fused to each other (such as by a genetic linkage), in the case of a) with, and in the case of b) either with or without modification by conjugation and/or fusion to a moiety, e.g., for [\*\*\*]. Such [\*\*\*] may include, without limitation, [\*\*\*], including [\*\*\*] based on Roche Technology.

**1.52 NDA**

The term “NDA” shall mean a new drug application, including all necessary documents, data, and other information concerning a Product, required for Regulatory Approval of the Product as a pharmaceutical product by the FDA or an equivalent application to the equivalent agency in any other country or group of countries (e.g. the marketing authorization application (MAA) in the EU).

**1.53 Net Sales**

The term “Net Sales” shall mean, for a Product in a particular period, the amount calculated by subtracting from the Sales of such Product for such period: (i) a lump sum deduction of [\*\*\*] ([\*\*\*]%) of Sales in lieu of those deductions that are not accounted for on a Product-by-Product basis (e.g., freight, postage charges, transportation insurance, packing materials for dispatch of goods, custom duties); (ii) actual uncollectible amounts accrued during such period and not already taken as a gross-to-net deduction in accordance with the then currently used IFRS in the calculation of Sales of such Product for such period; (iii) credit card charges (including processing fees) accrued during such period on such Sales; and (iv) government mandated fees and taxes and other government charges accrued (but excluding taxes based on the income of the selling party) during such period not already taken as a gross-to-net deduction in accordance with the then currently used IFRS in the calculation of Sales of such Product for such period, including, for example, any fees, taxes or other charges that become due in connection with any healthcare reform, change in government pricing or discounting schemes, or other action of a government or regulatory body. For clarity, no deductions taken in calculating Sales under Section 1.71 may be taken a second time in calculating Net Sales.

**1.54 Party**

The term “Party” shall mean Pieris or Roche, as the case may be, and “Parties” shall mean Pieris and Roche collectively.

**1.55 Patent Rights**

The term “Patent Rights” shall mean all rights under any patent or patent application, in any country of the Territory, including any patents issuing on such patent application, and further including any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, division, continuation or continuation-in-part of any of the foregoing.

**1.56 Phase I Study**

The term “Phase I Study” shall mean a human clinical trial in any country that would satisfy the requirements of 21 C.F.R. § 312.21(a) (FDCA), as amended from time to time, and the foreign equivalent thereof.

**1.57 Phase II Study**

The term “Phase II Study” shall mean a human clinical trial, for which the primary endpoints include a determination of dose ranges and/or a preliminary determination of efficacy in patients being studied as described in 21 C.F.R. § 312.21(b) (FDCA), as amended from time to time, and the foreign equivalent thereof.

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**1.58 Phase III Study**

The term “Phase III Study” shall mean a human clinical trial that is prospectively designed to demonstrate statistically whether a product is safe and effective for use in humans in a manner sufficient to obtain regulatory approval to market such product in patients having the disease or condition being studied as described in 21 C.F.R. § 312.21(c) (FDCA), as amended from time to time, and the foreign equivalent thereof.

**1.59 Phase-out Binder**

The term “Phase-out Binder” shall mean an Anticalin® discovered during the Phase-out Term that specifically binds to the Target.

**1.60 Phase-out Term**

The term “Phase-out Term” shall mean the period beginning at the end of the Research Term provided that Roche has opted for [\*\*\*] as described in Section 10.3.1, and ending at the latest five (5) years thereafter if Roche has paid the Annual Exclusive Target Access Fee and beyond the third year, the Phase-out Extension Fee, if applicable as per Sections 10.3.1. and 10.3.2.

**1.61 Pieris IP**

The term “Pieris IP” shall mean Know-How and Patent Rights that Pieris owns or Controls (i) as of the Effective Date, which include Patent Rights listed in Appendix 1.60; and (ii) during the Agreement Term that are necessary or useful for the discovery, manufacture, development or commercialization of an Anticalin®, or that are relating to Pieris Technology.

**1.62 Pieris Technology**

The term “Pieris Technology” shall mean Anticalin Libraries, Anticalin Selection, Anticalin Expression and Anticalin Affinity Maturation methods.

**1.63 Product**

The term “Product” shall mean any product or composition containing at least one Selected Binder, regardless of their finished forms or formulations or dosages. With regard to milestone and royalty payments, a Product shall differentiate itself from another Product by containing, in addition to at least one Selected Binder, a [\*\*\*] ([\*\*\*]Selected Binder) as active ingredient that binds to [\*\*\*]. Examples: 1) [\*\*\*]Selected Binders developed as separate products are considered the same Product; 2) a Selected Binder[\*\*\*] and a Selected Binder [\*\*\*] a pharmaceutically active molecule that [\*\*\*] are considered two distinct Products.

**1.64 Regulatory Approval**

The term “Regulatory Approval” shall mean any approvals, licenses, registrations or authorizations by Regulatory Authority, necessary for the sale of a Product in the Field in a regulatory jurisdiction in the Territory.

**1.65 Regulatory Authority**

The term “Regulatory Authority” shall mean any national, supranational (e.g., the European Commission, the Council of the European Union, the European Medicines Agency), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity including the FDA, in each country involved in the granting of Regulatory Approval for the Product.

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**1.66 Research Plan**

The term “Research Plan” shall mean the plan of research attached as Appendix 1.66 outlining the work expected to be performed by Pieris and Roche, as such plan may be updated from time to time as permitted in this Agreement.

**1.67 Roche Group**

The term “Roche Group” shall mean collectively Roche, its Affiliates and its Sublicensees.

**1.68 Roche IP**

The term “Roche IP” shall mean Know-How and Patent Rights that Roche owns or Controls as of the Effective Date and during the Agreement Term and that relate to Roche Technology. For purposes of clarity, the Patent Rights identified in Appendix 1.68 (“**Excluded Patent Rights**”) are specifically excluded from the Roche IP.

**1.69 Roche Technology**

The term “Roche Technology” shall mean Roche’s [\*\*\*] to be [\*\*\*] with the Binder(s) or Phase-out Binder(s) for [\*\*\*].

**1.70 Royalty Term**

The term “Royalty Term” shall mean, with respect to a Product and for a given country, the period of time commencing on the date of First Commercial Sale of the Product in such country and ending on the later of the date that is (a) ten (10) years after the date of the First Commercial Sale of the Product in such country, or (b) the expiration of the last to expire Composition of Matter Claim of a patent owned or Controlled by Roche (or Pieris pursuant to Section 14.5) in such country Covering the use, import, offering for sale, or sale of the Product. With regard to the countries of the EU, the ten (10) year period shall for each country begin at the earlier of (i) date of First Commercial Sale in the specific country or (ii) date of First Commercial Sale in [\*\*\*] ([\*\*\*]). For clarity, any Composition of Matter Claim Covering only [\*\*\*] that [\*\*\*] and which is comprised within Product shall not be relevant for determining the Royalty Term.

**1.71 Sales**

The term “Sales” shall mean, for a Product in a particular period, the sum of (i) and (ii):

- (i) the amount stated in the Roche Holding AG “Sales” line of its externally published audited consolidated financial statements with respect to such Product for such period (excluding sales to any Sublicensees that are not Affiliates of Roche). This amount reflects the gross invoice price at which such Product was sold or otherwise disposed of (other than for use as clinical supplies or free samples) by Roche and its Affiliates to such Third Parties (excluding sales to any Sublicensees that are not Affiliates of Roche) in such period reduced by gross-to-net deductions, if not previously deducted from such invoiced amount, taken in accordance with the then currently used IFRS, to the extent any of such gross-to-net deductions are actually allowed.

By way of example, the gross-to-net deductions taken in accordance with IFRS as of the Effective Date include the following:

- (a) credits, reserves or allowances granted for (i) damaged, outdated, returned, rejected, withdrawn or recalled Product, (ii) wastage replacement and short-shipments; (iii) billing errors and (iv) indigent patient and similar programs (e.g., price capitation);

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*Portions of the exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*



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- (b) governmental price reductions and government mandated rebates;
- (c) chargebacks, including those granted to wholesalers, buying groups and retailers;
- (d) customer rebates, including cash sales incentives for prompt payment, cash and volume discounts; and
- (e) taxes and any other governmental charges or levies imposed upon or measured by the import, export, use, manufacture or sale of a Product (excluding income or franchise taxes).

For purposes of clarity, sales by Roche and its Affiliates to any Sublicensee shall be excluded from “Sales”, but a subsequent sale to Third Parties by such Affiliate or Sublicensee shall be deemed a “Sale”.

- (ii) for Sublicensees that are not Roche Affiliates (and excluding Compulsory Sublicensees), the sales amounts reported to Roche and its Affiliates in accordance with the sublicensee contractual terms and their then-currently used accounting standards. For the purpose of clarity, any such Sublicensee sales as reported to Roche in accordance with Compulsory Sublicense agreements shall be excluded from the sales amount.

**1.72 Selected Binder**

The term “Selected Binder” shall mean a Binder or Phase-out Binder that originates from the pool of Binders discovered by screening any Pieris Anticalin Library, that may have undergone lead optimization, and is then selected by Roche for incorporation into a Product. At its discretion, Roche can select [\*\*\*]Binders or Phase-out Binders during the Research Term or the Phase-out Term and shall be free to [\*\*\*] Binders or Phase-out Binders during such period, with such [\*\*\*] to be [\*\*\*]

**1.73 Sublicensee**

The term “Sublicensee” shall mean an entity to which Roche has licensed any right (through one or multiple tiers), other than through a Compulsory Sublicense, pursuant to this Agreement.

**1.74 Target**

The term “Target” shall mean the biological target of a pharmacologically active drug compound. For this collaboration the [\*\*\*] Target is [\*\*\*] as described in Appendix 1.74.

**1.75 Territory**

The term “Territory” shall mean all countries of the world.

**1.76 Third Party**

The term “Third Party” shall mean a person or entity other than (i) Pieris or any of its Affiliates or (ii) a member of the Roche Group.

**1.77 US**

The term “US” shall mean the United States of America and its territories and possessions.

**1.78 Valid Claim**

The term “Valid Claim” shall mean a claim in any unexpired and issued Patent Rights that has not been disclaimed, revoked or held invalid by a final non-appealable decision of a court of competent jurisdiction or government agency.

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**1.79 Additional Definitions**

Each of the following definitions is set forth in the Section of this Agreement indicated below:

<u>Definition</u>	<u>Section</u>
Accounting Period	11.1
Acquired Party	19.2.3
Alliance Director	6.8
Annual Exclusive Target Access Fee	10.3.1
Bankruptcy Code	20
[***]	2.4
Breaching Party	19.2.1
Chairperson	6.2
Chugai	1.1
Companion Diagnostic Product	10.4
Compulsory Sublicensee	1.21
Development Event	10.4 (in table)
Disclosing Party	1.22
Excluded Patent Rights	1.68
Expert Committee	10.7
First Sales Based Event	10.5
Foundation	1.1
Indemnified Party	16.3
Indemnifying Party	16.3
Joint Invention	1.47
Members	6.2
Non-Acquired Party	19.2.3
Non-Breaching Party	19.2.1
Patent Term Extensions	14.11
Payment Currency	11.3
Peremptory Notice Period	19.2.1
Phase-out Extension Fee	0
Pieris Invention	1.47
Progress Reports	3.1.5
Publishing Notice	18.4
Publishing Party	18.4
Receiving Party	1.22
Reference Product Sponsor	14.10
Relative Commercial Value	10.7
Research Records	3.1.6
Research Term	3.1.4
Roche Invention	1.47
Roche Valid Claim	19.3.4 (b)
Samples	19.3.4 (b)
SEC	1.9
Second Sales Based Event	10.5
Sensitive Information	19.2.3
SPCs	14.11
Stand-alone Diagnostic Product	10.4
Third Sales Based Event	10.5

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*Portions of the exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

## **2. Grant of License**

### **2.1 Research Licenses**

Roche grants to Pieris during the Research Term a non-exclusive right and license under Roche IP that are necessary or useful for the discovery, manufacture or development of Binders, Phase-out Binders, Modified Binders, Selected Binders and Products solely to enable Pieris to perform the activities contemplated under the Research Plan under this Agreement.

Pieris grants to Roche during the Agreement Term an exclusive (even as to Pieris except for activities performed under the Research Plan and, if applicable, during the Phase-out Term for Roche) right and license under Pieris IP that are necessary or useful for the discovery, manufacture or development of Binders, Phase-out Binders, Modified Binders, Selected Binders and Products, in particular to enable Roche to identify and evaluate Binders and Phase-out Binders in order to enable selection of Selected Binders.

### **2.2 Commercial License to Roche**

Pieris hereby grants to Roche an exclusive (even as to Pieris) right and license, including the right to sublicense through multiple tiers, under Pieris' interest in the Pieris IP to research, have researched, develop, have developed, register, have registered, use, have used, make, have made, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sell and have sold Products in the Field in the Territory.

### **2.3 Sublicense**

Roche shall have the right to sublicense or subcontract (through multiple tiers); provided, however, that in the event of such sublicensing, (a) such Sublicensees will be subject to the same confidentiality and diligence obligations Roche has hereunder, and (b) Roche will remain liable for all the terms and conditions of this Agreement.

### **2.4 License to Pieris after Phase-out Term**

After expiration of the Phase-out Term and with respect to Target, Roche grants Pieris (subject to Roche's right of first negotiation as defined below) a non-exclusive license, including the right to sublicense through multiple tiers, under Roche's Patent Rights on Inventions made under the Agreement. Said license shall be limited to such Inventions (a) made (including conceived) during the time period starting at the Effective Date and ending [\*\*\*] and (b) related to Selected Binders to:

- (i) Select binders from the hits obtained [\*\*\*], performed after [\*\*\*] the Phase-out Term, of the Anticalin Libraries, that – per each individual binder – contain [\*\*\*] in the amino acid positions that Pieris randomizes in its Anticalin Libraries (in comparison to the amino acid sequence of the respective wild type lipocalin; for clarity, this means [\*\*\*] depending on the Anticalin Library used) as compared to each Selected Binder and
- (ii) On the basis of binders obtained under (i) above, research, have researched, develop, have developed, register, have registered, use, have used, make, have made, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sell and have sold products that, in addition to [\*\*\*] and which would infringe such Roche's Patent Rights but for a license granted hereunder (“[\*\*\*]”), in the Field in the Territory. [\*\*\*] may not bind to the [\*\*\*] as [\*\*\*] for which [\*\*\*] has [\*\*\*] and is developing using Commercially Reasonable Efforts at the time Pieris initiates an independent screening campaign as described under (i) above for a [\*\*\*]. Pieris shall have the right to make a written query to Roche's alliance manager (to be communicated by Roche in the annual reports under Section 6.11) in order to find out if [\*\*\*] has [\*\*\*] with regard to a [\*\*\*], which query shall be answered within thirty (30) days. For clarity, the license granted by Roche to Pieris for a [\*\*\*] shall be maintained even in the situation where Roche has, subsequent to Roche granting the license hereunder, [\*\*\*], provided, however, that Pieris has used

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*Portions of the exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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## **CONFIDENTIAL TREATMENT REQUESTED**

Commercially Reasonable Efforts to [\*\*\*]. For further clarity, the above license is limited to [\*\*\*] and does not include [\*\*\*]. Pieris shall inform Roche in writing about all [\*\*\*] for which it has reached [\*\*\*] within thirty (30) days after such [\*\*\*] has been reached. Furthermore, Pieris shall annually inform Roche on the development progress of such [\*\*\*] until completion of the first Phase II Study.

Example 1: If Pieris makes a query for a specific [\*\*\*] (i.e., [\*\*\*]), and Roche has reached [\*\*\*], then no license is granted to Pieris.

Example 2: If Pieris makes a query for a specific [\*\*\*] (i.e. [\*\*\*]), and Roche has reached [\*\*\*] (i.e., [\*\*\*]) that [\*\*\*], then no license is granted to Pieris.

Further, the above license is subject to Roche's right of first negotiation along the following lines: (i) if either Pieris decides to seek a licensing partnership with a third party with regards to a [\*\*\*], or to sell such [\*\*\*] to a third party (for clarity, a Change of Control of Pieris shall not be deemed a sale of such [\*\*\*]), or a [\*\*\*] that has not been partnered or sold has completed the first Phase II Study, it shall provide written notice of such intent to Roche; (ii) Roche shall then have [\*\*\*] to request access to any information Pieris' has with regard to such [\*\*\*]; (iii) in case Roche does request such access, then Roche shall have [\*\*\*] after Pieris has granted to Roche access to the relevant and complete files and provided corresponding information to Roche to decide whether it wants to develop and commercialize such [\*\*\*] itself and to provide a corresponding written notice to Pieris of its intent to do so; (iv) in case Roche does provide such written notice, then Roche shall have the exclusive right to negotiate an agreement with Pieris with regard to such [\*\*\*], under terms to be negotiated in good faith and such agreement to be put in writing within [\*\*\*] of Roche's written notification to Pieris of its intent to develop and commercialize such [\*\*\*] itself (hereinafter called "Negotiation Period"). If Roche and Pieris fail to agree upon the terms and conditions for such agreement during the Negotiation Period, Pieris will be free to enter into a transaction regarding such [\*\*\*] with any Third Party; provided that Pieris shall not enter into an agreement with any Third Party on financial terms and conditions that are more favourable for the Third Party when taken in their totality than the terms and conditions last offered in writing by Roche to Pieris during the Negotiation Period. Notwithstanding the foregoing, if Pieris intends to enter into a partnership to Generate [\*\*\*] (i.e., that have not been Generated at the time of notification from Pieris), Roche shall only have [\*\*\*] from receipt of such notification under (i) to assess and decide if it wants to request negotiations under (iv). In other words, the procedures foreseen in (ii) and (iii) of this paragraph shall in total [\*\*\*].

### **3. Research Collaboration**

#### **3.1.1 Scope**

The execution of the Research Plan shall begin on January 1, 2016. During the Research Term, Pieris commits, subject to FTE funding by Roche, to an average of [\*\*\*] as specified in the Research Plan and adjusted as necessary by the JRC from time to time, allowing the generation and testing of such Binders against the Target, the generation and testing of Modified Binders and Products, as well as any other activities to be performed according to the Research Plan. The criteria for successfully completing the Research Plan and handing over the deliverables are defined in the Research Plan. The activities conducted in connection with the Research Plan will be overseen by the JRC.

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**CONFIDENTIAL TREATMENT REQUESTED**

3.1.2 Diligent Efforts

Roche and Pieris shall each use Commercially Reasonable Efforts to perform their respective tasks and obligations in conducting all activities ascribed to it in the then-current Research Plan, in accordance with the time parameters set forth therein.

3.1.3 Research Plan

The Parties will conduct the research in accordance with the Research Plan. In alignment with Section 6.3, the Research Plan will be updated as needed by the JRC, with such updates to be documented in an updated Research Plan as part of the applicable JRC Minutes. The Research Plan will set forth (i) the scope of the research and the resources that will be dedicated to the activities contemplated within the scope of the research, including the responsibilities of each Party, (ii) specific objectives for each Research Plan task, which objectives will be updated or amended, as appropriate, by the JRC as research progresses, and (iii) budgets for such activities.

3.1.4 Research Term

The Research Term shall commence on January 1, 2016 and shall continue for twenty (20) months unless extended by Roche by providing written notice to Pieris no later than ninety (90) days prior to the end of the initial term and subject to further FTE funding for a period up to one additional year. If at the end of the Research Term (including any extension) the original objectives of the Research Plan are not met and Roche could not choose Selected Binders for product development, the Parties shall agree on whether to further extend the Research Term and the share of funding by each Party.

3.1.5 Progress Reports

At least quarterly during the Research Term, Pieris shall have the obligation to prepare and provide to the JRC a detailed written report summarizing the progress of the work performed by Pieris under the Research Plan during the preceding Calendar Quarter. Promptly upon expiry of the Research Term, Pieris shall provide a final written report summarizing its activities under the Research Plan and the results thereof. Upon the written request of Roche and not more than once in each Calendar Year, Pieris shall permit Roche, at Roche's expense, to have access during normal business hours to those records of Pieris that may be necessary to verify the basis for any payments hereunder.

3.1.6 Research Records

Each Party shall maintain records regarding the execution of the Research Plan (or cause such records to be maintained) in sufficient detail and in good scientific manner as will properly reflect all work done and results achieved by or on behalf of such Party in the performance of the Research Plan.

3.1.7 Work on Target by Pieris

During the Research Term and, if applicable, the Phase-out Term, Pieris shall work exclusively with Roche to identify and discover molecules that inhibit or specifically bind to the Target. For the avoidance of doubt, this obligation also precludes Pieris from working on the Target under its own independent research. In case Pieris undergoes a Change of Control and the Change of Control Group has or puts in place a research program targeting the Target, or if Pieris takes over control of a Third Party having such a research program, then Pieris shall put or have put

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in place appropriate fire walls in order to avoid any spillover of information regarding the Research Plan and associated Progress Reports, Research Records and Confidential Information received from Roche under this Agreement outside of the organisation of Pieris that exists before such Change of Control or take over takes place. Pieris may not perform work on Pieris Technology with regard to Target except as provided for under this Agreement (including, for clarity, as described under Section 2.4).

### **4. Diligence**

#### **4.1 In General**

Roche and Pieris shall use Commercially Reasonable Efforts to perform their respective activities contemplated by this Agreement or as may be agreed upon in any subsequent written agreements with respect to the subject matter hereof, including but not limited to any activities under the Research Plan. Specifically, Roche agrees to use Commercially Reasonable Efforts to pursue development and commercialization of Products in the Field in the Territory, which minimally shall require that Roche shall seek to market at least one Product in [\*\*\*] and in [\*\*\*] ([\*\*\*]). Notwithstanding anything to the contrary in this Agreement, Roche shall be deemed to not be using Commercially Reasonable Efforts, if, for whatever reason, it completely ceases all research, development or commercialization activities on all Products for a period longer than [\*\*\*] during the Agreement Term.

#### **4.2 Diligence of Roche prior to Initiation of Phase III Study**

If Roche or any of its Affiliates (i) acquires (e.g., by way of in-license or acquisition) a product targeting the Target for which [\*\*\*], or (ii) internally develops a product targeting the Target for which [\*\*\*], and that for (i) and (ii) does not utilize Pieris Technology, then, for as long as such competing product is more advanced than the first Product, Roche shall and shall ensure that its Affiliates with regards to any first Product commit to the following timelines: (a) Initiation of first GLP Tox Study within [\*\*\*], (b) Initiation of first Phase I Study within [\*\*\*], (c) Initiation of first Phase II Study within [\*\*\*], or, if such timelines are not deemed appropriate by Roche, and Roche provides acceptable reasons for delays as reasonably accepted by Pieris, such timelines may be extended by mutual written agreement. The diligence obligation under this Section 4.2 expires when such acquired or internally developed product is terminated.

#### **4.3 Limits**

For clarity, the foregoing limitations on acquiring or internally developing products targeting the Target as described in Section 4.2 shall not apply to [\*\*\*] of the [\*\*\*] or [\*\*\*] or that are [\*\*\*] or [\*\*\*], for as long as [\*\*\*].

### **5. Development**

#### **5.1 Development by Roche**

After a Selected Binder and/or Modified Binder has been transferred from Pieris to Roche as specified in the Research Plan, Roche, at its sole cost, shall be responsible for pursuing pre-clinical and clinical development of Products, subject to the terms of this Agreement.

#### **5.2 Provision of Information**

Pieris shall disclose and make available to Roche (i) all data and information developed under the Research Plan, and (ii) all additional data and information that Pieris reasonably believes are necessary to conduct development of Products. Pieris, through the JRC, shall answer any questions reasonably posed and provide any information reasonably requested. Notwithstanding the foregoing, Pieris shall not be obligated to disclose any confidential information received from a Third Party to Roche.

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**6. Governance**

**6.1 Joint Research Committee**

Within sixty (60) days after the Effective Date of this Agreement, the Parties shall establish a JRC to oversee the development activities under this Agreement.

**6.2 Members**

The JRC shall be composed of four (4) persons (“**Members**”). Roche and Pieris each shall be entitled to appoint two (2) Members with appropriate seniority and functional expertise. Each Party may replace any of its Members and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a Member shall notify the other Party at least ten (10) days prior to the next scheduled meeting of the JRC. Both Parties shall use reasonable efforts to keep an appropriate level of continuity in representation. Both Parties may invite a reasonable number of additional experts and/or advisors to attend part or the whole JRC meeting with prior notification to the JRC. Members may be represented at any meeting by another person designated by the absent Member. The JRC shall be chaired by a Roche Member (“**Chairperson**”).

**6.3 Responsibilities of the JRC**

The JRC shall have the responsibility and authority to:

- a) approve the Research Plan;
- b) review and revise the Research Plan;
- c) oversee the execution of the Research Plan;
- d) establish timelines and criteria for decision points;
- e) determine whether success- and other criteria have been met;
- f) evaluate Binders and select Selected Binders
- g) review the efforts of the Parties and allocate those resources for the Research Plan (including the budget);
- h) identify and agree on the appropriate resources (including FTE staffing requirements) necessary to conduct the Research Plan;
- i) establish a touch point site or similar tool to enable secured exchange of data generated under the Research Plan
- j) monitor and implement the transfer of the Selected Binders and Modified Binders, both in terms of material available at Pieris and the corresponding amino acid and nucleic acid sequences, and any associated data generated under the Research Plan to Roche;
- k) monitor the number of FTE funding and adaptation of such number as necessary as set forth in Section 3.1.1;
- l) recommend action items to its respective decision making bodies;
- m) in a JRC meeting towards the end of the Research Term, list the materials and information to be provided by Pieris to Roche according to Section 10.3.1;
- n) attempt to resolve any disputes on an informal basis;
- o) determine the mechanism of project information exchange, including project team meetings.

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*Portions of the exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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The JRC shall have no responsibility and authority other than that expressly set forth in this section or otherwise expressly provided in this Agreement.

**6.4 Meetings**

The Chairperson or his/her delegate is responsible for sending invitations and agendas for all JRC meetings to all Members at least ten (10) days before the next scheduled meeting of the JRC. The venue for the meetings shall be agreed by the JRC. The JRC shall hold meetings at least twice per calendar year, either in person or by tele-/video-conference (but at least once per year in person), and in any case as frequently as the Members of the JRC may agree shall be necessary, but not more than four times a year. The Alliance Director of each Party may attend the JRC meetings as a permanent participant and may be a JRC Member.

**6.5 Minutes**

The Chairperson is responsible for designating a Member to record in reasonable detail and circulate draft minutes of JRC meetings to all members of the JRC for comment and review within twenty (20) days after the relevant meeting. The Members of the JRC shall have ten (10) days to provide comments. The Party preparing the minutes shall incorporate timely received comments and distribute finalized minutes to all Members of the JRC within thirty-five (35) days of the relevant meeting. The Chairperson approves the final version of the minutes before its distribution.

**6.6 Decisions**

6.6.1 Decision Making Authority

The JRC shall decide matters within its responsibilities set forth in Section 6.3.

6.6.2 Consensus; Good Faith

The Members of the JRC shall act in good faith to cooperate with one another and seek agreement with respect to issues to be decided by the JRC. The Parties shall endeavor to make decisions by consensus.

6.6.3 Failure to Reach Consensus

If the JRC is unable to decide a matter by consensus, then Roche shall have the final decision authority on any matter. However, a unilateral decision by Roche shall not result in any material change of the day to day use or operational allocation of Pieris' personnel, equipment and resources, or in any material increase in the overall level of resources to be committed by Pieris to the Research Plan unless Roche compensates Pieris accordingly.

**6.7 Information Exchange**

Pieris and Roche shall exchange the information in relation to their activities under the Research Plan through the JRC and Pieris and Roche may ask reasonable questions in relation to the above information and offer advice in relation thereto. The JRC may determine other routes of information exchange.

**6.8 Alliance Director**

Each Party shall appoint one person to be the point of contact within each Party with responsibility for facilitating communication and collaboration between the Parties (each, an "**Alliance Director**"). The Alliance Directors may participate in the JRC meetings. The Alliance Directors shall facilitate resolution of potential and pending issues and potential disputes to enable the JRC to reach consensus and avert escalation of such issues or potential disputes.



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**6.9 Limitations of Authority**

The JRC shall have no authority to amend or waive any terms of this Agreement.

**6.10 Expenses**

Each Party shall be responsible for its own expenses including travel and accommodation costs incurred in connection with the JRC.

**6.11 Lifetime**

The JRC shall exist until the [\*\*\*] Research Term. Thereafter, Roche shall provide Pieris annual reports describing in reasonable detail the development and commercialization progress of the Product(s), including [\*\*\*] in Roche's opinion (these include activities related to milestone achievements under this Agreement).

**7. Supply**

**7.1 Clinical Supply of Product(s)**

Roche shall be responsible at its own expense for the manufacture and supply of clinical supplies of the Product(s).

**7.2 Commercial Supply of Product(s)**

Roche shall be solely and exclusively responsible at its own expense for the commercial manufacture and commercial supply of Product(s) for sale in the Territory, either by itself or through Third Parties.

**7.3 Provision of Information**

Pieris shall disclose and make available to Roche all additional data and information that Pieris reasonably believes are necessary or useful to manufacture and supply the Product(s).

**8. Regulatory**

**8.1 Responsibility**

Roche, at its sole cost, shall pursue all regulatory affairs related to Product(s) in the Territory including the preparation and filing of applications for regulatory approval, as well as any or all governmental approvals required to develop, have developed, make, have made, use, have used, manufacture, have manufactured, import, have imported, sell and have sold Products. Roche shall be responsible for pursuing, compiling and submitting all regulatory filing documentation, and for interacting with regulatory agencies, for all Products in all countries in the Territory. Roche or its Affiliates shall own and file in their discretion all regulatory filings and regulatory approvals for all Products in all countries of the Territory.

Roche, at its sole cost, shall report to appropriate authorities in accordance with local requirements all adverse events related to use of the Products in the Territory.

**9. Commercialization**

**9.1 Responsibility**

Roche, at its own expense, shall have sole responsibility and decision making authority for the marketing, promotion, sale and distribution of Products in the Territory.

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## **9.2 Updates to Pieris**

Upon request of Pieris, Roche shall update Pieris regarding the commercialization of the Product in the Territory in the Field by Roche, its Affiliates and Sublicensees. If Pieris requests an update, Roche shall provide a high level summary, in writing and/or through a meeting (face to face/ tele-presence/videoconference or telephone). Pieris shall not request an update more frequently than [\*\*\*].

## **10. Payment**

### **10.1 Initiation Payment**

Within thirty (30) days after the Effective Date and receipt of an invoice from Pieris, Roche shall pay to Pieris six and a half million Swiss francs (CHF 6,500,000).

### **10.2 Research Costs**

During the Research Term, Roche shall fund the work to be performed at Pieris for the Research Plan at the FTE Rate as specified in the Agreement.

Roche shall pay to Pieris such work to be performed during the Research Term, [\*\*\*], within [\*\*\*] after receiving a corresponding invoice from Pieris, corresponding to the [\*\*\*] for such [\*\*\*] according to the Research Plan (as it may be amended from time to time through the JRC). Within thirty (30) days after the end of each Calendar Quarter during the Research Term, Pieris shall provide to Roche a document specifying [\*\*\*] and [\*\*\*] incurred by Pieris during such Calendar Quarter. Any overpayment from Roche shall be credited to the invoice for the next quarter. Any underpayment from Roche shall be added to the invoice for the next quarter.

### **10.3 Annual Exclusive Target Access Fee and Phase-out Extension Fee**

#### 10.3.1 Annual Exclusive Target Access Fee

When (i) all Selected Binders and/or Modified Binders have been transferred to Roche, including material available at Pieris, information on the corresponding amino acid and nucleic acid sequences, and any relevant associated data generated under the Research Plan in accordance with the final report under Section 3.1.5 (excluding the Phase-out Binders) and as specified by the JRC in accordance with Section 6.3 (m), and Roche has confirmed the receipt of all materials, information and the final report as per 3.1.5 (such confirmation not to be unduly delayed), and (ii) the Research Term has ended, then Roche shall have [\*\*\*] to exercise its option to [\*\*\*] as specified in [\*\*\*] by giving written notice to Pieris. If Roche provides such written notice, it shall pay to Pieris an annual exclusive target access fee as specified in this Section (“**Annual Exclusive Target Access Fee**”). In case Roche opts for such continued exclusivity, then Roche shall have the right to terminate such continued exclusivity at the end of each anniversary date of the end of the Research Term, by providing written notice to Pieris at the latest [\*\*\*] prior to such anniversary.

The Annual Exclusive Target Access Fee shall be, if applicable:

- a) for each of the [\*\*\*] following the end of the Research Term:  
CHF [\*\*\*].
- b) for each of the [\*\*\*] following the end of the Research Term:  
CHF [\*\*\*].

10.3.2 Phase-out Extension Fee[\*\*\*]If Roche has opted for continued exclusivity as described in Section 10.3.1 above, then Roche shall pay to Pieris an additional phase-out extension fee (“**Phase-out Extension Fee**”) if (i) Roche does not terminate continued exclusivity as described in Section 10.3.1 before the [\*\*\*] of the end of the Research Term and (ii) Roche has [\*\*\*] with regard to the first Product reaching this development stage within [\*\*\*] of expiry of the Research Term.

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The Phase-out Extension Fee shall be, if applicable:

- a) for the [\*\*\*] following the end of the Research Term:  
CHF [\*\*\*].
- b) for the [\*\*\*] following the end of the Research Term:  
CHF [\*\*\*].

The Phase-out Extension Fee will be paid in addition to the Annual Exclusive Target Access Fee (if applicable) for the [\*\*\*] following the end of the Research Term. Roche shall pay to Pieris amounts due under this Section 10.3 within [\*\*\*] from receipt of the correct invoice from Pieris.

**10.4 Development Event Payments**

For Products Generated during the Research Term or the Phase-out Term (the Phase-out Term shall be deemed to be (i) five (5) years [\*\*\*], and (ii) for any other Product as long as specified in Section 1.60, but in any event at least three (3) years), Roche shall pay to Pieris the following one-time payments at the following respective amounts for the applicable Development Events (as listed in the table below) upon reaching the respective Development Event:

<b>Development Event</b>	<b>first Event ([***] CHF)</b>	<b>[***] ([***] CHF)</b>	<b>[***] ([***] CHF)</b>
Initiation of GLP Tox Study	[***]	[***]	[***]
Initiation of Phase I Study	[***]	[***]	[***]
Initiation of Phase II Study	[***]	[***]	[***]
Initiation of Phase III Study	[***]	[***]	[***]
NDA Filing [***]	[***]	[***]	[***]
NDA Filing [***]	[***]	[***]	[***]
NDA Filing [***]	[***]	[***]	[***]
First Commercial Sale [***]*	[***]	[***]	[***]
First Commercial Sale [***]*	[***]	[***]	[***]
First Commercial Sale [***]*	[***]	[***]	[***]
Total	[***]	[***]	[***]

\* Payments for a [\*\*\*] of a Product shall be payable upon achievement of Regulatory Approval in the respective portion of the Territory.

The amounts specified in the table immediately above shall be reduced by [\*\*\*] for Products Generated during the five (5) years following expiry of the Phase-out Term. For clarity, the respective Development Event shall be deemed to have been paid in full, even if such reduction applies. For Products Generated later than five (5) years following expiry of the Phase-out Term, no milestone payments shall be paid.

For clarity, the total potential development event payments for a first Event shall not exceed [\*\*\*] Swiss francs (CHF [\*\*\*]), the total potential development event payments for each of a [\*\*\*] shall not exceed [\*\*\*] Swiss francs (CHF [\*\*\*]), the total potential development event payments for each of a [\*\*\*] shall not exceed [\*\*\*] Swiss francs (CHF [\*\*\*]), and in no case shall the total development event payments paid to Pieris under this Section exceed [\*\*\*] Swiss francs (CHF [\*\*\*]).

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[\*\*\*]). In case [\*\*\*] and/or [\*\*\*] is not [\*\*\*], then the [\*\*\*] and/or [\*\*\*] becomes [\*\*\*] and/or [\*\*\*] with regard to [\*\*\*] to the extent of the [\*\*\*], and [\*\*\*] with regard to the [\*\*\*] and/or [\*\*\*]. Payments with regards to a Development Event for a [\*\*\*], respectively, are payable only once under this Agreement, upon the first occurrence of the applicable Development Event irrespective of the number of times such Development Event may subsequently occur through the development of a subsequent Product and/or Indication.

Example: [\*\*\*].

Upon reaching Development Events, Roche shall timely notify Pieris and Development Event payments shall be paid by Roche to Pieris within [\*\*\*] from occurrence of the applicable event and receipt of a correct invoice from Pieris.

Notwithstanding anything contained in this Section 10.4, no development event payments shall be paid to Pieris in the event that a Product is itself developed as a companion diagnostic, i.e. for predicting and/or monitoring the response of a human being to treatment with another Product (e.g. as a biomarker that is used to detect or quantify the presence or amount of Target in body or tissue; such Product a “**Companion Diagnostic Product**”). The same rule shall apply (no development event payments) in case a Product is developed as a stand-alone diagnostic product, i.e. for detecting the presence and/or quantifying the amount of Target in body fluids or tissue (“**Stand-alone Diagnostic Product**”).

**10.5 Sales Based Events**

Roche shall pay to Pieris the following one-time sales based event payments as specified in the table below (First Sales Based Event, Second Sales Based Event, Third Sales Based Event) up to a total of one hundred twenty million Swiss francs (CHF 120,000,000) at the following respective amounts for the applicable events for the first Product to achieve the following levels of Net Sales:

<u>Net Sales Threshold</u>	<u>Payment</u>	
	<u>if Product is Generated during the Research Term or the Phase-out Term*</u>	<u>if Product is Generated during [***] of the Phase-out Term*</u>
First Calendar Year in which worldwide calendar year Net Sales of a Product exceed CHF [***] (“ <b>First Sales Based Event</b> ”)	CHF [***]	CHF [***]
First Calendar Year in which worldwide calendar year Net Sales of a Product exceed CHF [***] (“ <b>Second Sales Based Event</b> ”)	CHF [***]	CHF [***]
First Calendar Year in which worldwide calendar year Net Sales of a Product exceed CHF [***] (“ <b>Third Sales Based Event</b> ”)	CHF [***]	CHF [***]

\* The Phase-out Term shall be deemed to be (i) five (5) years for [\*\*\*], and (ii) for any other Product as long as specified in Section 1.60, but in any event at least three (3) years.

*Portions of the exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

**CONFIDENTIAL TREATMENT REQUESTED**

For Products Generated later than five (5) years following expiry of the Phase-out Term, no milestone payments shall be paid.

Each of the sales based event payments shall be paid no more than once during the Agreement Term, at first occurrence of the event for the Product in the Territory first reaching the respective Net Sales Threshold, irrespective of whether or not the previous sales based event payment was triggered by the same or by a different Product, and shall be non-refundable, and shall be paid within [\*\*\*] after the end of the Calendar Year in which the event first occurs.

Notwithstanding anything contained in this Section 10.5, no sales event payments shall be paid to Pieris in the event that a Product is itself developed, used and commercialized as a Companion Diagnostic Product or as a Stand-alone Diagnostic Product.

**10.6 Royalty Payments**

10.6.1 Royalty Term

Royalties shall be payable by Roche on Net Sales of Products on a Product-by-Product and country-by-country basis until the expiry of the Royalty Term. Thereafter, the licenses granted to Roche shall be fully paid up, irrevocable, and royalty-free.

10.6.2 Royalty Rates

Roche shall, on a Product-by-Product basis, for any Product that was Generated during the Research Term or the Phase-out Term (the Phase-out Term shall be deemed to be (i) five (5) years for [\*\*\*], and (ii) for any other Product as long as specified in Section 1.60, but in any event at least three (3) years), pay to Pieris royalties by applying the following royalty rates on Calendar Year Net Sales of a given Product in the Territory as follows:

<b>Tier of Calendar Year Net Sales in CHF of a Product:</b>	<b>Percent (%) of Net Sales:</b>
Up to CHF [***] Net Sales	[***]
More than CHF [***] Net Sales and up to CHF [***] Net Sales	[***]
More than CHF [***] Net Sales and up to CHF [***] Net Sales	[***]
More than CHF [***] Net Sales and up to CHF [***] Net Sales	[***]
More than CHF [***] Net Sales	[***]

For Products Generated during the five (5) years following expiry of the Phase-out Term, Roche shall pay royalties to Pieris by applying [\*\*\*] of the applicable royalty rate specified in this Section. For Products Generated later than five (5) years following expiry of the Phase-out Term, no royalty payments shall be paid.

10.6.3 Royalty Reductions

For the purpose of calculating royalties of a Product, Calendar Year Net Sales and the royalty rates shall be subject to the following adjustments, as applicable:

10.6.3.1 No Valid Claim

If no Composition of Matter Claim of a patent owned or Controlled by Roche exists in a given country Covering the use, import, offering for sale, or sale of the Product, or if such claim that previously existed loses its validity during the applicable Calendar Year, then the royalty payments due to Pieris for such Product in such country shall be reduced by [\*\*\*]

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**CONFIDENTIAL TREATMENT REQUESTED**

10.6.3.2 Biosimilar Product

Upon the first entry in a given country of a Biosimilar Product, the royalties in such country for such Product shall be reduced as follows:

- a) If in any Calendar Quarter after entry of a Biosimilar Product there has been a decline of the Net Sales of the applicable Product in such country greater than [\*\*\*] of the level of the Net Sales of such Product achieved in the two consecutive Calendar Quarters immediately prior to such entry, then the royalty payments due to Pieris for such Product in such country shall be reduced by [\*\*\*] for the remainder of the Royalty Term as from such Calendar Quarter.
- b) If in any Calendar Quarter after entry of a Biosimilar Product there has been a decline of the Net Sales of the applicable Product in such country greater than [\*\*\*] of the level of the Net Sales of such Product achieved in the two consecutive Calendar Quarters immediately prior to such entry, then the royalty payments due to Pieris for such Product in such country shall end as from such Calendar Quarter and no royalties shall be due by Roche in such country for such Product, and the license in that country for such Product shall be fully paid-up and irrevocable.

10.6.4 Products used as Diagnostics

Notwithstanding anything contained in this Section 10.6, no royalty payments shall be paid to Pieris in the event that a Product is itself developed, used and commercialized as a Companion Diagnostic Product.

In case a Product is developed, used and commercialized as a Stand-alone Diagnostic Product, the Parties shall agree on royalties to be paid on Net Sales of such Product in good faith, but in any case lower than those specified in this Section.

**10.7 Combination Product**

If Roche or its Affiliates intend to sell a Combination Product, then the Parties shall meet approximately [\*\*\*] prior to the anticipated First Commercial Sale of such Combination Product in the Territory to negotiate in good faith and agree to an appropriate adjustment to Net Sales to reflect the relative commercial value contributed by the components of the Combination Product (the “**Relative Commercial Value**”). If, after such good faith negotiations not to exceed [\*\*\*], the Parties cannot agree to an appropriate adjustment, the dispute shall be initially referred to the executive officers of the Parties in accordance with Section 21.2. Should the Parties fail to agree [\*\*\*] of such referral, then the Relative Commercial Value shall be determined by an Expert Committee under the procedures of this Section.

If the Parties are unable to agree on the Relative Commercial Value, then Roche will select one (1) individual who would qualify as an Expert, Pieris will select (1) individual who would qualify as an Expert, and those two (2) individuals shall select one (1) individual who would qualify as an Expert and who shall be chairman of a committee of the three Experts (the “**Expert Committee**”), each with a single deciding vote. The Expert Committee will promptly hold a meeting to review the issue under review, at which it will consider memoranda submitted by each Party at least [\*\*\*] before the meeting, as well as reasonable presentations that each Party may present at the meeting. The determination of the Expert Committee as to the issue under review will be binding on both Parties. The Parties will share equally in the costs of the Expert Committee. Unless otherwise agreed to by the Parties, the Expert Committee may not decide on issues outside the scope mandated under terms of this Agreement.

Notwithstanding the foregoing, for any Combination Product that includes a Companion Diagnostic Product (i.e., not a Companion Diagnostic), the Relative Commercial Value of such Companion Diagnostic Product shall be [\*\*\*]

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*Portions of the exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

### **10.8 Third Party Payments**

With the exception of Pieris IP, Roche shall be responsible for and pay or have paid any consideration owed to any Third Party in relation to Third Party intellectual property rights. Roche shall have the right to deduct a maximum of

- a) [\*\*\*], if such Third Party intellectual property rights Cover the [\*\*\*] in such Product; or
- b) [\*\*\*] if such Third Party intellectual property rights Cover any other part of the Product, provided, however, that no such [\*\*\*] reduction shall apply if (i) such Third Party intellectual property rights Cover a molecule targeting an antigen other than the Target and such molecule is part of a Combination Product whose sales have been deducted from Net Sales per Section 10.7, or (ii) such Third Party intellectual property rights Cover Roche Technology existing as of the Effective Date and used in the Product;

of such consideration actually paid to a Third Party from any payments otherwise due and payable by Roche to Pieris under this Agreement. Any such deduction shall be permitted on a Product-by-Product and country-by-country basis. In no event shall the amount of royalties payable to Pieris for a given Calendar Year be reduced to lower than [\*\*\*] of the royalties otherwise due for the Net Sales of such Product for the applicable Calendar Year as a result of deductions made under this Section.

### **10.9 Disclosure of Payments**

Each Party acknowledges that the other Party may be obligated to disclose this financial arrangement, including all fees, payments and transfers of value, as may be advisable or required under Applicable Law, including the US Sunshine Act.

## **11. Accounting and reporting**

### **11.1 Timing of Payments**

Roche shall calculate royalty payments set forth in Section 10.6 quarterly as of March 31, June 30, September 30 and December 31 (each being the last day of a reporting period). Roche shall pay such payments quarterly within [\*\*\*] after the end of each reporting period in which Net Sales occur.

### **11.2 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 [\*\*\*] 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.

### **11.3 Method of Payment**

Royalties on Net Sales and all other amounts payable by Roche hereunder shall be paid by Roche in Swiss francs (the “**Payment Currency**”) to account(s) designated by Pieris, except Research Costs according to Section 10.2 which shall be paid to such account(s) in Euros.

### **11.4 Currency Conversion**

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

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*Portions of the exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

**11.5 Reporting**

With each payment Roche shall provide Pieris in writing for the relevant Calendar Quarter on a Product-by-Product and [\*\*\*] (i.e. [\*\*\*) basis the following information:

- a) Sales in the Payment Currency;
- b) Net Sales in the Payment Currency;
- c) adjustments made pursuant to Section 10.7;
- d) Net Sales in the Payment Currency after adjustments made pursuant to Section 10.7 in the Payment Currency;
- e) royalty rate pursuant to Section 10.6.2;
- f) adjustments made pursuant to Sections 10.6.3 and 10.8; and
- g) total royalty payable in the Payment Currency.

**12. Taxes**

Pieris shall pay all sales, turnover, income, revenue, value added, and other taxes levied on account of any payments accruing or made to Pieris under this Agreement. Roche agrees to reasonably assist Pieris in claiming exemption from such taxes and in minimizing the amount required to be so paid.

If provision is made in law or regulation of any country for withholding of taxes of any type, levies or other charges with respect to any royalty or other amounts payable under this Agreement to Pieris, then Roche shall promptly pay such tax, levy or charge for and on behalf of Pieris to the proper governmental authority, and shall promptly furnish Pieris with receipt of payment. Roche shall be entitled to deduct any such tax, levy or charge actually paid from royalty or other payment due to Pieris or be promptly reimbursed by Pieris if no further payments are due to Pieris. Each Party agrees to reasonably assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

**13. Auditing**

**13.1 Pieris' Right to Audit**

Roche shall keep, and shall require its Affiliates and Sublicensees to keep, full, true and accurate books of account containing all particulars that may be necessary for the purpose of calculating all royalties payable under this Agreement. Such books of accounts shall be kept at their principal place of business. At the expense of Pieris, Pieris shall have the right to engage an independent public accountant reasonably acceptable to Roche to perform, on behalf of Pieris an audit of such books and records of Roche and its Affiliates, its licensees and Sublicensees, that are deemed necessary by Roche's independent public accountant to report on Net Sales of Product for the period or periods requested by Pieris, and the correctness of any financial report or payments made under this Agreement.

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*Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*



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**CONFIDENTIAL TREATMENT REQUESTED**

Upon timely request and at least [\*\*\*] prior written notice from Pieris, such audit shall be conducted in the countries specifically requested by such independent public accountant, during regular business hours in such a manner as to not unnecessarily interfere with Roche'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 [\*\*\*] nor more frequently than once with respect to records covering any specific period of time.

All information, data documents and abstracts herein referred to shall be used only for the purpose of verifying royalty statements, shall be treated as Roche's Confidential Information subject to the obligations of this Agreement and need neither be retained more than [\*\*\*] after completion of an audit hereof, if an audit has been requested; nor more than [\*\*\*] from the end of the Calendar Year to which each shall pertain; nor more than [\*\*\*] after the date of termination of this Agreement.

### **13.2 Audit Reports**

The auditors shall only state factual findings in the audit reports and shall not interpret the agreement. The auditors shall share all draft audit reports with Roche before the draft report is shared with Pieris and before the final document is issued. The final audit report shall be shared with Roche at the same time it is shared with Pieris.

### **13.3 Over- or Underpayment**

If the audit reveals an overpayment, Pieris shall reimburse Roche for the amount of the overpayment within [\*\*\*]. If the audit reveals an underpayment, Roche shall make up such underpayment with the next royalty payment or, if no further royalty payments are owed by Roche, Roche shall reimburse Pieris for the amount of the underpayment within [\*\*\*]. Roche shall pay for the audit costs if the underpayment of Roche exceeds [\*\*\*] of the aggregate amount of royalty payments owed with regard to the royalty statements subject to the audit. Section 11.2 shall apply to this Section 13.3.

### **13.4 Duration of Audit Rights**

The failure of Pieris to request verification of any royalty calculation within the period during which corresponding records must be maintained under this Article 13 will be deemed to be acceptance of the royalty payments and reports.

## **14. Intellectual Property**

### **14.1 Ownership of Pieris IP and Roche IP**

Pieris shall remain the owner of Pieris IP, and Roche of Roche IP.

### **14.2 Ownership of Inventions**

Pieris and Roche shall own Pieris Inventions and Roche Inventions, respectively. Joint Inventions shall be jointly owned by the Parties.

Notwithstanding the foregoing, Pieris shall own Inventions and Know-How solely related to improvements to the Pieris Technology, and Roche shall own Inventions and Know-How solely related to improvements to the Roche Technology. Each Party shall, to the extent legally permitted, require all of its employees to assign all Inventions related to such improvements made by them.

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*Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

Pieris shall own any Inventions and Know-How related to Binders and Phase-out Binders. Roche shall, to the extent legally permitted, require all of its employees to assign all Inventions related to Binders and Phase-out Binders made by them.

Roche shall own any Inventions and Know-How related to Selected Binders, Modified Binders, and Products. Pieris shall require all of its employees to assign all Inventions related to Selected Binders, Modified Binders, and Products made by them.

Except as specifically set forth herein, this Agreement shall not be construed as (i) giving any of the Parties any license, right, title, interest in or ownership to the Confidential Information; (ii) granting any license or right under any intellectual property rights; or (iii) representing any commitment by either Party to enter into any additional agreement, by implication or otherwise.

**14.3 German Statute on Employee's Inventions**

In accordance with the German Statute on Employees' Inventions, each Party agrees to claim the unlimited use of any Invention conceived, reduced to practice, developed, made or created in the performance of, or as a result of, any research program by employees of any German Affiliates or any other persons acting on behalf of such German Affiliates. For the avoidance of doubt, each Party is responsible for fulfilling the obligations towards their employees under the German Statute of Employee's Inventions.

**14.4 Prosecution of Patent Rights by Pieris**

Pieris shall have the right to Handle its Patent Rights on Inventions assigned to Pieris pursuant to Section 14.2 at its own expense and with Roche's prior written consent (such consent not to be unreasonably withheld with regard to improvements to Pieris Technology) to the time point of filing any Patent Rights on such Inventions. When Handling its Patent Rights on Inventions made under this Agreement, Pieris shall, at its own expense, (i) consult with Roche as to the Handling of such Patent Rights, and (ii) furnish to Roche copies of all documents relevant to any such Handling. Pieris shall furnish such documents and consult with Roche in sufficient time before any action by Pieris is due to allow Roche to provide comments thereon, which comments Pieris must consider. At Pieris' expense and reasonable request, Roche shall cooperate, in all reasonable ways with the Handling of all of Pieris' Patent Rights relating to Inventions.

**14.5 Prosecution of Patent Rights by Roche**

Roche shall, at its own expense and discretion, Handle (including abandon) all its Patent Rights, including all Patent Rights claiming any Selected Binders, Modified Binders, and Products, provided, however, that prior to abandoning of any Valid Claims of any Patent Rights related to Selected Binders, Roche shall provide reasonable advanced written notice to Pieris before abandoning such Patent Rights, in which case Pieris shall have the right to assume, at Pieris' cost, ownership of such Patent Rights as well as the right to continue maintenance thereof.

**14.6 CREATE Act**

It is the intention of the Parties that this Agreement is a "joint research agreement" as that phrase is defined in 35 USC §103(c)(3).

**14.7 Defense**

If the manufacture, use, importation, offer for sale or sale of any Product pursuant to this Agreement results in any claim, suit or proceeding alleging patent infringement or trade secret misappropriation against Pieris or a member of the Roche Group, then such Party shall promptly notify the other Party hereto. The Parties shall cooperate with each other in connection with any such claim, suit or proceeding and shall keep each other reasonably informed of all material developments in connection with any such claim, suit or proceeding.

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## **CONFIDENTIAL TREATMENT REQUESTED**

If a Third Party asserts that Patent Rights owned by or licensed to it are infringed by the development, manufacture, use, importation, offer for sale or sale of Products by a member of the Roche Group, or that its trade secrets were misappropriated in connection with such activity, then Roche shall have the exclusive right and responsibility to resolve any such claim, whether by obtaining a license from such Third Party, by defending against such Third Party's claims or otherwise, and shall be solely responsible for the defense of any such action, any and all costs incurred in connection with such action (including, without limitation, attorneys' and expert fees) and all liabilities incurred in connection therewith. Notwithstanding the above, Roche shall not enter into any settlement of any such claim without the prior written consent of Pieris if such settlement would require Pieris to be subject to an injunction or to make any monetary payment to Roche or any Third Party, or admit any wrongful conduct by Pieris or its Affiliates, or would limit or restrict the claims of or admit any invalidity and/or unenforceability of any of the Patent Rights Controlled by Pieris, or have any impact on activities outside the Field.

If an action for infringement is commenced against Pieris, its licensees or its sublicensees related to Pieris's conduct of the research program within the scope of the Research Plan or the discovery of a Product, then Pieris shall have the right (but not the obligation) to defend such action at its own expense, and Roche shall assist and cooperate with Pieris, at Pieris' expense, to the extent necessary in the defense of such suit. Pieris shall have the right to settle the suit or consent to an adverse judgment thereto, in its sole discretion, so long as such settlement or adverse judgment does not adversely affect the rights of Roche and its Affiliates (including any patent rights Controlled by any of them). Pieris shall assume full responsibility for the payment of any award for damages, or any amount due pursuant to any settlement entered into by it with such Third Party.

### **14.8 Enforcement**

#### **14.8.1 Enforcement of Patent Rights relating to Selected Binders, Modified Binders and Products**

Roche shall have the full and unrestricted right, but not the obligation, to bring and control an appropriate suit or other action against any person or entity engaged in any infringement action or proceeding to the extent directly relating to Patent Rights relating to Selected Binders, Modified Binders and Products, in its own name and entirely under its own direction and control. If Roche requests so, Pieris shall reasonably cooperate with Roche in the planning and execution of any such action to enforce such Patent Rights (including the obligation to be named or joined as a party in a lawsuit, as applicable). All monies recovered upon the final judgment or settlement of any such suit or action to enforce such Patent Rights subtracting any costs that Roche bore in connection with such suit or action shall be calculated as Net Sales. In the event that Roche does not wish to enforce such Patent Rights against such a potential infringer, then Roche shall deliver prompt written notice thereof to Pieris.

#### **14.8.2 Enforcement of Patent Rights related to Pieris IP**

Pieris shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in any infringement action or proceeding to the extent directly relating to Pieris IP and to Patents relating to Binders and Phase-out Binders (but excluding Patents relating to Selected Binders, Modified Binders and Products). If Pieris fails to commence a suit to enforce the applicable Pieris IP and to Patents relating to Binders and Phase-out Binders or to settle or otherwise secure the abatement of such action or proceeding within a reasonable period, then Roche shall have the right, but not the obligation, to commence a suit or take action to enforce such Patent Rights against such infringement action or proceeding in the Field in the Territory at its own cost and expense, and only to the extent such action or proceeding is related to the Product(s).

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*Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

**14.9 Common Interest Disclosures**

With regard to any information or opinions disclosed pursuant to this Agreement by one Party to each other regarding intellectual property and/or technology owned by Third Parties, the Parties agree that they have a common legal interest in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the Research Plan and/or Compounds and/or Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the conduct of the Research Plan and/or Compounds and/or Products. Accordingly, the Parties agree that all such information and materials obtained by Pieris and Roche from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of the Agreement. All information and materials will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party.

**14.10 Biosimilar or interchangeable biological products**

If Roche requests so, within four (4) years after the approval of a Product that has been licensed in the US as a biological product under 42 USC §262(a), and as may be needed from time to time thereafter, the Parties shall consult as to potential strategies with respect to unexpired US Patent Rights that Cover the Product. Specifically, in anticipation of a receipt by the Product's reference product sponsor ("**Reference Product Sponsor**") of a biosimilar or interchangeable product application pursuant to the Biologics Price Competition and Innovation Act of 2009 (Public Law 111-148), the Parties will discuss the Reference Product Sponsor's likely course of action with regard to each such US Patent Right in the procedural steps set forth under 42 USC §262(l), including a general plan for timely communication between the Parties in light of the statutory response deadlines.

**14.11 Patent Term Extensions**

The Parties shall use Commercially Reasonable Efforts to obtain all available patent term extensions, adjustments or restorations, or supplementary protection certificates ("**SPCs**", and together with patent term extensions, adjustments and restorations, "**Patent Term Extensions**"). Pieris shall execute such authorizations and other documents and take such other actions as may be reasonably requested by Roche to obtain such Patent Term Extensions, including designating Roche as its agent for such purpose as provided in 35 U.S.C. Section 156. All filings for such Patent Term Extensions shall be made by Roche; provided, that in the event that Roche elects not to file for a Patent Term Extension, Roche shall (a) promptly inform Pieris of its intention not to file and (b) grant Pieris the right to file for such Patent Term Extension. Each Party shall execute such authorizations and other documents and take such other actions as may be reasonably requested by the other Party to obtain such extensions. The Parties shall cooperate with each other in gaining patent term restorations, extensions and/or SPCs wherever applicable to such Patent Rights.

**15. Representations and Warranties**

**15.1 Third Party Patent Rights**

As of the Effective Date, Pieris has no knowledge of the existence of any patent or patent application owned by or licensed to any Third Party that could prevent Roche from making, having made, using, offering for sale, selling or importing Selected Binders, Modified Binders and Products in the Territory.

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*Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

**15.2 Ownership of Patent Rights**

Pieris is the exclusive owner of all right, title and interest in, or is the exclusive licensee, with the right to sublicense in the Field and in the Territory of, the Patent Rights related to Pieris IP.

**15.3 Inventors**

Pieris warrants that, for Patent Rights owned by Pieris and its Affiliates, the inventors of the Inventions disclosed and/or claimed in Pieris IP have transferred to Pieris full ownership of the patent rights and know-how licensed under this Agreement.

**15.4 Grants**

To the best of Pieris' knowledge and belief, Pieris has the lawful right to grant Roche and its Affiliates the rights and licenses described in this Agreement.

**15.5 Authorization**

The execution, delivery and performance of this Agreement by either Party and all instruments and documents to be delivered by a Party hereunder: (i) are within the corporate power of such Party; (ii) have been duly authorized by all necessary or proper corporate action; (iii) are not in contravention of any provision of the certificate of formation or limited liability company agreement of such Party; (iv) to the knowledge of such Party, will not violate any law or regulation or any order or decree of any court of governmental instrumentality; (v) will not violate the terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which such Party is a party or by which such Party or any of its property is bound, which violation would have an adverse effect on the financial condition of such Party or on the ability of such Party to perform its obligations hereunder; and (vi) do not require any filing or registration with, or the consent or approval of, any governmental body, agency, authority or any other person, which has not been made or obtained previously (other than approvals required under the HSR Act, Regulatory Approvals required for the sale of Products and filings with Regulatory Authorities required in connection with Products).

**15.6 Validity of Patent Rights**

As of the Effective Date, Pieris is not in possession of information that could render invalid and/or unenforceable any claims that are in any of the Patent Rights related to Pieris IP. Pieris has no knowledge of any inventorship disputes concerning any Patent Rights related to Pieris IP.

**15.7 Ownership and Validity of Know-How**

The Know-How of each Party is legitimately in the possession of such Party and has not been misappropriated from any Third Party. The Parties have taken reasonable measures to protect the confidentiality of its Know-How.

**15.8 No Claims**

There are no claims or investigations, pending or threatened against Pieris 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 and that would materially adversely affect Pieris' ability to perform its obligations hereunder.

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*Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

**15.9 No Conflict**

Neither Party nor any of their respective Affiliates is or will be under any obligation to any person, contractual or otherwise, that is conflicting with the terms of this Agreement or that would impede the fulfillment of their respective obligations hereunder.

**15.10 No Other Representations**

EXCEPT AS OTHERWISE PROVIDED IN THIS AGREEMENT, THE FOREGOING REPRESENTATIONS AND WARRANTIES ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF PRODUCTS, VALIDITY AND ENFORCEABILITY OF ANY PATENT RIGHT LICENSED HEREUNDER, AND NON-INFRINGEMENT OF ANY PRODUCT.

**16. Indemnification**

**16.1 Indemnification by Roche**

Roche shall indemnify, hold harmless and defend Pieris and its directors, officers, employees and agents from and against any and all losses, expenses, cost of defense (including without limitation attorneys' fees, witness fees, damages, judgments, fines and amounts paid in settlement) and any amounts Pieris becomes legally obligated to pay because of any claim or claims against it to the extent that such claim or claims arise out of activities conducted by or on behalf of Roche under this Agreement, except to the extent such losses, expenses, costs and amounts are due to the gross negligence or willful misconduct or failure to act of Pieris.

**16.2 Indemnification by Pieris**

Pieris shall indemnify, hold harmless and defend Roche and its directors, officers, employees and agents from and against any and all losses, expenses, cost of defense (including without limitation attorneys' fees, witness fees, damages, judgments, fines and amounts paid in settlement) and any amounts Roche becomes legally obligated to pay because of any claim or claims against it to the extent that such claim or claims arise out of activities conducted by or on behalf of Pieris under this Agreement, except to the extent such losses, expenses, costs and amounts are due to the gross negligence or willful misconduct or failure to act of Roche.

**16.3 Procedure**

In the event of a claim by a Third Party against a Party entitled to indemnification under this Agreement ("**Indemnified Party**"), the Indemnified Party shall promptly notify the other Party ("**Indemnifying Party**") in writing of the claim and the Indemnifying Party shall undertake and solely manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnified Party shall cooperate with the Indemnifying Party and may, at its option and expense, be represented in any such action or proceeding by counsel of its choice. The Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party's written consent. The Indemnifying Party shall not settle any such claim unless such settlement fully and unconditionally releases the Indemnified Party from all liability relating thereto, unless the Indemnified Party otherwise agrees in writing.

**17. Liability**

**17.1 Limitation of Liability**

Subject to Section 4.2, neither Party shall be liable to the other Party as a result of failure or delay to develop and/or commercialize the Product(s), as applicable, including but not limited to, a) a delay in timelines, or b) delay or failure to recruit patients, or c) a change in its respective study protocols, or d) failure of the other Party to obtain regulatory approval for the Product(s), as applicable.

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**CONFIDENTIAL TREATMENT REQUESTED**

**17.2 Disclaimer**

THE FOREGOING REPRESENTATIONS AND WARRANTIES ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES NOT EXPRESSLY SET FORTH HEREIN. PIERIS AND ROCHE DISCLAIM ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, WITH RESPECT TO EACH OF THEIR RESEARCH, DEVELOPMENT AND COMMERCIALIZATION EFFORTS HEREUNDER, INCLUDING, WITHOUT LIMITATION, WHETHER THE PRODUCTS CAN BE SUCCESSFULLY DEVELOPED OR MARKETED, THE ACCURACY, PERFORMANCE, UTILITY, RELIABILITY, TECHNOLOGICAL OR COMMERCIAL VALUE, COMPREHENSIVENESS, MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE WHATSOEVER OF THE PRODUCTS. IN NO EVENT SHALL EITHER PIERIS OR ROCHE BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY.

**18. Obligation Not to Disclose Confidential Information**

**18.1 Non-Use and Non-Disclosure**

During the Agreement Term and for [\*\*\*] thereafter, a Receiving Party shall (i) treat Confidential Information provided by Disclosing Party as it would treat its own information of a similar nature, (ii) take all reasonable precautions not to disclose such Confidential Information to Third Parties, without the Disclosing Party's prior written consent, and (iii) not use such Confidential Information other than for fulfilling its obligations under this Agreement.

**18.2 Permitted Disclosure**

Notwithstanding the obligation of non-use and non-disclosure set forth in Section 18.1, the Parties recognize the need for certain exceptions to this obligation, specifically set forth below, with respect to press releases, patent rights, publications, and certain commercial considerations.

**18.3 Press Releases**

The Parties may issue a press release announcing the existence and selected key terms of this Agreement, as attached as Appendix 18.3.

Roche shall issue press releases in accordance with its internal policy that typically does not issue a second press release until proof of concept has been achieved for a Product. Roche shall provide Pieris with a copy of any draft press release related to the Agreement at least [\*\*\*] prior to its intended publication for Pieris' review. Pieris may provide Roche with suggested modification to the draft press release. Roche shall consider Pieris' timely suggestions in issuing its press release.

Pieris shall only issue press releases related to the activities contemplated by this Agreement that have either (i) been approved by Roche (such approval not to be unreasonably withheld), or (ii) are required to be issued by Pieris as a matter of law and Pieris has a competent legal opinion to that effect. In all circumstances, Pieris shall provide Roche with a draft press release at least [\*\*\*] prior to its intended publication for Roche's review. During such period, Roche shall (i) approve the draft press release and permit Pieris to issue the press release, (ii) contact Pieris to discuss modification to the draft press release, or (iii) contact Pieris and disapprove the press release. If Roche asks for modification, then Pieris shall either make such modification or work with Roche to arrive at a press release that Roche approves. If Pieris issues a press release without Roche's approval, then Pieris must obtain a competent legal opinion that the release was required to be issued by Pieris as a matter of law.

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*Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

**18.4 Publications**

During the Agreement Term, the following restrictions shall apply with respect to disclosure by any Party of Confidential Information relating to the Product in any publication or presentation:

- a) Both Parties acknowledge that it is their policy for the studies and results thereof to be registered and published in accordance with their internal guidelines. Roche, in accordance with its internal policies and procedures, shall have the right to publish all studies, clinical trials and results thereof on the clinical trial registries that are maintained by or on behalf of Roche.
- b) A Party (“**Publishing Party**”) shall provide the other Party with a copy of any proposed publication or presentation at least [\*\*\*] prior to submission for publication so as to provide such other Party with an opportunity to recommend any changes it reasonably believes are necessary to continue to maintain the Confidential Information disclosed by the other Party to the Publishing Party in accordance with the requirements of this Agreement. The incorporation of such recommended changes shall not be unreasonably refused; and if such other Party notifies (“**Publishing Notice**”) the Publishing Party in writing, within [\*\*\*] after receipt of the copy of the proposed publication or presentation, that such publication or presentation in its reasonable judgment (i) contains an invention, solely or jointly conceived and/or reduced to practice by the other Party, for which the other Party reasonably desires to obtain patent protection or (ii) could be expected to have a material adverse effect on the commercial value of any Confidential Information disclosed by the other Party to the Publishing Party, the Publishing Party shall prevent such publication or delay such publication for a mutually agreeable period of time. In the case of inventions, a delay shall be for a period reasonably sufficient to permit the timely preparation and filing of a patent application(s) on such invention, and in no event less than [\*\*\*] from the date of the Publishing Notice.

**18.5 Commercial Considerations**

- (a) Nothing in this Agreement shall prevent Roche or its Affiliates from disclosing Confidential Information of Pieris to (i) governmental agencies to the extent required or desirable to secure government approval for the development, manufacture or sale of Product(s) in the Territory, (ii) Third Parties acting on behalf of Roche, to the extent reasonably necessary for the development, manufacture or sale of Product(s) in the Territory, or (iii) Third Parties to the extent reasonably necessary to market the Product in the Territory, provided that for disclosures according to (ii) or (iii) of this Section, such Third Parties will be subject to the same confidentiality obligations as Roche has hereunder.
- (b) Nothing in this Agreement shall prevent Pieris or its Affiliates from disclosing (1) Confidential Information of Roche to (i) governmental agencies to the extent required or desirable to secure government approval for the development, manufacture or sale of Product(s) in the Territory as provided for in Section 19.3.4, (ii) Third Parties acting on behalf of Pieris, to the extent reasonably necessary for (A) Pieris to perform its activities and obligations under the Research Plan, or (B) the development, manufacture or sale of Product(s) in the Territory as provided for in Section 19.3.4, or (iii) Third Parties to the extent reasonably necessary to market the Product in the Territory as provided for in Section 19.3.4, or (2) to a Third Party the terms of this Agreement as part of confidential due diligence carried out by such Third Party in connection with a potential Change of Control of Pieris; provided that for disclosures according to (1) (ii) and (iii) or (2) of this Section, such Third Parties will be subject to the same confidentiality obligations as Pieris has hereunder.



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**CONFIDENTIAL TREATMENT REQUESTED**

- (c) The Receiving Party may disclose Confidential Information of the Disclosing Party to the extent that such Confidential Information is required to be disclosed by the Receiving Party to comply with Applicable Law, to defend or prosecute litigation or to comply with governmental regulations, provided that the Receiving Party provides prior written notice of such disclosure to the Disclosing Party and, to the extent practicable, takes reasonable and lawful actions to minimize the degree of such disclosure.

**19. Term and Termination**

**19.1 Commencement and Term**

This Agreement shall commence upon the Effective Date and continue for the Agreement Term.

**19.2 Termination**

19.2.1 Termination for Breach

A Party ("**Non-Breaching Party**") shall have the right to terminate this Agreement in its entirety or on a country-by-country basis in the event the other Party ("**Breaching Party**") is in breach of any of its material obligations under this Agreement. The Non-Breaching Party shall provide written notice to the Breaching Party, which notice shall identify the breach and the countries in which the Non-Breaching Party intends to have this Agreement terminate. The Breaching Party shall have a period of ninety (90) days after such written notice is provided ("**Peremptory Notice Period**") to cure such breach. If the Breaching Party has a dispute as to whether such breach occurred or has been cured, it will so notify the Non-Breaching Party, and the expiration of the Peremptory Notice Period shall be tolled until such dispute is resolved pursuant to Section 21.2. Upon a determination of breach or failure to cure, the Breaching Party may have the remainder of the Peremptory Notice Period to cure such breach. If such breach is not cured within the Peremptory Notice Period, then absent withdrawal of the Non-Breaching Party's request for termination, this Agreement shall terminate in such countries effective as of the expiration of the Peremptory Notice Period.

19.2.2 Insolvency

A Party shall have the right to terminate this Agreement, if the other Party incurs an Insolvency Event; provided, however, in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the Party that incurs the Insolvency Event consents to the involuntary bankruptcy or such proceeding is not dismissed within [\*\*\*] after the filing thereof.

19.2.3 Effects of Change of Control

If there is a Change of Control, then the Party experiencing such Change of Control ("**Acquired Party**") shall provide written notice to the other Party ("**Non-Acquired Party**") at least [\*\*\*] to completion of such Change of Control, subject to any confidentiality obligations of the Acquired Party then in effect (but in any event shall notify the Non-Acquired Party within [\*\*\*] after completion of such Change of Control).

The Change of Control Group in connection with such Change of Control shall agree in writing with the Non-Acquired Party that it will not utilize any of the Non-Acquired Party's Know-How, Patent Rights, Inventions, or Confidential Information (collectively, "**Sensitive Information**") for the research, development or commercialization of any product for the treatment of any indication or patient population for which a Product may be developed or commercialized.

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*Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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## **CONFIDENTIAL TREATMENT REQUESTED**

Following consummation of the Change of Control, the Non-Acquired Party and the Change of Control Group shall adopt in writing reasonable procedures to prevent the disclosure of Sensitive Information beyond the Acquired Party's personnel who need to know the Sensitive Information solely for the purpose of fulfilling the Acquired Party's obligations under this Agreement. The Non-Acquired Party may restrict the Acquired Party's participation in the JRC and any other committee in effect at the time of the Change of Control, and decisions of the JRC and other such committees shall be made by Roche.

If there is a Change of Control of Pieris involving a company that develops or commercializes biopharmaceutical products (for clarity, generally for itself and not typically on a contract basis for other companies), then Roche may, in its sole discretion, immediately terminate the Agreement in its entirety. Upon any such termination by Roche, Pieris will immediately cease all activity and transfer to Roche all data developed by Pieris. Pieris shall provide an invoice to Roche specifying the, and reconcile [\*\*\*] made by Roche. Within [\*\*\*] of such reconciliation, Pieris will refund to Roche the difference between the [\*\*\*] by Roche and Pieris actual FTE expenditures [\*\*\*]. All licenses granted by Pieris to Roche shall remain in effect subject to the payment and diligence obligations under this Agreement. Pieris shall lose the right to query Roche for the [\*\*\*] as foreseen in Section 2.4, and all licenses granted by Roche to Pieris shall terminate, except for the licenses under Section 2.4 with regards to licenses for [\*\*\*] already granted and for which Pieris is [\*\*\*] and provided that the Change of Control Group or its sublicensees develop such [\*\*\*] without the use of any Sensitive Information. Further, the right to query Roche for the [\*\*\*] and Roche's grant of licenses for such [\*\*\*] as foreseen under Section 2.4 shall remain in effect provided that the Change of Control of Pieris involves a company as described above that, at the time of such Change of Control, (i) has a market capitalization of less than [\*\*\*] US dollars (USD [\*\*\*]) and (ii) has [\*\*\*].

### 19.2.4 Voluntary Termination by Roche

#### Termination Without a Cause

After fifteen (15) months from the Effective Date, Roche shall have the right to terminate this Agreement at any time as a whole, or on a Product-by-Product and country-by-country basis upon ninety (90) days prior written notice before First Commercial Sale of a Product or upon one hundred eighty (180) days prior written notice after the First Commercial Sale of a Product. For clarity, Roche shall have the right to provide written notice of termination before the end of the initial fifteen (15) months, but such termination shall only take effect when the initial eighteen (18) months have ended.

#### Effective Date of Termination

The effective date of termination under this Section 19.2.4 shall be the date ninety (90) days (or one hundred eighty (180) days as the case may be) after Roche provides such written notice to Pieris.

## 19.3 Consequences of Termination

### 19.3.1 Termination by Pieris for Breach by Roche

Upon any termination by Pieris for breach by Roche, the rights and licenses granted by Pieris to Roche under this Agreement shall terminate in their entirety or on a country-by-country and Product-by-Product basis, as applicable, on the effective date of termination, and all licenses granted by Roche to Pieris under Section 2.4 shall remain in effect.

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*Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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19.3.2 Termination by Roche for Breach by Pieris or Pieris' Insolvency

Upon any termination by Roche for breach by Pieris or Pieris' Insolvency, Roche and its Affiliates may upon notice retain all rights and licenses granted to Roche by Pieris under this Agreement; provided that after the effective date of termination the amounts of such payments and royalties that otherwise would have become due and payable shall continue to be due and payable to Pieris or its successor in interest (as applicable).

19.3.3 Voluntary Termination by Roche

Upon any voluntary termination by Roche, the rights and licenses granted by Pieris to Roche under this Agreement shall terminate in their entirety or on a country-by-country and Product-by Product basis, as applicable, on the effective date of termination, and all licenses granted by Roche to Pieris under Section 2.4 shall remain in effect.

19.3.4 Continuation Election Notice

In the case of termination by Pieris for breach by Roche (Section 19.3.1) or in case of voluntary termination by Roche (Section 19.3.3), if Pieris desires to continue development and/or commercialization of Product(s), Pieris shall give a Continuation Election Notice to Roche within [\*\*\*] of receipt of Pieris' or Roche's notice of termination, as applicable, and pay [\*\*\*] Swiss francs (CHF [\*\*\*]) within [\*\*\*] after receipt of respective invoice from Roche. If Roche receives such a timely Continuation Election Notice, and to the extent reasonably requested by Pieris:

- a) At Roche's choice, Roche shall either grant to Pieris an exclusive (with respect to the terminated territory and Product only) and royalty free license to Patent Rights only to the extent covering Inventions relating to Selected Binders that Roche received from Pieris under Section 14.2 and to the extent necessary to continue development and/or commercialization of the terminated Product in the terminated territory, or assign and transfer to Pieris such Patent Rights, free of charge. For clarity, if such Patent Rights also cover Inventions relating to Modified Binders, Products or other subject matters, the license to such Inventions shall be subject to Section 19.3.4 (b).
- b) The Parties shall enter into good faith negotiations with regards to a royalty-bearing license, with the right to grant sublicenses (through multiple tiers), under intellectual property and rights owned by Roche not covered under Section 19.3.4 (a) and relating to Products [\*\*\*] (for clarity, [\*\*\*] are excluded from such license). Such license shall be under terms to be negotiated in good faith between the Parties, taking into account the value of such intellectual property and rights and the contribution made by Roche to the development of the Product(s) and their development stage. The good faith negotiations for a license described in this Section shall in particular address:
  - i. The obligation of Roche to, to the extent Roche has the right to do so, transfer to Pieris all material regulatory correspondence, filings (including all Filings) and approvals (including all Regulatory Approvals), all final pre-clinical and clinical study reports and clinical study protocols, and all data, including clinical data, in Roche's possession or control related to Product(s) in the country useful or necessary for Pieris to continue to develop, manufacture and commercialize the Product(s). All data shall be transferred in the form and format in which it is maintained by Roche. Original paper copies shall only be transferred, if legally required. Roche shall not be required to prepare or finalize any new data, reports or information solely for purposes of transfer to Pieris. In connection with

**CONFIDENTIAL TREATMENT REQUESTED**

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, in particular as Samples may qualify as personal identifiable information. Roche shall transfer any such Samples to Pieris to the extent permitted by the informed consents as originally established with respect to such Samples and Applicable Laws.

- ii. Assignment of all clinical trial agreements and any other Third Party agreement relating to the development, manufacture or commercialization of a Product, to the extent such agreements have not been cancelled and are assignable without Roche paying any consideration or commencing litigation in order to effect an assignment of any such agreement (and the obligation of Roche to use Commercially Reasonable Efforts to obtain consent from the concerned Third Party to such a transfer).
- iii. The obligation of Pieris to [\*\*\*] incurred by or on behalf of Roche for transfer activities from Roche to Pieris to the extent such costs and expenses exceed the fee of [\*\*\*] Swiss francs (CHF [\*\*\*]) paid by Pieris under this Section.
- iv. The obligation of Pieris to pay royalties to Roche on Net Sales of such Product(s). Such royalties shall be dependent on the then-current development stage of the Product(s) according to the following table:

<b>Development stage of Product(s)</b>	<b>Royalty rate</b>
Prior to start of Phase II Study	[***]
After start of Phase II Study but before Start of Phase III Study	[***]
After Start of Phase III Study but before First Commercial Sale	[***]
After First Commercial Sale	[***]

The above royalty rates shall be reduced by [\*\*\*] on a Product-by-Product and country-by-country basis in each country in which the manufacture, use, sale or import of the Product(s) is not covered by a Composition of Matter Claim of Roche.

Pieris’ obligation to pay royalties to Roche shall, with respect to such Product(s) and for a given country, start on the date of First Commercial Sale of such Product(s) in such country and end on the later of the date that is (a) ten (10) years after the date of the First Commercial Sale of such Product(s) in such country, or (b) the expiration of the last to expire Composition of Matter Claim of a patent owned or Controlled by Roche (or by Pieris pursuant to Sections 14.5 or 19.3.4) in such country Covering the use, import, offering for sale, or sale of such Product(s). Sections 10.6.3.2, 10.7 and 10.8 shall apply mutatis mutandis to the royalty rate owed by Pieris to Roche.

- v. The obligation of Roche to manufacture and supply the Product(s) to Pieris during a transition period at [\*\*\*], until such time as Pieris has procured or developed its own source of Product supply, provided that Pieris can demonstrate it has been diligently seeking an alternative manufacturer and provided further that in any case Roche’s manufacture and supply obligation shall in no event exceed [\*\*\*] from the effective date of the termination of this Agreement, except as provided below. Pieris shall use Commercially Reasonable Efforts to establish or take over the manufacturing as soon as possible after the effective date of termination. In case termination occurs before Phase II Studies have been Initiated, Pieris shall, at the request of Roche, use Commercially Reasonable Efforts to develop their [\*\*\*] to be used in pivotal studies. In case

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termination occurs when Phase II Studies have already been Initiated or later, Roche shall reasonably cooperate in assisting Pieris in the transfer of manufacturing process for such Product to a Third Party manufacturer, provided such Third Party manufacturer is acceptable to Roche; and Roche shall transfer the [\*\*\*] to such Third Party manufacturer. Except as provided herein, Roche shall be under no obligation to provide, transfer or allow Pieris to use proprietary [\*\*\*], or disclose proprietary [\*\*\*] related to the Product(s). In case termination occurs after Initiation of Phase III Studies, Roche shall, upon Pieris' request, [\*\*\*] for the manufacture of Product(s) to the Third Party manufacturer acceptable to Roche.

- vi. In case the necessary transfers under subsections (i), (ii) and (v) have not been achieved within the foreseen timelines due to difficulties not under control of the Parties, then Roche shall reasonably cooperate and assist Pieris for a reasonable additional period not to exceed [\*\*\*] (such difficulties can consist in, for example, a regulatory approval being delayed).
- c) For clarity, the licenses under this Section 19.3.4.a) and b) shall not include (i) any licenses that Roche has with a Third Party for which such grant would be prohibited or under which a member of the Roche Group would incur financial obligations to such Third Party, provided, however, that Roche shall (a) sublicense such Third Party licenses to Pieris if allowed in the respective license agreement, subject to Pieris committing to assume full responsibility for any and all financial obligations owed by Roche to such Third Party for the sublicense, and (b) reasonably support Pieris in getting in contact with such Third Party, for which a sublicense is not permitted, to get access to such Third Party rights, and (ii) the Excluded Patent Rights.

#### 19.3.5 Direct License

Irrespective of anything to the contrary in this Agreement, any existing, permitted sublicense granted by Roche under Section 2.3 of this Agreement (and any further sublicenses thereunder) shall, upon the written request of Roche, remain in full force and effect, provided that (i) such Sublicensee is not then in breach of its sublicense agreement (and, in the case of termination by Pieris for breach by Roche, that such Sublicensee and any further sublicenses did not cause the breach that gave rise to the termination by Pieris); and (ii) and such Sublicensee agrees to be bound to Pieris under the terms and conditions of such sublicense agreement, provided that the payments due to Pieris by such Sublicensee under such sublicense agreement are no less than the payments that would have been due to Pieris by Roche under this Agreement.

#### 19.3.6 Other Activities

##### 19.3.6.1 Ongoing Activities

If Pieris does not provide timely Continuation Election Notice (Section 19.3.4), then Roche (a) shall have the right to cancel all ongoing activities and (b) shall complete all non-cancellable activities at its own expense.

If Pieris provides such timely Continuation Election Notice, then from the date of notice of termination until the effective date of termination, Roche shall, at Pieris' request and expense, continue activities performed by or on behalf of Roche, including preparatory activities, ongoing as of the date of notice of termination. However, subject to Section 19.3.4, Roche shall not be obliged to initiate any new activities not ongoing at the date of notice of termination.

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## **CONFIDENTIAL TREATMENT REQUESTED**

After the effective date of termination and to the extent that Pieris has not made a request as described above, Roche shall not have any obligation to perform and/or complete any activities or to make any payments for performing or completing any activities under this Agreement, except as expressly stated herein.

### 19.3.6.2 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 Pieris that are due and payable prior to the effective date of termination.

## **19.4 Survival**

Section 11.2 (Late Payment), Article 13 (Auditing), Article 14 (Intellectual Property), Article 16 (Indemnification), Article 18 (Obligation Not to Disclose Confidential Information), Article 19 (Term and Termination), Section 21.1 (Governing Law), Section 21.2 (Disputes), Section 21.12 (Notice) and all definitions used in such Articles and Sections shall survive any expiration or termination of this Agreement for any reason.

## **20. Bankruptcy**

All licenses (and to the extent applicable rights) granted under or pursuant to this Agreement by Pieris to Roche are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, US Code (the “**Bankruptcy Code**”) licenses of rights to “intellectual property” as defined under Section 101(60) of the Bankruptcy Code. Unless Roche elects to terminate this Agreement, the Parties agree that Roche, as a licensee or sublicensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code, subject to the continued performance of its obligations under this Agreement.

## **21. Miscellaneous**

### **21.1 Governing Law**

This Agreement shall be governed by and construed in accordance with the laws of Germany, without reference to its conflict of laws principles, and shall not be governed by the United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention).

### **21.2 Disputes**

- (a) Unless otherwise set forth in this Agreement, in the event of any dispute in connection with this Agreement, such dispute shall be referred to the respective executive officers of the Parties designated below or their designees, for good faith negotiations attempting to resolve the dispute. The designated executive officers are as follows:

For Pieris: CEO

For Roche: Head of Roche Partnering

- (b) Should the Parties fail to agree within [\*\*\*] after such dispute has been referred to the Parties’ designated executive officers, then either Party shall be entitled to request resolution of the dispute through arbitration, which shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators appointed in accordance with said Rules. The place of arbitration shall be Basel, Switzerland. The language to be used in the arbitration proceeding shall be English.

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*Portions of the exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

**21.3 Assignment**

Neither Party shall have the right to assign the present Agreement or any part thereof to any Third Party other than Affiliates without the prior written approval of the other Party which shall not unreasonably be withheld, provided however, if a Party is acquired or is to be acquired by a third party by merger, acquisition, or the sale of substantially all of the assets of the division of such Party to which the subject matter of this Agreement relates, then such Party may effect such an assignment or transfer to such acquiring Third Party without the consent of the other Party.

**21.4 Debarment**

Each Party represents and warrants that it has never been debarred or otherwise sanctioned by the FDA, or a corresponding regulatory authority. Neither Party has been debarred under 21 U.S.C. §335a, disqualified under 21 C.F.R. §312.70 or §812.119, sanctioned by a Federal Health Care Program (as defined in 42 U.S.C §1320 a-7b(f)), including without limitation the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any other similar Federal or state agency or program. In the event either Party receives notice of debarment, suspension, sanction, exclusion, ineligibility or disqualification under the above-referenced statutes, such Party shall immediately notify the other Party in writing and such other Party shall have the right, but not the obligation, to terminate this Agreement, effective, at such Party's option, immediately or at a specified future date.

**21.5 Independent Contractor**

No employee or representative of either Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever or to create or impose any contractual or other liability on the other Party without said Party's prior written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Pieris' legal relationship to Roche under this Agreement shall be that of independent contractor.

**21.6 Unenforceable Provisions and Severability**

If any of the provisions of this Agreement are held to be void or unenforceable, then such void or unenforceable provisions shall be replaced by valid and enforceable provisions that will achieve as far as possible the economic business intentions of the Parties. However the remainder of this Agreement will remain in full force and effect, provided that the material interests of the Parties are not affected, i.e. the Parties would presumably have concluded this Agreement without the unenforceable provisions.

**21.7 Waiver**

The failure by either Party to require strict performance and/or observance of any obligation, term, provision or condition under this Agreement will neither constitute a waiver thereof nor affect in any way the right of the respective Party to require such performance and/or observance. The waiver by either Party of a breach of any obligation, term, provision or condition hereunder shall not constitute a waiver of any subsequent breach thereof or of any other obligation, term, provision or condition.

**21.8 Appendices**

All Appendices to this Agreement shall form an integral part to this Agreement.

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*Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

**21.9 Entire Understanding**

This Agreement contains the entire understanding between the Parties hereto with respect to the within subject matter and supersedes any and all prior agreements, understandings and arrangements, whether written or oral.

**21.10 Amendments**

No amendments of the terms and conditions of this Agreement shall be binding upon either Party hereto unless in writing and signed by both Parties.

**21.11 Invoices**

All invoices that are required or permitted hereunder shall be in writing and sent by Pieris to Roche at the following address or other address as Roche may later provide:

F. Hoffmann-La Roche Ltd  
[\*\*\*]  
Switzerland

**21.12 Notice**

All notices that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Pieris, to:           Pieris Pharmaceuticals GmbH  
Lise-Meitner-strasse 30  
85354 Freising  
Germany  
Attn: CEO  
Facsimile No.: [\*\*\*]

and:                       Pieris Pharmaceuticals, Inc.  
255 State Street, 9<sup>th</sup> floor  
Boston, MA 02109  
U.S.A  
Attn: CEO  
Facsimile No.: [\*\*\*]

if to Roche, to:       F. Hoffmann-La Roche Ltd  
[\*\*\*]  
Switzerland  
Attn: Legal Department  
Facsimile No.: [\*\*\*]

and:                       Hoffmann-La Roche Inc.  
[\*\*\*]  
U.S.A.  
Attn. Corporate Secretary  
Facsimile No.: [\*\*\*]

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*Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*



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**CONFIDENTIAL TREATMENT REQUESTED**

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith.

*[Signature Page Follows]*

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*Portions of the exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

**Pieris Pharmaceuticals GmbH**

/s/ Stephen S. Yoder

Name: Stephen S. Yoder

Title: President & CEO

**Pieris Pharmaceuticals, Inc.**

/s/ Stephen S. Yoder

Name: Stephen S. Yoder

Title: President & CEO

**F. Hoffmann-La Roche Ltd**

/s/ Vikas Kabra

Name: Vikas Kabra

Title: Head of Transaction Excellence

/s/ Dr. Christof Burri

Name: Dr. Christof Burri

Title: Legal Counsel

**Hoffmann-La Roche Inc.**

/s/ John P. Parise

Name: John P. Parise

Title: Authorized Signatory

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*Portions of the exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

**Appendix 1.60**

**Pieris IP**

[\*\*\*, 1 page]

*Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

**Appendix 1.66**

**Research Plan**

[\*\*\*, 11 pages]

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*Portions of the exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

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**CONFIDENTIAL TREATMENT REQUESTED**

**Appendix 1.68**

**Excluded Patent Rights**

[\*\*\*, 2 pages]

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**CONFIDENTIAL TREATMENT REQUESTED**

**Appendix 1.74**

[\*\*\*, 2 pages]

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**Appendix 18.3**

**Press Release**



***PRESS RELEASE***

**Pieris Pharmaceuticals Announces  
First Cancer Immunotherapy Collaboration**

**Agreement with Roche Leverages Proprietary Anticalin® Technology Platform**

**Boston, MA, December 8, 2015** – Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS), a biotechnology company advancing novel bio therapeutics through its proprietary Anticalin® technology platform, today announced a research collaboration and license agreement with Roche in cancer immunotherapy (CIT). Under the terms of the agreement, Pieris will discover, characterize and optimize Anticalin®-based drug candidates against an undisclosed target. Roche and Pieris will evaluate different drug formats against this target and advance them through preclinical development, with Roche being responsible for IND-enabling activities, clinical development and worldwide marketing of any resulting products. Pieris will receive an upfront payment of CHF 6.5 million (~\$6.4 million USD) and committed research funding, and may receive development and regulatory-based milestone payments, sales-based milestone payments as well as mid single-digit to low double-digit royalties on any future product sales. If all milestones and other conditions are met, the total payments to Pieris could surpass CHF 415 million (~\$409.3 million USD), excluding royalties.

“Our partnership with Roche is a significant step forward for Pieris,” commented Stephen Yoder, President and CEO of Pieris. “The decision by the leader in the development and commercialization of cancer biologics to collaborate with Pieris underscores the unique potential of Anticalin-based proteins as a differentiated class of immuno-oncology drugs. As we initiate this collaboration, we will continue to vigorously advance our fully proprietary programs, including our lead CD137-HER2 bispecific.”

With its immuno-oncology PRS-300 Series, which remains proprietary to the Company, Pieris is developing bispecific Anticalin-based protein therapeutics against a variety of tumor and immunomodulatory targets. These compounds, including its lead program PRS-343 (CD137/HER2 bispecific), aim to activate the immune system in the tumor microenvironment, with the goal of increasing efficacy as well as improving safety compared to existing

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**CONFIDENTIAL TREATMENT REQUESTED**

approaches. This collaboration represents Pieris' first partnered immuno-oncology program and leverages Pieris' capability to address a target in multiple ways through Anticalin-based drug candidates in different formats.

**About Pieris Pharmaceuticals:**

Pieris Pharmaceuticals is a clinical stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immuno-oncology multi-specifics tailored for the tumour micro-environment, an inhaled Anticalin to treat uncontrolled asthma and a half-life-optimized Anticalin to treat anemia. Proprietary to Pieris, Anticalins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin<sup>®</sup>, Anticalins<sup>®</sup> are registered trademarks of Pieris. For more information visit [www.pieris.com](http://www.pieris.com).

**About Anticalins:**

Anticalins are derived from lipocalins, small human proteins that naturally bind, store and transport a wide spectrum of molecules. Anticalins feature the typical four-loop variable region and a rigidly conserved beta-barrel backbone of lipocalins, which, together, form a shapeable cup-like binding pocket. Proprietary to Pieris, Anticalins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies.

Anticalin<sup>®</sup>, Anticalins<sup>®</sup> are registered trademarks of Pieris.

**Forward Looking Statements**

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to novel technologies and methods; our business, research and product development plans; our liquidity and ability to fund our future operations; our ability to achieve certain milestones and receive future milestone or royalty payments; or market information. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, our ability to raise the additional funding we will need to continue to pursue our business, research and product development plans; the inherent uncertainties associated with developing new products or technologies and operating as a development stage company; our ability to develop, complete clinical trials for, obtain approvals for and commercialize any of our product candidates; competition in the industry in which we operate and market conditions. These forward-looking statements are made as of the date of this press release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents we file with the SEC available at [www.sec.gov](http://www.sec.gov), including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and the Company's Quarterly Reports on Form 10-Q.

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**CONFIDENTIAL TREATMENT REQUESTED**

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##END##

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CERTIFICATIONS UNDER SECTION 302

I, Stephen S. Yoder, certify that:

1. I have reviewed this Amendment No. 2 on Form 10-K/A of Pieris Pharmaceuticals, Inc.; and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: July 20, 2016

/s/ Stephen S. Yoder

Stephen S. Yoder

Title: Chief Executive Officer and President  
(principal executive officer)

CERTIFICATIONS UNDER SECTION 302

I, Darlene Deptula-Hicks, certify that:

1. I have reviewed this Amendment No. 2 on Form 10-K/A of Pieris Pharmaceuticals, Inc.; and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: July 20, 2016

/s/ Darlene Deptula-Hicks

Darlene Deptula-Hicks

Title: Senior Vice President and Chief Financial  
Officer

(principal accounting and financial officer)