

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

Form 10-Q/A
Amendment No. 1

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended March 31, 2017

or

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Commission file number: 001-37471

PIERIS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of
incorporation or organization)

33-0784346
(I.R.S. Employer
Identification No.)

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

02109
(Zip Code)

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

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

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

| | | | |
|-------------------------|--|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> (Do not check if a smaller reporting company) | Smaller reporting company | <input checked="" type="checkbox"/> |
| Emerging growth company | <input checked="" type="checkbox"/> | | |

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

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

The number of outstanding shares of the registrant’s common stock, par value \$0.001 per share, as of May 9, 2017 was 43,068,790.

EXPLANATORY NOTE

Pieris Pharmaceuticals, Inc. (the “Company”) is filing this Amendment No. 1 (this “Amendment”) to its Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 (the “Form 10-Q”), originally filed on May 15, 2017. This Amendment is an exhibit-only filing in response to comments received from the Securities and Exchange Commission (the “Commission”) in connection with a request for confidential treatment of certain portions of Exhibit 10.3, as originally filed with the Form 10-Q. This Amendment is being filed solely to re-file Exhibit 10.3 based on comments from the Commission. In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, new certifications by our principal executive officer and principal financial officer are filed as exhibits to this Amendment.

This Amendment is limited in scope to the items identified above and should be read in conjunction with the Form 10-Q. This Amendment does not reflect events occurring after the filing of the Form 10-Q and no revisions are being made to the Company’s financial statements pursuant to this Amendment. Other than the filing of the information identified above, this Amendment does not modify or update the disclosure in the Form 10-Q in any way.

PART II

Item 6. Exhibits

| <u>Exhibit No.</u> | <u>Exhibit Description</u> |
|-------------------------------|---|
| <u>10.1</u> ± | Collaboration Agreement by and among the Registrant, Pieris Pharmaceuticals GmbH, Les Laboratoires Servier and Institut de Recherches Internationales Servier, dated as of January 4, 2017 (incorporated by reference to Exhibit 10.15 of the Registrant's Amendment No. 1 to the Annual Report on Form 10-K filed April 26, 2018 (File No. 001-37471)) |
| <u>10.2</u> ± | Non-Exclusive Anticalin Platform Technology License Agreement by and among the Registrant, Pieris Pharmaceuticals GmbH, Les Laboratoires Servier and Institut de Recherches Internationales Servier, dated as of January 4, 2017 (incorporated by reference to Exhibit 10.16 of the Registrant's Amendment No. 1 to the Annual Report on Form 10-K filed April 26, 2018 (File No. 001-37471)) |
| <u>10.3</u> ± | Exclusive Option Agreement by and among the Registrant, Pieris Pharmaceuticals GmbH and ASKA Pharmaceutical Co., Ltd., dated as of February 27, 2017 |
| <u>10.4</u> | Amendment No.1 to Definitive License and Transfer Agreement by and between the Company and Enumeral Biomedical Holdings, Inc. effective as of January 3, 2017 (incorporated by reference to Exhibit 10.14 of the Registrant's Annual Report on Form 10-K filed March 30, 2017 (File No. 001-37471)) |
| <u>10.5</u> * | Separation Agreement by and between the Registrant and Darlene Deptula-Hicks, dated as of February 7, 2017 (incorporated by reference to Exhibit 10.26 of the Registrant's Annual Report on Form 10-K filed March 30, 2017 (File No. 001-37471)) |
| <u>10.6</u> * | Consulting Agreement by and between the Registrant and Danforth Advisors, LLC, dated as of February 1, 2017 (incorporated by reference to Exhibit 10.26 of the Registrant's Annual Report on Form 10-K filed March 30, 2017 (File No. 001-37471)) |
| <u>31.1</u> | Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Principal Executive Officer |
| <u>31.2</u> | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Principal Financial Officer |
| <u>32.1</u> | Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Principal Executive Officer (previously filed as part of the Form 10-Q) |
| <u>32.2</u> | Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Principal Financial Officer (previously filed as part of the Form 10-Q) |
| 101.INS | XBRL Instance Document (previously filed as part of the Form 10-Q) |
| 101.SCH | XBRL Taxonomy Extension Schema Document (previously filed as part of the Form 10-Q) |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document (previously filed as part of the Form 10-Q) |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document (previously filed as part of the Form 10-Q) |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document (previously filed as part of the Form 10-Q) |
| 101.PRE | XBRL Taxonomy Presentation Linkbase Document (previously filed as part of the Form 10-Q) |

± Confidential treatment has been requested as to certain portions, which portions have been omitted and submitted separately to the Securities and Exchange Commission.

* Indicates management contract or compensatory plan.

SIGNATURES

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

Date: April 26, 2018

Pieris Pharmaceuticals, Inc.

By: /s/Stephen S. Yoder

Stephen S. Yoder

President, Chief Executive Officer and Director

Date: April 26, 2018

By: /s/Allan Reine

Allan Reine

Chief Financial Officer

CONFIDENTIAL TREATMENT REQUESTED**EXCLUSIVE OPTION AGREEMENT**

This Exclusive Option Agreement (the “**Agreement**”) is entered into by and between Pieris Pharmaceuticals Inc., a Nevada corporation with an address of 255 State Street, 9th Floor, Boston, MA 02109 and Pieris Pharmaceuticals GmbH, a German company with an address of Lise-Meitner-Strasse 30 85354 Freising, Germany (collectively, “**Pieris**”), and ASKA Pharmaceutical Co., Ltd., a Japanese corporation with an address of 2-5-1 Shibaura, Minato-ku, Tokyo, Japan 108-8532 (“**ASKA**”), is effective on February 27, 2017 (the “**Effective Date**”). Pieris and ASKA are also individually referred to herein as a “**Party**” and collectively as the “**Parties**”.

RECITALS

WHEREAS, Pieris and its Affiliates (capitalized terms as defined below) own or control the proprietary, lipocalin-derived Anticalin® technology and have developed the Licensed Product, Pieris’ Anticalin protein targeting hepcidin, and own or control certain patents, proprietary technology, know-how and information relating to such technology and product; and

WHEREAS, ASKA wishes to obtain an exclusive option to license, and Pieris wishes to grant such exclusive option to license to ASKA, certain patents and know-how, in order for ASKA to develop, manufacture, import, sell, export, and offer for sale and export the Licensed Product in the Licensed Field and in the Licensed Territory in accordance with this Agreement.

NOW, THEREFORE, in consideration of the promises and mutual covenants herein below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. **DEFINITIONS.** The following capitalized terms or derivatives thereof (verbs, nouns, singular, plural), when used in this Agreement, shall have the following meanings:
 - 1.1 “**Additional Indication**” means any disease within the Licensed Field other than the Initial Indication.
 - 1.2 “**Affiliate**” means, with respect to a Party, any person or entity, which directly or indirectly controls, is controlled by, or is under common control with such Party. Solely as used in this definition, the term “control” means (a) the ownership, directly or indirectly, beneficially or legally, of at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a person or entity in a particular jurisdiction) of such Party or other person or entity, as applicable, or such other comparable ownership interest with respect to any person or entity that is not a corporation; or (b) the power, direct or indirect, whether through ownership of voting securities or partnership or other ownership interests of more than fifty percent (50%), by

*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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contract or otherwise, to direct the management and policies of a Party or such other person or entity, as applicable.

- 1.3 “**Anticalin**” means, whether in nucleic acid or protein form, (a) any lipocalin mutein isolated from the Anticalin Libraries, or (b) 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 (a) of this definition, in each case, which binds and recognizes a specific target. For the sake of this Section, “mutein” shall mean a protein arising as a result of a mutation or a recombinant DNA procedure.
- 1.4 “**Anticalin Affinity Maturation**” means the process of engineering for an Anticalin protein to enhance its developability profile, such as increasing binding activities and specificity by introducing, e.g., one or more amino acid mutations.
- 1.5 “**Anticalin Characterization**” means the assessment of binding and functional potency and/or the evaluation of the developability profile of Anticalin proteins.
- 1.6 “**Anticalin Expression**” means the heterologous expression of an Anticalin protein in a host cell.
- 1.7 “**Anticalin Libraries**” means any phage display library based on the [***] (Uniprot [***]).
- 1.8 “**Anticalin Selection**” means 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 Anticalin proteins, from the solution containing non-binding Anticalin proteins.
- 1.9 “**ASKA**” has the meaning set forth in the preamble of this Agreement.
- 1.10 “**Breakup Fee**” has the meaning set forth in Section 2.2.
- 1.11 “**CDA**” has the meaning set forth in Section 8.1.
- 1.12 “**Competing Product**” means any biologic [***] in the Licensed Field and in the Licensed Territory.
- 1.13 “**Competing Transaction**” has the meaning set forth in Section 2.5.
- 1.14 “**Commercially Reasonable Efforts**” means such level of efforts required to carry out such obligation in a manner consistent with the efforts that a pharmaceutical company comparable with Pieris would devote at the same stage of development or commercialization, as

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applicable, for its own internally developed therapeutic products in a similar area with similar market potential, at a similar stage of its 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, intellectual property considerations, 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.

- 1.15 “**Definitive Agreements**” has the meaning set forth in Section 2.1.
- 1.16 “**Effective Date**” has the meaning set forth in the preamble of this Agreement.
- 1.17 “**Evaluation Period**” has the meaning set forth in Section 2.2.
- 1.18 “**Initial Indication**” means
[***].
- 1.19 “**Intellectual Property Rights**” means, collectively, Patent Rights, copyrights, trademarks, designs, domain names, moral rights and all other intellectual property and proprietary rights.
- 1.20 “**JCC**” has the meaning set forth in Section 4.9.
- 1.21 “**JDC**” has the meaning set forth in Section 4.7.
- 1.22 “**Know-How**” means any and all ideas, concepts, designs, technical information, techniques, data, database rights, discoveries, inventions, practices, methods, procedures, processes, algorithm, knowledge, skill, experience, test data and any other information or technology, whether in written, electronic, graphic or any other form, including pharmaceutical, chemical, biological and biochemical compositions, formulations, assays, active pharmaceutical ingredients (“**APIs**”), molecules, samples, cell lines, journals and laboratory notebooks.
- 1.23 “**Licensed Field**” means, with respect to the Licensed Product,
[***].
- 1.24 “**Licensed Platform IP**” means those Patents Rights in the Licensed Territory controlled by Pieris directed to the Pieris Platform Technology as set forth in Exhibit A.
- 1.25 “**Licensed Product IP**” means (a) all Know-How that is controlled by Pieris and is (i) used in connection with or otherwise covers the development, manufacture, import, sale, export, and offer for sale and export of the Licensed Product or (ii) reasonably necessary for the development, manufacture, import, sale, export, and offer for sale and export of a Licensed Product, but excludes the Licensed Platform IP and (b) any Patent Rights that are solely or

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jointly developed, or owned by Pieris as of the Effective Date and thereafter during the of the term of the Definitive Agreements, and that cover or are necessary for the development, manufacture, import, sale, export, and offer for sale and export of the Licensed Product, but excluding the Licensed Platform IP. The Patent Rights within the Licensed Product IP are set forth in Exhibit B.

- 1.26 “**Licensed Product**” means any pharmaceutical formulation containing PRS-080, Pieris’ pegylated Anticalin protein targeting hepcidin, as the active pharmaceutical ingredient.
- 1.27 “**Licensed Territory**” means Japan, [***].
- 1.28 “**Net Sales**” means all gross amounts invoiced by ASKA, its Affiliates or sublicensees for the sale of Licensed Product in the Licensed Territory to a Third Party, less the following items, provided that they are bona fide and determined in the ordinary course of business in accordance with generally accepted accounting standards, consistently applied:
- (a) credits, refunds or allowances actually issued or granted to Third Party customers for spoiled, damaged, rejected, recalled, outdated and returned Licensed Product; and
 - (b) sales, use or excise taxes and import/export duties or tariffs and similar governmental charges actually due or incurred in connection with the sales of Licensed Product to Third Party customers (but excluding taxes on income), if shown separately in the invoice.

In no event shall Net Sales of the Licensed Product be less than [***] percent ([***]%) of [***].

For purposes of this definition of Net Sales, [***] shall be considered [***] and not [***].

- 1.29 “**Up-Front License Fees**” has the meaning set forth in Section 2.2.
- 1.30 “**Option Rights**” has the meaning set forth in Section 2.1.
- 1.31 “**Patent Right**” means any and all patent rights and all right, title and interest in all patent applications and patents that issue from them, all letters patent or equivalent rights and applications in each case to the extent the same has not been held, by a court of competent jurisdiction, to be invalid or unenforceable in a decision from which no appeal can be taken or from which no appeal was taken within the time permitted for appeal. Patent Rights include any extension, registration, confirmation, reissue, continuation, supplementary

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protection certificate, divisional, continuation-in-part, re-examination or renewal thereof or foreign counterparts of any of the foregoing.

- 1.32 “**Party**” and “**Parties**” have the meaning set forth in the preamble of this Agreement.
- 1.33 “**Phase 2a Study**” means, for the purposes of this Agreement, that certain upcoming clinical study of the Licensed Product conducted by Pieris in the European Union, where the Licensed Product is administered repeatedly to hemodialysis patients with chronic kidney disease. ASKA acknowledges that the final protocol for the Phase 2a Study is still under discussion and subject to further changes before the Phase 2a Study will be initiated.
- 1.34 “**Pieris**” has the meaning set forth in the preamble of this Agreement.
- 1.35 “**Pieris Platform Technology**” means Anticalin Libraries, Anticalin Selection, Anticalin Expression, Anticalin Characterization, and Anticalin Affinity Maturation methods, all to the extent controlled by Pieris.
- 1.36 “**PL Claim**” has the meaning set forth in Section 4.15.
- 1.37 “**Royalty Term**” has the meaning set forth in Section 4.10.
- 1.38 “**Satisfaction Notice**” has the meaning set forth in Section 2.2.
- 1.39 “**SIAC**” has the meaning set forth in Section 10.3.
- 1.40 “**SIAC Rules**” has the meaning set forth in Section 10.3.
- 1.41 “**Success Criteria**” means the criteria set forth in Exhibit C.
- 1.42 “**Term**” has the meaning set forth in Section 6.1.
- 1.43 “**Third Party**” means any person or entity other than Pieris, ASKA or their Affiliates.

2. OPTION GRANT AND EXERCISE

- 2.1 Exclusive Option Grant. Subject to the terms and conditions of this Agreement, Pieris grants ASKA an option during the Term to acquire a non-exclusive license to use the Licensed Platform IP and an exclusive license to use the Licensed Product IP to develop, manufacture, import, sale, export, and offer for sale and export the Licensed Product in the Licensed Field and Licensed Territory (collectively “**Option Rights**”). For the avoidance of doubt, Pieris shall not develop, manufacture, import, sale, export, and offer for sale and export the Licensed Product in the Licensed Field and Licensed Territory after ASKA exercises the

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Option Rights and Pieris and ASKA execute license agreements granting ASKA licenses to the Licensed Platform IP and Licensed Product IP under the terms and conditions of this Agreement (the “**Definitive Agreements**”). For further avoidance of doubt, the Option Rights do not give ASKA any rights to any Intellectual Property Rights, Patent Rights, or Know-How; such rights shall be granted only under the Definitive Agreements.

- 2.2 Success Criteria and Option Exercise Rights and Up-Front License Fees. Pieris shall use Commercially Reasonable Efforts to complete the Phase 2a Study for the Licensed Product and shall submit to ASKA in writing the final results of its Phase 2a Study of the Licensed Product when such results are available. Such results shall be Confidential Information under the CDA. Upon receipt thereof, ASKA shall have [***] to evaluate such results (“**Evaluation Period**”). By the end of the Evaluation Period, ASKA may notify Pieris in writing of its decision to exercise its Option Rights and its intent to enter into the Definitive Agreements (“**Satisfaction Notice**”), and within [***] of the Parties’ execution of the Definitive Agreements and in consideration of the licenses granted to ASKA under the Definitive Agreements, ASKA shall pay Pieris the Up-Front Licensee Fees set forth in Exhibit D and Exhibit E (the “**Up-Front License Fees**”). If ASKA fails to provide a Satisfaction Notice by the end of the Evaluation Period, this Agreement including the Option Rights shall immediately terminate. Notwithstanding the foregoing, if the final results of the Phase 2a Study meet the Success Criteria, but ASKA fails to provide a Satisfaction Notice, then ASKA shall pay Pieris [***] Dollars (\$[***] USD) (the “**Breakup Fee**”) within [***] of the end of the Evaluation Period.
- 2.3 Negotiation. ASKA and Pieris will make commercially reasonable efforts to prepare and negotiate the Definitive Agreements starting on the Effective Date (and prior to ASKA’s exercise of the Option Rights). The Parties will further make commercially reasonable efforts to execute the Definitive Agreements no later than [***] after the date of ASKA’s exercise of the Option Rights hereunder. The detailed terms and conditions of the Definitive Agreements shall be decided upon good faith negotiation between ASKA and Pieris during the Term of this Agreement. The Definitive Agreements, if executed, will include the provisions set forth in Section 4 of this Agreement as well as other standard and customary terms.
- 2.4 Specific Exclusion. Pieris does not grant to ASKA any license, implied or otherwise, to any Licensed Platform IP or Licensed Product IP, Patent Rights, Intellectual Property Rights or other rights of Pieris other than those rights expressly granted under the Agreement. Notwithstanding the foregoing, ASKA and Pieris hereby confirm that Licensed Platform IP and Licensed Product IP include all Intellectual Property Rights and Know-How controlled

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by Pieris necessary for the sale, distribution, develop, manufacture, import, export, and offer for sale and export of Licensed Product by ASKA in the Licensed Territory, regardless whether or not recognized at the time of this Agreement.

- 2.5 No-Talk Provision. During the Term of this Agreement, Pieris will not, and will not cause nor permit any of its Affiliate or any of its or their directors, officers, employees, agents or representatives to, (a) negotiate, authorize, recommend, enter into or propose to enter into, with any person other than ASKA, any transaction involving the grant of a license under the Licensed Platform IP and Licensed Product IP to the Licensed Product in the Licensed Field and Licensed Territory (a “**Competing Transaction**”), (b) continue to engage in any pending discussions or negotiations with any Third Party concerning any previously proposed Competing Transaction (if any), (c) encourage, solicit or initiate discussions, negotiations or submissions of proposals, indications of interest or offers in respect of a Competing Transaction, or (d) furnish or cause to be furnished to any person any information in furtherance of a Competing Transaction.[***]

3. EXCLUSIVE OPTION FEE

- 3.1 Subject to the terms and conditions of this Agreement, in consideration of the grant by Pieris of the Option Rights and for Pieris’ forbearance from licensing the Licensed Product to any Third Party other than ASKA in the Licensed Field and Licensed Territory during the Term, ASKA shall pay Pieris Two Million Seven Hundred and Fifty Thousand Dollars (\$2,750,000 USD) within [***] of receipt of an invoice from Pieris after the Effective Date.

4. PROSPECTIVE TERMS OF THE DEFINITIVE AGREEMENTS

- 4.1 Terms of Definitive Agreements. The Definitive Agreements, if any, will include, but not be limited to, the terms and conditions set forth in this Section 4.
- 4.2 Exclusivity of Definitive Agreements. Subject to the terms and conditions of this Agreement, Pieris will (if the Definitive Agreements are executed) grant to ASKA a non-exclusive license to the Licensed Platform IP and an exclusive license to the Licensed Product IP in the Licensed Field and Licensed Territory. The Definitive Agreements will commence on the effective date of the Definitive Agreements and will expire after the end of the all payments due under the Definitive Agreements have been made.[***]
- 4.3 Additional Grants. Subject to the terms and conditions of this Agreement, Pieris will (if the Definitive Agreements are executed) grant to ASKA the right to use and reference any data (such as clinical, CMC, or technical information) related to the Licensed Product that is

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necessary or useful for the development, manufacture or commercialization of the Licensed Product in the Licensed Field and in the Licensed Territory. Such grant would include data generated by Pieris or its sublicensees engaged in the development, manufacture or commercialization of the Licensed Product outside the Licensed Territory to the extent that Pieris has the ability to grant such right.

- 4.4 Sublicensing in Definitive Agreements. The Definitive Agreements will include the right for ASKA to grant sublicenses (through multiple tiers) during the term of the Definitive Agreements. Any sublicenses granted by ASKA:
- (a) will be subject to the Definitive Agreements;
 - (b) will expressly include the obligations described in this Section 4 for the benefit of Pieris; and
 - (c) will require the transfer of all obligations, including the payment of milestones and royalties specified in the sublicense, to Pieris or its designee, if the Definitive Agreements are terminated.
- 4.5 Grantback Licenses. Subject to the terms and conditions of this Agreement, ASKA will (if the Definitive Agreements are executed) grant Pieris the right (with the right to sublicense through multiple tiers) to use and reference any data (such as clinical, CMC, or technical information) related to the Licensed Product and generated by or on behalf of ASKA in the Licensed Territory and controlled by ASKA, that is necessary or useful for the development or manufacture of the Licensed Product outside the Licensed Territory. Such grant would include any data generated by ASKA or its sublicensees engaged in the development of the Licensed Product in the Licensed Territory.
- 4.6 Non-Compete. During the term of the Definitive Agreements, neither Party shall in-license, manufacture or commercialize any Competing Product for use in the Licensed Field in the Licensed Territory (or assist any Third Party in doing so). The Parties shall negotiate appropriate provisions with respect to this non-compete in the event of a change of control of either Party in the Definitive Agreements. Until the first commercial sale of the Licensed Product in Japan, ASKA shall not develop any Competing Product (or assist any Third Party in doing so).
- 4.7 Development. ASKA will take primary responsibility for developing the Licensed Product in the Licensed Territory. All of the manufacturing, development and regulatory costs in the Territory will be borne by ASKA. Pieris will commit to provide ASKA reasonable assistance, at ASKA's cost, which may include relevant supplies of clinical materials, and

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access to related regulatory correspondence and other related materials in Pieris's control to the extent required by ASKA to enable them to fulfill their responsibilities and exploit their rights granted to them by Pieris under the Definitive Agreements.

Pieris and ASKA will form a joint development committee (" **JDC**") to assist with and monitor execution of the development plan, which shall be approved by such JDC (including approving the protocols for such clinical trials). Decisions shall be made by consensus with (i) ASKA having the casting vote for all matters solely related to development of the Licensed Product in the Licensed Territory, unless such a decision could reasonably be expected to have a negative effect on the development or commercialization of the Licensed Product outside the Licensed Territory, and (ii) Pieris having the casting vote on all other matters, to the extent such decision does not increase the costs to be borne by ASKA.

- 4.8 Regulatory. ASKA shall use commercially reasonable efforts (to be defined in the Definitive Agreements) to obtain regulatory approval in its name or to cause authorized sublicensees to obtain regulatory approval for the Licensed Product in the Licensed Field in the Licensed Territory on the timelines to be agreed by the Parties and included in a development plan approved by the JDC, the initial version of which shall be attached to the Definitive Agreements, including conducting all development and regulatory activities needed to obtain such approvals. ASKA shall keep Pieris fully informed of all such development and regulatory activities, including access to all data and results thereof. For the avoidance of doubt, Pieris will control the regulatory strategy for the Licensed Product outside of the Territory.
- 4.9 Commercialization. ASKA will control the commercial strategy for the Licensed Product within the Licensed Territory, including all pricing and reimbursement discussions for the Licensed Product. No later than the application for marketing authorization in the Licensed Territory, the Parties will form a joint commercialization committee ("**JCC**") to oversee the marketing and commercialization strategies for the Licensed Product in the Licensed Territory.
- 4.10 Royalty Term. ASKA's obligation to pay to Pieris royalties on Net Sales of the Licensed Product in the Licensed Territory shall begin on a country-by-country basis on the first commercial sale of the Licensed Product in such country and ending on the later of (i) ten (10) years after such first commercial sale of the Licensed Product in such country, (ii) the expiration of regulatory exclusivity for such Licensed Product in such country, or (iii) the last to expire valid claim of the Patent Rights in the Licensed Platform IP and the Licensed Product IP covering or claiming the Licensed Product in such country ("**Royalty Term**").

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- 4.11 Intellectual Property. Pieris shall own all Licensed Platform IP and Licensed Product IP and will be responsible for prosecution and maintenance thereof. Pieris shall keep ASKA reasonably informed of progress of the prosecution of Licensed Product IP in the Licensed Territory, and Pieris will be responsible for all associated costs of such prosecution and maintenance of such Licensed Platform IP and Licensed Product IP. Any Patent Rights generated by ASKA during the term of the Definitive Agreements that cover the Licensed Product (including its manufacture or use) shall be jointly owned by the Parties and Pieris shall have the right to sublicense (through multiple tiers) such Patent Rights outside of the Licensed Territory.
- 4.12 Trademarks. ASKA may select and shall own any trademarks for commercialization of the Licensed Product in the Licensed Territory. The Parties shall discuss in good faith any trademark licenses to the extent they agree that there should be a common mark for commercialization of the Licensed Product in the Licensed Territory and other countries.
- 4.13 Marketing Authorization. ASKA or its sublicensee shall make commercially reasonable efforts to obtain and own any marketing authorization for the Licensed Product in the Licensed Field and Licensed Territory.
- 4.14 Payments. The Definitive Agreements, if executed, will include the fees, royalties, milestone payments, and other terms listed in the attached Exhibit D and Exhibit E unless the Parties mutually agree to revise any such terms.
- 4.15 Warranties. The Definitive Agreements, if executed, will include customary warranties and shall require ASKA to defend and indemnify Pieris from all liabilities resulting from ASKA's fraud or willful misconduct, except to the extent that a claim arises due to Pieris's fraud or willful misconduct. Pieris warrants that the Licensed Product shall be free from defects in material and workmanship, and (when supplying the Licensed Product) that the Licensed Product shall conform to product specifications separately agreed by the Parties in writing. With respect to any actual, potential, or threatened product liability claim, action, or proceeding relating to any Licensed Product ("**PL Claim**"), Pieris shall in case of a PL Claim against Pieris, communicate with ASKA from time to time and observe the instructions of ASKA, and, in case of a PL Claim against ASKA, cooperate with ASKA in investigating the facts and circumstances surrounding the PL Claim and in litigating the matter.
- 4.16 Indemnification. The Parties shall negotiate indemnification provisions to be included in the Definitive Agreements.

CONFIDENTIAL TREATMENT REQUESTED**5. INDEMNITY, LIMITATION ON LIABILITY, AND DISCLAIMER**

- 5.1 Limitation on Liability. Except with respect to breaches of any confidentiality obligations between the Parties, neither Party will be liable for any special, consequential, lost profit, expectation, punitive, or other indirect damages in connection with any claim arising out of or related to this Agreement, whether grounded in tort (including negligence), strict liability, contract, or otherwise.
- 5.2 Disclaimer. THIS OPTION IS PROVIDED “AS IS”. OTHER THAN AS EXPRESSLY PROVIDED HEREIN, PIERIS DOES NOT MAKE ANY WARRANTIES, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR TITLE AND NONINFRINGEMENT.

6. TERM AND TERMINATION

- 6.1 Term. The term of this Agreement, including the Option Rights, (“**Term**”) begins on the Effective Date and ends on the earlier of:
- (a) ASKA’s written notice to Pieris of ASKA’s decision not to exercise its Option Rights;
 - (b) ASKA’s failure to timely deliver a Satisfaction Notice as described in Section 2.2;
 - (c) three (3) months from date on which Pieris delivers to ASKA the investigator’s report of the final results of the Phase 2a Study in the European Union; or
 - (d) the Parties’ execution of the Definitive Agreements, if any.

ASKA agrees to promptly notify Pieris at any time during the Term if ASKA decides not to exercise its Option Rights. ASKA also agrees to exercise commercially reasonable efforts to provide Pieris with the basis for this determination.

- 6.2 Termination by Pieris. Pieris may terminate this Agreement only in the case of material breach by ASKA of the terms of this Agreement. Pieris shall provide written notice of any such breach to ASKA and ASKA shall have sixty (60) days to cure any such breach prior to termination becoming effective.
- 6.3 No Residual Rights. Upon expiration or termination of this Agreement, ASKA will have no residual or other rights in the Licensed Platform IP or Licensed Product IP.

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7. NOTICES

All notices under this Agreement are deemed fully given when written, addressed, and sent as follows:

All general notices to ASKA are e-mailed or mailed to:

ASKA Pharmaceutical Co., Ltd.
2-5-1, Shibaura, Minato-ku
Tokyo 108-8532 Japan
E-mail: [***]
Attn: [***]

All general notices to Pieris are e-mailed or mailed to:

Pieris Pharmaceuticals
255 State Street, 9th Floor
Boston, MA 02109
Email: [***]
Attn: [***]

Either Party may change its address with written notice to the other Party.

8. CONFIDENTIALITY & PUBLICITY

- 8.1 Confidentiality. The mutual confidential disclosure agreement entered by the Parties [***], (the “CDA”) shall remain in effect after the execution of this Agreement and shall cover the exchange of any Confidential Information (as defined in the CDA) in connection with this Agreement. This Agreement including its terms shall be treated as Confidential Information under the CDA.
- 8.2 Publicity. ASKA and Pieris are authorized to publicly disclose the existence of this Agreement and the Definitive Agreements (if signed). Where disclosure of portions of the terms of this Agreement are required by law (such as a Form 8-K filing or the filing of a redacted copy of this Agreement as may be required by the U.S. Securities and Exchange Commission), the Party making the disclosure shall provide notice and the opportunity for the other Party to comment on such disclosure prior to filing. The Parties may make a press release or other announcement disclosing any terms of this Agreement only with the prior written consent of the other Party. Either Party may make disclosures that includes only

CONFIDENTIAL TREATMENT REQUESTED

information contained in any prior public disclosure without prior permission from the other Party.

9. REPRESENTATIONS AND WARRANTIES

9.1 Mutual Representations and Warranties. Pieris and ASKA each represent and warrant to the other, as of the Effective Date (except as otherwise noted), as follows:

9.1.1 Organization. It is a corporation or company duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement.

9.1.2 Authorization. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate or company action and will not violate (a) such Party's certificate of incorporation or bylaws (or equivalent organizational documents), (b) any agreement, instrument or contractual obligation to which such Party is bound in any material respect, (c) any requirement of any applicable laws, or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party.

9.1.3 Binding Agreement. This Agreement is a legal, valid and binding obligation of such Party, enforceable against it in accordance with its terms and conditions.

9.1.4 No Inconsistent Obligation. It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

9.1.5 Compliance with Law. During the Term, it will comply, and will ensure that its Affiliates comply, with all local, state, federal and international laws and regulations in all material respects in connection with its obligations hereunder.

10. MISCELLANEOUS

10.1 Scope of Agreement. This Agreement constitutes the entire agreement between the Parties pertaining to the subject matter hereof. No representative of Pieris or ASKA has been authorized to make any representation, warranty, or promise not contained herein.

CONFIDENTIAL TREATMENT REQUESTED

- 10.2 Choice of Law. This Agreement shall be governed by and construed in accordance with the laws of New York, without reference to its conflict of laws principles.
- 10.3 Arbitration. In the event of any dispute arising out of or in relation to this Agreement, the Parties will initially attempt to resolve such dispute through good-faith negotiation between Pieris' [***] and ASKA's [***], for a period of not more than [***] following written notification of such dispute to the other Party. If such dispute cannot be resolved by means of such negotiations during such period, then, such dispute, including any question regarding the existence, validity or termination of the Agreement, shall be referred to and finally resolved by arbitration administered by the Singapore International Arbitration Centre ("SIAC") in accordance with the Arbitration Rules of the Singapore International Arbitration Centre ("SIAC Rules") in force at the time, which rules are deemed to be incorporated by reference in this clause. The seat of the arbitration shall be Singapore. The language to be used in the arbitration proceedings will be English. The Arbitration will be conducted by one arbitrator to be agreed upon by the Parties. If the Parties are unable to agree, the arbitrator will be appointed in accordance with SIAC rules. The arbitrator must have at least ten (10) years of experience in biotechnology license agreements and ten (10) years of experience as an arbitrator and shall be thoroughly familiar with New York law. The arbitrator will have the authority to decide the arbitrability of the dispute and to award fees and expenses, including reasonable attorney's fees and the costs of the arbitration, to a Party. The arbitration shall be completed and the award issued within [***] of the appointment of the arbitrator. The Parties agree that all settlement discussions will be confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. The Parties further agree that the arbitration shall be kept confidential and that the existence of the arbitration proceeding and any element of it (including but not limited to any pleadings, briefs or other documents submitted or exchanged, any testimony or other oral submissions, and any awards) shall not be disclosed beyond the tribunal, the SIAC, the Parties, their counsel, accountants and auditors, insurers and re-insurers, and any person or entity necessary to the conduct of the proceeding. The confidentiality obligations in this Section 10.3 shall not apply (i) if disclosure is required by law, or in judicial or administrative proceedings or by financial instruments exchanges, or (ii) as far as disclosure is necessary to enforce the rights arising out of the arbitration award. The award may be confirmed by any court having jurisdiction. The parties consent to the jurisdiction of the state and federal courts of New York for the confirmation and enforcement of the award.
- 10.4 Interim Relief. Without otherwise limiting the requirements imposed by Section 10.3, a Party may seek from any court having jurisdiction any interim or provisional relief provided for by the laws of New York that may be necessary to protect its interests hereunder, including,

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without limitation, injunctive relief for a breach or threatened breach of Section 8 pending the resolution of any dispute in accordance with this Section 10.4. The parties consent to the jurisdiction of the state and federal courts of New York for any interim or provisional relief pursuant to this Section 10.4.

- 10.5 Non-Assignment. ASKA may not assign or delegate its interests or any of its obligations hereunder without the express prior written approval of Pieris.
- 10.6 Headings. No headings in this Agreement affect its interpretation.
- 10.7 Electronic Copy. The Parties to this document agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. The Parties further waive any right to challenge the admissibility or authenticity of this document in a court of law based solely on the absence of an original signature.

[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.*

CONFIDENTIAL TREATMENT REQUESTED

The Parties execute this Agreement in duplicate originals by their duly authorized officers or representatives.

PIERIS PHARMACEUTICALS, INC.

Signature /s/ Stephen S. Yoder

Name Stephen Yoder

Title President and CEO

Date February 24, 2017

PIERIS PHARMACEUTICALS GMBH

Signature /s/ Stephen S. Yoder

Name Stephen Yoder

Title Managing Director

Date February 24, 2017

ASKA PHARMACEUTICAL CO., LTD.

Signature /s/ Takashi Yamaguchi, Ph.D.

Name Takashi Yamaguchi, Ph.D.

Title President and Representative Director

Date February 27, 2017

CONFIDENTIAL TREATMENT REQUESTED

EXHIBIT A

Patent Rights within the Licensed Platform IP

[***]

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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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EXHIBIT B

Patent Rights within the Licensed Product IP

[***]

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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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EXHIBIT C

Success Criteria for Phase 2a Study

[***]

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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.*

CONFIDENTIAL TREATMENT REQUESTED**EXHIBIT D**

The Definitive Agreements, if executed, will include the following upfront and milestone payments, royalties and other terms in consideration of the rights granted under the Licensed Product IP:

- (a) Up-Front Payment Fee. The Definitive Agreements shall include a [***] Dollar (\$ [***] USD) up-front payment fee paid by ASKA to Pieris and due within [***] of the effective date of the Definitive Agreements.
- (b) Initial Indication Development Milestone Payments. The Definitive Agreements shall include the following developmental milestone payments to be paid by ASKA to Pieris:
 - (i) [***] Dollars (\$ [***] USD) upon [***];
 - (ii) [***] Dollars (\$ [***] USD) upon [***]
 - (iii) [***] Dollars (\$ [***] USD) upon [***]
 - (iv) [***] Dollars (\$ [***] USD) upon [***]
 - (v) [***] Dollars (\$ [***] USD) upon [***]
- (c) Initial Indication Development Milestone Payments for [***]. The Parties shall negotiate in good faith regarding appropriate development milestone payments for development of the Licensed Product in [***], taking into account relevant factors including market size and sales forecast.
- (d) Additional Indication Development Milestone Payment. In the event that ASKA decides to develop the Licensed Product for Additional Indications, then the parties shall negotiate in good faith regarding the amount of such development milestone payments, taking into account relevant favors including market size and sales forecast.
- (e) Commercial Milestone Payments. ASKA shall pay Pieris the milestone payments set forth below within [***] after achievement (first occurrence) of the applicable commercial milestone event. For clarity, if multiple commercial milestone events are achieved in a calendar year, then ASKA shall remit to Pieris the milestone payment for all commercial milestones that are first achieved in such calendar year.

CONFIDENTIAL TREATMENT REQUESTED

- (i) [***] Dollars (\$[***] USD) (one-time) upon ASKA first achieving [***] Dollars (\$[***] USD) annual Net Sales of Licensed Product in the Licensed Territory;
 - (ii) [***] Dollars (\$[***] USD) (one-time) upon ASKA first achieving [***] Dollars (\$[***] USD) annual Net Sales of Licensed Product in the Licensed Territory;
 - (iii) [***] Dollars (\$[***] USD) (one-time) upon ASKA first achieving [***] Dollars (\$[***] USD) annual Net Sales of Licensed Product in the Licensed Territory;
 - (iv) [***] Dollars (\$[***] USD) (one-time) upon ASKA first achieving [***] Dollars (\$[***] USD) annual Net Sales of Licensed Product in the Licensed Territory;
 - (v) [***] Dollars (\$[***] USD) (one-time) upon ASKA first achieving [***] Dollars (\$[***] USD) annual Net Sales of Licensed Product in the Licensed Territory;
 - (vi) [***] Dollars (\$[***] USD) (one-time) upon ASKA first achieving [***] Dollars (\$[***] USD) annual Net Sales of Licensed Product in the Licensed Territory;
 - (vii) [***] Dollars (\$[***] USD) (one-time) upon ASKA first achieving [***] Dollars (\$[***]0 USD) annual Net Sales of Licensed Product in the Licensed Territory;
 - (viii) [***] Dollars (\$[***] USD) (one-time) upon ASKA first achieving [***] Dollars (\$[***] USD) annual Net Sales of Licensed Product in the Licensed Territory.
- (f) Royalties. The Definitive Agreements shall include the following royalties on Net Sales to be paid by ASKA to Pieris during the Royalty Term on a country-by-country basis within the Licensed Territory:

| Aggregate Annual Net Sales Amount | Royalty Rate |
|--|---------------------|
|--|---------------------|

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Up to [***] USD [***]%

Between \$[***] and \$[***] USD [***]%

Between \$[***] and \$[***]0 USD [***]%

In excess of \$[***] USD [***]%

- (g) Profit Margin Royalty Adjustments. In the event that gross profits associated with the sale of the Licensed Product in a country of the Licensed Territory falls below [***] percent ([***]%) at the time of the first commercial sale of the Licensed Product or in any subsequent calendar quarter, then the Parties shall discuss in good faith a reduction of royalty burden to Pieris in such country. In the event that gross profits associated with the sale of the Licensed Product in a country of the Licensed Territory rises above [***] percent ([***]%) at the time of first commercial sale of the Licensed Product or in any subsequent calendar quarter, then the Parties shall discuss in good faith an increase in the royalty payable to Pieris for sales of the Licensed Product in such country. In the event that royalties are reduced or increased under this section and gross profits are subsequently restored to above [***]% or below [***]% within a calendar quarter, as applicable, then the royalty rate shall be restored to the level set forth in this agreement. For avoidance of doubt, in case gross profits after such restoration fall again below [***]% or raise above [***]% in any calendar quarter, the previously agreed reduction or increase shall again become effective. In no event, however, shall royalties to Pieris fall below [***] percent ([***]%) of Net Sales. Gross profit shall be further defined in the Definitive Agreements but shall essentially be calculated as Net Sales minus the royalties set forth above and minus cost of goods sold (to be defined in the Definitive Agreement) for the Licensed Product.
- (h) Biosimilar Royalty Reductions. The royalty applicable to the Net Sales of a Licensed Product in the Licensed Territory will be reduced by up to: (i) [***] percent ([***]%) if there is one (1) biosimilar product (to be defined in the Definitive Agreements) for the Licensed Product being commercially sold in the Licensed Territory at the time of such sale; (ii) [***] percent ([***]%) if there are [***] ([***]) biosimilar products for the Licensed Product being sold in the Licensed Territory at the time of such sale; or (iii) [***] percent ([***]%) if there are [***] ([***]) or more

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biosimilar products for the Licensed Product being sold in the Licensed Territory at the time of such sale, in each case, being marketed by a Third Party in the Licensed Territory and where the sales (on a units basis) of at least [***] such generic product exceed [***] ([***]%) of the sales of the Licensed Product (on a units basis) (during the applicable calendar quarter). The actual percentage reduction adjustment (as above) will be negotiated in good faith by the Parties to reflect the impact of the biosimilar product on ASKA, taking into consideration (i) increased marketing costs incurred by ASKA in marketing the Licensed Product, (ii) reduced Net Sales of the Licensed Product or reduced growth of total Net Sales of the Licensed Product and (iii) reduced market share of the Licensed Product, in each case, caused by the entry of such biosimilar product in the Licensed Territory, and in any case not to exceed the applicable cap in reduction set forth above.

- (i) Supply Price. For as long as Pieris has access, Pieris will supply ASKA with Licensed Product drug substance at a price equal to the fully burdened manufacturing cost (to be defined in the Definitive Agreements) of such drug substance plus an additional [***] percent ([***]%).

CONFIDENTIAL TREATMENT REQUESTED**EXHIBIT E**

The Definitive Agreements, if executed, will include the following upfront and milestone payments, royalties and other terms in consideration of the rights granted under the Licensed Platform IP:

- (j) Up-Front Payment Fee. The Definitive Agreements shall include a [***] Dollar (\$[***]USD) up-front payment fee paid by ASKA to Pieris and due within [***] of the effective date of the Definitive Agreements.
- (k) Initial Indication Development Milestone Payments. The Definitive Agreements shall include the following developmental milestone payments to be paid by ASKA to Pieris:
 - (i) [***] Dollars (\$[***] USD) upon [***];
 - (ii) [***] Dollars (\$[***] USD) upon [***];
 - (iii) [***] Dollars (\$[***] USD) upon [***];
 - (iv) [***] Dollars (\$[***]) upon [***].
- (l) Royalties. The Definitive Agreements shall include a [***] royalty on Net Sales of the Licensed Product to be paid by ASKA to Pieris during the Royalty Term on a country-by-country basis within the Licensed Territory.

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

I, Stephen S. Yoder, certify that:

1. I have reviewed this Amendment No. 1 to the quarterly report on Form 10-Q 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: April 26, 2018

/s/ Stephen S. Yoder

Stephen S. Yoder

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

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

I, Allan Reine, certify that:

1. I have reviewed this Amendment No. 1 to the quarterly report on Form 10-Q 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: April 26, 2018

/s/ Allan Reine

Allan Reine

Title: Chief Financial Officer
(principal financial officer)