

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

---

**FORM 10-Q**

---

(Mark One)

**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**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

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)

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)

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, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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.

---

---

---

[Table of Contents](#)

**PIERIS PHARMACEUTICALS, INC.**  
**FORM 10-Q — QUARTERLY REPORT**  
**FOR THE QUARTERLY PERIOD ENDED March 31, 2017**  
**TABLE OF CONTENTS**

	<u>Page</u>
<b><u>PART I – FINANCIAL INFORMATION</u></b>	<b>1</b>
<b><u>Item 1. Financial Statements</u></b>	<b>1</b>
<u>Condensed Consolidated Balance Sheets at March 31, 2017 (unaudited) and December 31, 2016</u>	1
<u>Condensed Consolidated Statements of Operations (unaudited) for the three months ending March 31, 2017 and March 31, 2016</u>	2
<u>Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the three months ending March 31, 2017 and March 31, 2016</u>	3
<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the three months ending March 31, 2017 and March 31, 2016</u>	4
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	5
<b><u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u></b>	<b>15</b>
<b><u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u></b>	<b>21</b>
<b><u>Item 4. Controls and Procedures</u></b>	<b>22</b>
<b><u>PART II – OTHER INFORMATION</u></b>	
<b><u>Item 1. Legal Proceedings</u></b>	<b>22</b>
<u>Item 1A. Risk Factors</u>	22
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	22
<u>Item 3. Defaults Upon Senior Securities</u>	22
<u>Item 4. Mine Safety Disclosures</u>	23
<u>Item 5. Other Information</u>	23
<u>Item 6. Exhibits</u>	24
<b><u>SIGNATURES</u></b>	<b>25</b>

---

## [Table of Contents](#)

### **Currency Presentation and Currency Translation**

Unless otherwise indicated, all references to “dollars,” “\$,” “U.S. \$” or “U.S. dollars” are to the lawful currency of the United States. All references in this Report to “euro” or “€” are to the currency introduced at the start of the third stage of the European Economic and Monetary Union pursuant to the Treaty establishing the European Community, as amended. We prepare our financial statements in U.S. dollars.

The functional currency for most of our operations is the euro. With respect to our financial statements, the translation from the euro to U.S. dollars is performed for balance sheet accounts using exchange rates in effect at the balance sheet date and for revenue and expense accounts using a weighted average exchange rate during the period. The resulting translation adjustments are recorded as a component of other comprehensive income.

Where in this Report we refer to amounts in euros, we have for your convenience also in certain cases provided a conversion of those amounts to U.S. dollars in parentheses. Where the numbers refer to a specific balance sheet account date or financial statement account period, we have used the exchange rate that was used to perform the conversions in connection with the applicable financial statement. In all other instances, unless otherwise indicated, the conversions have been made using the noon buying rate of €1.00 to U.S. \$1.06816 based on [www.oanda.com](http://www.oanda.com) as of March 31, 2017.

### **Forward Looking Statements**

This section and other parts of this Quarterly Report on Form 10-Q contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that involve risks and uncertainties, principally in the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” All statements other than statements of historical fact contained in this Quarterly Report on Form 10-Q, including statements regarding future events, our future financial performance, expectations for growth and revenues, anticipated timing and amounts of milestone and other payments under collaboration agreements, business strategy and plans, objectives of management for future operations, timing and outcome of legal and other proceedings, and our ability to finance our operations are forward-looking statements. We have attempted to identify forward-looking statements by terminology including “anticipates,” “believes,” “can,” “continue,” “ongoing,” “could,” “estimates,” “expects,” “intends,” “may,” “appears,” “future,” “likely,” “plans,” “potential,” “projects,” “predicts,” “should,” “would,” or “will” or the negative of these terms or other comparable terminology. Although we do not make forward looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under “Risk Factors” or elsewhere in our most recent Annual Report on Form 10-K, which may cause our or our industry’s actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements to differ materially.

Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements. Actual results could differ materially from our forward-looking statements due to a number of factors, including, without limitation, risks related to: the results of our research and development activities, including uncertainties relating to the discovery of potential drug candidates and the preclinical and ongoing or planned clinical testing of our drug candidates; the early stage of our drug candidates presently under development; our ability to obtain and, if obtained, maintain regulatory approval of our current drug candidates and any of our other future drug candidates; our need for substantial additional funds in order to continue our operations and the uncertainty of whether we will be able to obtain the funding we need; our future financial performance; our ability to retain or hire key scientific or management personnel; our ability to protect our intellectual property rights that are valuable to our business, including patent and other intellectual property rights; our dependence on third-party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators; our ability to successfully market and sell our drug candidates in the future as needed; the size and growth of the potential markets for any of our approved drug candidates, and the rate and degree of market acceptance of any of our approved drug candidates; competition in our industry; and regulatory developments in the United States and foreign countries.

You should not place undue reliance on any forward-looking statement, each of which applies only as of the date of this Quarterly Report on Form 10-Q. Before you invest in our securities, you should be aware that the occurrence of the events described in Part I, Item 1A (Risk Factors) of our Annual Report on Form 10-K for the year ended December 31, 2016 filed on March 30, 2017, could negatively affect our business, operating results, financial condition and stock price. All forward-looking statements included in this document are based on information available to us on the date hereof, and except as required by law, we undertake no obligation to update or revise publicly any of the forward-looking statements after the date of this Quarterly Report on Form 10-Q to conform our statements to actual results or changed expectations.

[Table of Contents](#)

## PART I — FINANCIAL INFORMATION

## Item 1. Financial Statements.

**CONDENSED CONSOLIDATED BALANCE SHEETS**

	<u>March 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash	\$ 55,241,957	\$ 29,355,528
Accounts receivable	39,013	57,582
Prepaid expenses and other current assets	<u>3,475,013</u>	<u>3,259,503</u>
<b>Total current assets</b>	58,755,983	32,672,613
Property and equipment, net	2,993,005	2,264,477
Other non-current assets	<u>126,193</u>	<u>125,741</u>
<b>Total assets</b>	<u>\$ 61,875,181</u>	<u>\$ 35,062,831</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 3,317,122	\$ 2,386,183
Accrued expenses and other current liabilities	2,958,877	3,719,457
Deferred revenues, current portion	<u>5,168,614</u>	<u>2,274,514</u>
<b>Total current liabilities</b>	11,444,613	8,380,154
Deferred revenue, net of current portion	32,352,662	1,409,483
Other long-term liabilities	<u>42,086</u>	<u>46,667</u>
<b>Total liabilities</b>	<u>43,839,361</u>	<u>9,836,304</u>
<b>Stockholders' equity:</b>		
Preferred stock, \$0.001 par value per share, 4,963 shares authorized and 4,963 and 4,963 issued and outstanding at March 31, 2017 and December 31, 2016	5	5
Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 43,058,827 and 43,058,827 issued and outstanding at March 31, 2017 and December 31, 2016	43,059	43,059
Additional paid-in capital	130,101,961	129,349,768
Accumulated other comprehensive loss	(1,450,617)	(1,501,452)
Accumulated deficit	<u>(110,658,588)</u>	<u>(102,664,853)</u>
<b>Total stockholders' equity</b>	<u>18,035,820</u>	<u>25,226,527</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 61,875,181</u>	<u>\$ 35,062,831</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

---

[Table of Contents](#)

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**

	<b>Three months ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
Revenue	\$ 1,343,300	\$ 1,246,644
Operating expenses:		
Research and development	5,359,956	3,659,435
General and administrative	3,988,880	1,967,883
Total operating expenses	9,348,836	5,627,318
Loss from operations:	(8,005,536)	(4,380,674)
Interest income, net	100	—
Other income (expense), net	11,701	219,620
Loss before income taxes	(7,993,735)	(4,161,054)
Provision for income tax	—	—
Net Loss	<u>\$ (7,993,735)</u>	<u>\$ (4,161,054)</u>
Net loss per share		
Basic and diluted	\$ (0.19)	\$ (0.10)
Weighted average number of shares outstanding		
Basic and diluted	<u>43,063,790</u>	<u>39,833,023</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

---

[Table of Contents](#)

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)**

	<b>Three months ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
Net loss	\$ (7,993,735)	\$ (4,161,054)
Other comprehensive income/(loss) components:		
Foreign currency translation	50,834	(163,340)
Total other comprehensive income/(loss)	50,834	(163,340)
Comprehensive loss	\$ (7,942,901)	\$ (4,324,394)

The accompanying notes are an integral part of these condensed consolidated financial statements.

[Table of Contents](#)**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**

	<b>Three months ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Operating activities:</b>		
Net loss	\$ (7,993,735)	\$ (4,161,054)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	100,348	94,521
Stock-based compensation	752,193	368,383
Changes in operating assets and liabilities:		
Accounts receivable	19,328	(68,870)
Prepaid expenses and other assets	(81,149)	(1,185,384)
Deferred Revenue	33,516,454	5,838,737
Accounts payable	263,025	597,189
Accrued expenses and other current liabilities	(805,903)	543,037
Net cash provided by operating activities	<u>25,770,561</u>	<u>2,026,559</u>
<b>Investing activities:</b>		
Purchase of property and equipment	(179,066)	(67,919)
Net cash used in investing activities	<u>(179,066)</u>	<u>(67,919)</u>
<b>Financing activities:</b>		
Net cash used in financing activities	—	—
Effect of exchange rate change on cash and cash equivalents	294,934	(119,236)
Net increase in cash and cash equivalents	25,886,429	1,839,403
Cash and cash equivalents at beginning of year	<u>29,355,528</u>	<u>29,349,124</u>
Cash and cash equivalents at end of year	<u>\$55,241,957</u>	<u>\$31,188,527</u>
Supplemental cash flow disclosures:		
Property and equipment included in accounts payable	\$ 613,406	\$ —

The accompanying notes are an integral part of these condensed consolidated financial statements.



**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)**

**1. Interim Consolidated Financial Statements**

The accompanying unaudited interim condensed consolidated financial statements of Pieris Pharmaceuticals, Inc. (“Pieris” or the “Company”) were prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”) for interim financial information. All significant intercompany balances and transactions have been eliminated in the consolidation. Certain information and footnotes normally included in financial statement prepared in accordance with U.S. GAAP have been omitted pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Accordingly, the statements do not include all of the information and notes required by U.S. GAAP for complete annual consolidated financial statements. It is recommended that these financial statements be read in conjunction with the consolidated financial statements and related footnotes that appear in the Annual Report on Form 10-K of the Company for the year ended December 31, 2016 filed with the SEC on March 30, 2017 (the “2016 Annual Report”).

In the opinion of management, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited condensed consolidated financial statements for the year ending December 31, 2016, and all adjustments, including normal recurring adjustments, considered necessary for the fair presentation of the Company’s unaudited interim consolidated financial statements have been included. The results of operations, for the three months ended March 31, 2017, are not necessarily indicative of the results that may be expected for the year ending December 31, 2017 or any future period.

**Use of estimates**

The preparation of the condensed consolidated financial statements in accordance with U.S. GAAP requires management to make estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities, the reported amounts of revenues, and expenses in the financial statements and disclosures in the accompanying notes. Significant estimates are used for, but are not limited to, revenue recognition, deferred tax assets, liabilities and valuation allowances, fair value of stock options and various accruals. Management evaluates its estimates on an ongoing basis. Actual results and outcomes could differ materially from management’s estimates, judgments and assumptions.

**2. Critical Accounting Policies**

**Research and development expenses**

Research and development expenses are charged to the statement of operations as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries and benefits, facilities costs, pre-clinical and clinical costs, contract services, consulting, depreciation and amortization expense, and other related costs. Costs associated with acquired technology, in the form of upfront fees or milestone payments, are charged to research and development expense as incurred.

**Revenue Recognition**

Pieris has entered into several licensing and development agreements with collaboration partners for the development of Anticalin<sup>®</sup> therapeutics against a variety of targets in diseases and conditions. The terms of these agreements contain multiple elements and deliverables, which may include: (i) licenses, or options to obtain licenses, to Pieris’ Anticalin technology and (ii) research activities to be performed on behalf of the collaborative partner. Payments to Pieris, under these agreements, may include upfront fees (which include license and option fees), payments for research activities, payments based upon the achievement of certain milestones and royalties on product sales. There are no performance, cancellation, termination, or refund provisions in any of the arrangements. Pieris follows the provisions of the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements* and ASC Topic 605-28, *Revenue Recognition—Milestone Method* in accounting for these agreements.

Multiple-Element Arrangements

When evaluating multiple-element arrangements, Pieris identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting based on whether the delivered element has stand-alone value to the customer or if the arrangement includes a general right of return for delivered items.

---

## Table of Contents

The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units of accounting. Pieris has used best estimate of selling price (“BESP”) methodology to estimate the selling price for licenses and options to acquire additional licenses to its proprietary technology because Pieris does not have vendor specific objective evidence (“VSOE”) or third party evidence (“TPE”) of selling price for these deliverables. To determine the estimated selling price of a license to its proprietary technology, Pieris considers market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements, terms of previous collaborative agreements, similar agreements entered into by third parties, market opportunity, estimated development costs, probability of success, and the time needed to commercialize a product candidate pursuant to the license. In validating Pieris’ best estimate of selling price, Pieris evaluates whether changes in the key assumptions used to determine the best estimate of selling price will have a significant effect on the allocation of arrangement consideration among multiple deliverables.

Multiple element arrangements, such as license and development arrangements, are analyzed to determine whether the deliverables, which often include a license and performance obligations such as research and steering committee services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with U.S. GAAP. The Company recognizes up-front license payments as revenue upon delivery of the license only if the license has stand-alone value. If the license is considered to not have stand-alone value, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

If the Company is involved in a steering committee as part of a multiple element arrangement, the Company assesses whether its involvement constitutes a performance obligation or a right to participate. Steering committee services that are determined to be performance obligations, are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its aggregate performance obligations.

The Company recognizes arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605 are satisfied for that particular unit of accounting. Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. The Company recognizes revenue using the proportional performance method provided the Company can reasonably estimate the level of effort required to complete its performance obligations under an arrangement and such performance obligations are provided on a best-effort basis. Full-time equivalents are typically used as the measure of performance.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement.

The accounting treatment for options granted to collaborators is dependent upon the nature of the option granted to the collaborative partner. Options are considered substantive if, at the inception of an agreement, Pieris is at risk as to whether the collaborative partner will choose to exercise the options to secure additional goods or services. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the agreement without exercising the options, the cost to exercise the options relative to the total upfront consideration, and the additional financial commitments or economic penalties imposed on the collaborator as a result of exercising the options.

In arrangements where options to obtain additional deliverables are considered substantive, Pieris determines whether the optional licenses are priced at a significant and incremental discount. If the prices include a significant and incremental discount, the option is considered a deliverable in the arrangement. However, if not priced at a discount, the elements included in the arrangement are considered to be only the non-contingent elements. When a collaborator exercises an option to acquire an additional license, the exercise fee that is attributed to the additional license and any incremental discount allocated at inception are recognized in a manner consistent with the treatment of up-front payments for licenses (*i.e.*, license and research services). In the event an option expires un-exercised, any incremental discounts deferred at the inception of the arrangement are recognized into revenue upon expiration. For options that are non-substantive, the additional licenses to which the options pertain are considered deliverables upon inception of the arrangement, and Pieris applies the multiple-element revenue recognition criteria to determine accounting treatment. All of Pieris’ agreements with options have been determined to include substantive options.

Payments or reimbursements resulting from Pieris’ research and development efforts in multi-element arrangements, in which Pieris’ research and development efforts are considered deliverable, are recognized as the services are performed and are presented on a gross

---

## Table of Contents

basis so long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is reasonably assured. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets.

### Milestone Payments and Royalties

At the inception of each agreement that includes milestone payments, Pieris evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. Pieris evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

Pieris aggregates milestones into four categories: (i) research milestones, (ii) development milestones, (iii) commercial milestones and (iv) sales milestones. Research milestones are typically achieved upon reaching certain success criteria as defined in each agreement related to developing an Anticalin protein against the specified target. Development milestones are typically reached when a compound reaches a defined phase of clinical research or passes such phase, or upon gaining regulatory approvals. Commercial milestones are typically achieved when an approved pharmaceutical product reaches the status for commercial sale or certain defined levels of net sales by the licensee, such as when a product first achieves global sales or annual sales of a specified amount. Sales milestones are typically achieved when an approved pharmaceutical product exceeds net sales as defined in each agreement.

For revenues from research, development, and sales milestone payments, if the milestones are deemed substantive and the milestone payments are nonrefundable, such amounts are recognized entirely upon successful accomplishment of the milestones. Milestones that are not considered substantive are accounted for as license payments and recognized on a straight-line basis over the period of performance. Revenues from commercial milestone payments are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. Royalty payments are recognized in revenues based on the timing of royalty payments earned in accordance with the agreements, which typically is the period when the relevant sales occur, assuming all other revenue recognition criteria are met.

## **3. Revenues**

### **General**

Pieris has not generated revenues from product sales to date. Pieris has generated revenues from: (i) license and collaboration agreements, which include upfront payments for licenses or options to obtain licenses, payments for research and development services and milestone payments and (ii) government grants.

### *F.Hoffmann-La Roche Ltd. and Hoffmann- La Roche Inc.*

In December 2015, the Company entered into a Research Collaboration and License Agreement (the "Roche Agreement") with F.Hoffmann- La Roche Ltd. and Hoffmann- La Roche Inc., ("Roche"), for the research, development, and commercialization of Anticalin®-based drug candidates against a predefined, undisclosed target in cancer immune therapy. The parties will jointly pursue a preclinical research program with respect to the identification and generation of Anticalin proteins that bind to a specific target for an initial period of 20 months, which may be extended by Roche for up to an additional 12 months. Roche has the ability to continue certain exclusivity rights for up to an additional 5 years following the end of the research program. Both Roche and the Company will participate in a joint research committee in connection with this agreement. Following the research program, Roche will be responsible for subsequent pre-clinical and clinical development of any product developed through the research plan and will have worldwide commercialization rights to any such product.

Roche has paid \$6.5 million of an upfront payment for the research collaboration. Additionally, Roche will pay Pieris for research services provided by Pieris in conjunction with the research program. Roche will also pay Pieris for certain milestones relating to development, regulatory, and sales milestones as they are achieved. As of March 31, 2017 and March 31, 2016, deferred revenue, related to Roche collaboration, is \$3.1 million and \$6.0 million, respectively.

Pieris recorded \$1.0 million and \$1.2 million in revenue for the three months ended March 31, 2017 and March 31, 2016, respectively, related to the recognition of the upfront payment associated with the portion of the research services performed during the period as well as the value of research services provided by Pieris in connection with the ongoing research program.

---

## Table of Contents

The Company identified the research and commercial licenses, performance of R&D services, and participation in the joint research committee as deliverables under the Roche Agreement. For revenue recognition purposes, management has determined that there are two units of accounting at the inception of the agreement representing (i) the research and commercial licenses and the performance of R&D services which do not have standalone value, and (ii) the participation in the joint research committee.

In addition to the upfront payment, under the Roche Agreement, the Company is eligible to receive research funding, development and regulatory, and sales based milestone payments up to approximately \$406.5 million, plus royalties on future sales of any commercial products. The total potential milestones are categorized as follows: development and regulatory milestones—\$282.7 million; and sales milestones—\$119.9 million. Management has determined that the development milestones are not substantive because they do not relate solely to past performance of the Company and the Company's involvement in the achievement is limited to progress reports and other updates. Non-substantive milestones will be recognized when achieved to the extent the Company has no remaining performance obligations under the arrangement.

### Les Laboratoires Servier and Institut de Recherches Internationales Servier

On January 4, 2017, Pieris entered into a License and Collaboration Agreement (“Collaboration Agreement”), and Non-Exclusive Anticalin Platform Technology Agreement (the “License Agreement” and together with the Collaboration Agreement, the “Agreements”) with Les Laboratoires Servier and Institut de Recherches Internationales Servier (collectively “Servier”) pursuant to which Pieris and Servier will initially pursue five bispecific therapeutic programs, led by the PRS-332 program (the “Lead Product”), a PD-1-targeting bispecific checkpoint inhibitor. Pieris and Servier will jointly develop PRS-332 and split commercial rights geographically, with Pieris retaining all commercial rights in the United States and Servier having commercial rights in the rest of the world. Each party is responsible for an agreed upon percentage of shared costs, as set forth in the budget for the joint development plan, and as further discussed below.

Four additional committed programs have been defined, which may combine antibodies from the Servier portfolio with one or more Anticalin proteins based on Pieris' proprietary platform to generate innovative immuno-oncology bispecific drug candidates. The collaboration may be expanded by up to three additional therapeutic programs. Pieris has the option to co-develop and retain commercial rights in the United States for up to three programs beyond PRS-332 (“Co-Development Collaboration Products”), while Servier will be responsible for development and commercialization of the other programs worldwide (“Servier Worldwide Collaboration Products”). Each party is responsible for an agreed upon percentage of shared costs, as set forth in the budget for the collaboration plan, and further discussed below.

Co-Development Collaboration Products may be jointly developed, according to a collaboration plan, through marketing approval from the FDA or EMA. Servier Worldwide Collaboration Products may be jointly developed, according to a collaboration plan, through specified preclinical activities, at which point Servier becomes responsible for the further development of the collaboration product.

At inception, Servier is granted the following licenses: (i) development license for the Lead Product, (ii) commercial license for the Lead Product, (iii) individual research licenses for each of the four collaboration programs, and (iv) individual non-exclusive platform technology licenses for each of the Lead Product and four collaboration programs. Upon achievement of certain development activities, specified by the collaboration for each Collaboration Product, Servier will be granted a development license and a commercial license. For the Lead Product and Co-Development Collaboration Products, the licenses granted are with respect to the entire world except for the United States. For Servier Worldwide Collaboration Products, the licenses granted are with respect to the entire world.

The Agreements will be managed on an overall basis by a joint executive committee (“JEC”) formed by an equal number of members from the Company and Servier. Decisions by the JEC will be made by consensus, however, in the event of a disagreement, each party will have final-decision making authority as it relates to the applicable territory in which such party has commercialization rights for the applicable product. In addition to the JEC, the Collaboration Agreement, also requires the participation of both parties on: (i) a joint steering committee (“JSC”), (ii) a joint development committee (“JDC”), (iii) a joint intellectual property committee (“JIPC”), and (iv) a joint research committee (“JRC”). The responsibilities of these committees vary, depending on the stage of development and commercialization of each of the Lead Product and collaboration programs.

For the Lead Product and Co-Development Collaboration Products, Pieris and Servier are responsible for an undisclosed amount of the shared costs required to develop the products through commercialization. In the event that Pieris fails to exercise their option to co-develop the Co-Development Collaboration Products, and Servier has the right to continue with development alone.

---

## Table of Contents

Under the Agreements, the Company received an upfront, non-refundable payment of €30.0 million (approximately \$32.0 million). In addition, the Company is eligible to receive development and regulatory and sales-based milestone payments. The total potential milestones are categorized as follows: development and regulatory milestones – up to €569.0 million; and sales milestones – up to €515.0 million. The initial research collaboration term, as it relates to the collaboration programs, shall continue for three years from the effective date, and may be mutually extended for two one-year terms consecutively applied. The term of the Agreements ends upon the expiration of all Servier's payment obligations under such Agreement.

The Company accounted for the Agreements, as a multiple element arrangement under ASC 605-25. The arrangement with Servier contains the following initial deliverables: (i) five non-exclusive platform technology licenses, (ii) development license for the Lead Product, (iii) commercial license for the Lead Product, (iv) research and development services for the Lead Product, (v) participation on each of the committees, (vi) four research licenses for collaboration programs, and (vii) research and development services for the collaboration programs. Additionally, as the development and commercial licenses on the collaboration programs may be granted at discount in the future, the Company determined that discounts should be included as an element of the arrangement at inception.

Management considered whether any of the deliverables could be considered separate units of accounting. The Company determined that the licenses granted at the inception of the arrangement did not have standalone value from the research and development services to be provided for the Lead Product and collaboration programs, over the term of the Agreements, due to the specific nature of the intellectual property and knowledge required to perform the services. The Company determined that the participation on the various committees did have standalone value as the services could be performed by an outside party.

As a result, management concluded that there were fourteen units of accounting at the inception of the agreement: (i) combined unit of accounting representing a non-exclusive platform technology license, commercial license, development license and research and development services for the Lead Product, (ii) four units of accounting each representing a combined non-exclusive platform technology license, research license, and research and development services for each collaboration program, (iii) one unit of accounting representing the participation of the various governance committees, and (iv) four units of accounting representing the discounts on the development and commercial licenses granted for the collaboration programs upon the achievement of specified preclinical activities.

The Company determined that neither VSOE nor TPE is available for any of the units of accounting identified at the inception of the arrangement. Accordingly, the selling price of each unit of accounting was developed using management's BEP. The Company developed their best estimate of selling price for licenses by applying a risk adjusted, net present value, of estimate of future potential cash flow approach, which included the cost of obtaining research and development services at arm's length from a third-party provider, as well as internal full time equivalent costs to support these services.

The Company developed the BEP for committee participation by using management's best estimate of the anticipated participation hours multiplied by a market rate for comparable participants.

---

## Table of Contents

The Company developed the best estimate of selling price for the discounts granted on the licenses by probability weighting multiple cash flow scenarios using the income approach.

Allocable arrangement consideration at inception is comprised of the upfront fee of €30.0 million (approximately \$32.0 million) and was allocated among the separate units of accounting using the relative selling price method as follows (i) combined unit of accounting for the Lead Product: (ii) four units of accounting for the collaboration programs, (iii) one unit of accounting representing participation in each of the committees, and (iv) four units of accounting representing the discount on development and commercial licenses granted in the future.

The amounts allocated to the combined unit of accounting for the Lead Product and four units of accounting for the collaboration programs will be recognized on a proportional performance basis as the activities are conducted over the life of the arrangement. The term of the performance at inception of the agreement for the Lead Product and each of the co-developed collaboration programs may be through approval of certain regulatory bodies; a period which could be many years. The term of the performance at inception of the agreement for each of the other collaboration programs for which Servier obtained world-wide rights is approximately two to three years. The amounts allocated to the participation on each of the committees will be recognized ratably over the anticipated performance period over the entirety of the arrangement with Servier. The amounts allocated to the discounts of the development and commercial licenses granted in the future will be recognized upon delivery of each of the licenses assuming no other performance obligations.

Additionally, the Company evaluated payments required to be made between both parties as a result of the shared development costs of the Lead Product and Co-Development Collaboration Products. The Company will classify payments made as research and development expenses and will classify payments received as a reduction in research and development expenses, in the period they are incurred.

Under the agreement the Company is eligible to receive various development and regulatory and sales milestones. Management determined that certain of the development and regulatory milestones which may be received under the Servier Agreements are substantive when the Company is involved in the development and commercialization of the applicable product. Payments related to the achievement of such milestones, if any, will be recognized as revenue when the milestone is achieved. Total potential substantive development and regulatory milestones are up to €163.0 million. Development and regulatory milestones are deemed non-substantive if they are based solely on the performance of another party. Non-substantive milestones will be treated as contingent revenue and will be recognized when achieved to the extent the Company has no remaining performance obligations under the arrangement. Milestone payments earned upon the achievement of sales events will be recognized when earned. Total potential non-substantive development and regulatory milestones are up to €406.0 million and sales milestones are up to €515.0 million.

The Company will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

Pieris recorded \$0.3 million in revenue for the three months ended March 31, 2017, with respect to the Agreements with Servier. Research and development expense incurred by the Company in relation to its performance under the agreement for the three months ended March 31, 2017 was \$0.5 million. As of March 31, 2017, there is \$2.9 million and \$28.9 million of deferred revenue and non-current deferred revenue, respectively, related to the Company's collaboration with Servier.

### ASKA Pharmaceutical Co. Ltd.

On February 27, 2017 the Company entered into an Exclusive Option Agreement (the "Agreement") with ASKA Pharmaceutical Co., Ltd. ("ASKA") to grant ASKA an option to acquire (1) a non-exclusive license to certain intellectual property rights associated with the Pieris' Anticalin platform ("Licensed Platform IP") and (2) an exclusive license to certain intellectual property rights specifically related to Pieris' PRS-080 Anticalin protein ("Licensed Product IP") in order to develop, manufacture, import, sale, export, and offer for sale and export any pharmaceutical formulation containing PRS-080, the Company's pegylated Anticalin protein targeting hepcidin ("Licensed Product") in Japan and certain other Asian territories ("Licensed Territory").

ASKA has paid \$2.75 million of an upfront option payment. Pieris is obliged to use commercially reasonable efforts to complete the Phase 2a Study for PRS-080 and to submit to ASKA in writing the final results of the study when available. Upon receipt, ASKA will have 60 days to evaluate the results of the Phase 2a Study ("Evaluation Period"). ASKA agreed to notify Pieris in writing its decision to exercise its option to acquire rights to the Licensed Product. In consideration of the licenses granted as part of the Agreement, ASKA will pay an undisclosed license fee. If the Phase 2a Study meets the applicable success criteria and ASKA fails to provide notification that it will exercise its option, ASKA shall pay the Company an undisclosed fee within thirty days of the end of the Evaluation Period (the "Break-Up Fee"). If ASKA exercises the option, ASKA and the Company will enter into a definitive arrangement governing the future development and commercialization activities.

Pieris has an obligation to use all reasonable commercial efforts to complete the Phase 2a Study for the Licensed Product and to submit to ASKA in writing the final results of said study. Failure to do so would result in a significant contractual penalty. The completed Phase 2a Study represents a deliverable under the arrangement. As the arrangement only contains one deliverable, there is only one unit of accounting to be considered at the inception of the contract. The total allocable arrangement consideration at



## [Table of Contents](#)

inception is \$2.75 million and this is allocated to the single unit of accounting. The Company noted that while the completion of the Phase 2a trial requires the completion of a number of actions, the finalization of the data and evaluation of results is of such significance that the value of the Phase 2a Study Results is realized at this point. As a result, the Company will recognize revenue for this unit of accounting upon delivery of the Phase 2a Study Results to ASKA. Therefore, no revenue in connection with this arrangement was recognized in the three months ended March 31, 2017. As of March 31, 2017, there is \$2.75 million of non-current deferred revenue related to the Company's option agreement with ASKA.

### 4. Net Loss per Share

Basic net loss per share was determined by dividing net loss by the weighted average shares outstanding during the period. Diluted net loss per share was determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflect the dilutive effect, if any, of common stock options based on the treasury stock method.

For all financial statement periods presented the number of basic and diluted weighted average shares outstanding remained the same as an increase in the number of shares of common stock equivalents for the periods presented would be antidilutive.

For the three months ended March 31, 2017 and 2016, approximately 11.2 million and 3.5 million weighted average shares, subject to stock options and warrants, respectively, as calculated using the treasury stock method, were excluded from the calculation of diluted weighted average shares outstanding as their effect was antidilutive.

### 5. Fair Value Measurement

ASC Topic 820 *Fair Value Measurement* defines fair value as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants at the measurement date. Pieris applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement:

Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.

Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

For the periods presented in these interim financial statements, Pieris has no cash equivalents and debt instruments as of each balance sheet date presented.

All other current assets and current liabilities on our consolidated balance sheets approximate their respective carrying amounts.

### 6. Accrued expenses

The Company has recorded the following accrued expenses as of March 31, 2017 and December 31, 2016, respectively:

	March 31, 2017	December 31, 2016
Accrued expenses		
Accrued compensation expense	\$ 844,786	\$ 1,198,448
Accrued professional fees	782,203	867,969
Accrued R&D fees	777,573	1,040,321
Accrued audit and tax fees	374,548	454,931
Accrued other	179,767	157,788
<b>Total accrued expenses</b>	<b><u>\$2,958,877</u></b>	<b><u>\$ 3,719,457</u></b>

## [Table of Contents](#)

### 7. Stock-based compensation

#### 2014 Stock Plan

Pieris granted 1,068,881 options to employees, consultants, and directors under its 2014 Employee, Director, and Consultant Equity Incentive Plan, (the "2014 Plan") during the three months ended March 31, 2016. The 2014 Plan was terminated on June 28, 2016 when the Company adopted its 2016 Employee, Director and Consultant Equity Incentive Plan, (the "2016 Plan"). Therefore, no options were granted for the three months ended March 31, 2017 under the 2014 Plan.

#### 2016 Stock Plan

In June 2016, the Company adopted the 2016 Plan which provides for the grant of stock options, restricted and unrestricted stock awards, and other stock-based awards to employees of the Company, non-employee directors of the Company, and certain other consultants performing services for the Company as designated by the Compensation Committee of the Board of Directors or the Board of Directors. The vesting periods of equity incentives issued under the 2016 Plan are determined by the Compensation Committee of the Company's Board of Directors, with stock options generally vesting over a four-year period.

The Company granted 1,140,338 options to employees and directors under the 2016 Plan during the three months ended March 31, 2017. No options were granted under the 2016 Plan during the three months ended March 31, 2016. As of March 31, 2017, there were 2,201,828 shares available for future grant under the 2016 Plan. The shares available for future grant under the 2016 Plan include 217,530 shares which were forfeited under the 2016 Plan and 90,000 shares which were forfeited under the 2014 Plan. These forfeited shares were added back to the 2016 Plan.

Stock-based compensation expense was \$0.8 million and \$0.4 million for the three months ended March 31, 2017 and 2016, respectively.

Total stock-based compensation expense was recorded to operating expenses based upon the functional responsibilities of the individuals holding the respective options as follows:

	Three months ended March 31,	
	2017	2016
Research and development	\$166,611	\$126,441
General and administrative	585,581	241,942
Total stock-based compensation	\$752,193	\$368,383

There were no options exercised during the three months ended March 31, 2017 and 2016, respectively.

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for stock-based awards. Option-pricing models require the input of various subjective assumptions, including the option's expected life, expected dividend yield, price volatility, risk free interest rate, and forfeitures of the underlying stock. Accordingly, the weighted-average fair value of the options granted was \$1.31 and \$1.00 for the three months ended March 31, 2017 and 2016, respectively. The calculation was based on the following assumptions:

	Three months ended March 31,	
	2017	2016
Risk free interest rate	2.04%-2.16%	1.35%-1.61%
Expected term	5.0 – 5.7 years	5.0 – 5.7 years
Dividend yield	—	—
Expected volatility	75.09%-75.13%	75.53%-76.00%

Option-pricing models require the input of various subjective assumptions, including the option's expected life and the price volatility of the underlying stock. Pieris' estimated expected stock price volatility is based on the average volatilities of other guideline companies in the same industry. Pieris' expected term of options granted during the three months ended March 31, 2017 and 2016, respectively was derived using the SEC's simplified method. The risk-free rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant.



---

## [Table of Contents](#)

The Company's stock options have a maximum term of ten years from the date of grant. Stock options granted under the 2016 Plan may be either incentive stock options ("ISOs"), or nonqualified stock options ("NQSOs"). The exercise price of stock options granted under the 2016 Plan must be at least equal to the fair market value of the common stock on the date of grant.

### **8. Liquidity and Going Concern**

The Company believes its cash of \$55.2 million as of March 31, 2017 and the \$57.5 million to be received from the AstraZeneca subsequent to March 31, 2017 will be sufficient to fund the Company's current operating plan for at least twelve months from the date of filing. The Company may need to raise additional funds in order to execute the current operating plan in the future. There can be no assurance that the Company will be able to obtain future additional debt, equity financing, or generate product revenue or revenues from collaborative partners, on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations, and financial condition.

### **9. Recent Accounting Pronouncements**

#### Adopted standards for current period

In August 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" which is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its financial obligations as they become due within one year after the date that the financial statements are issued (or are available to be issued). ASU No. 2014-15 provides guidance to an organization's management, with principles and definitions intended to reduce diversity in the timing and content of disclosures commonly provided by organizations in the footnotes of their financial statements. ASU No. 2014-15 is effective for annual reporting periods ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. This standard has been adopted as of March 31, 2017, and the Company does not believe it is required to make any additional disclosures.

#### Standards not yet adopted

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"). Subsequently, the FASB also issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606), which adjusted the effective date of ASU 2014-09; ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which amends the principal-versus-agent implementation guidance and illustrations in ASU 2014-09; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies identifying performance obligation and licensing implementation guidance and illustrations in ASU 2014-09; and ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, which addresses implementation issues and is intended to reduce the cost and complexity of applying the new revenue standard in ASU 2014-09 (collectively, the "Revenue ASUs").

---

## Table of Contents

The Revenue ASUs provide an accounting standard for a single comprehensive model for use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The accounting standard is effective for interim and annual periods beginning after December 15, 2017, with an option to early adopt for interim and annual periods beginning after December 15, 2016. The guidance permits two methods of adoption: retrospectively to each prior reporting period presented (the full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). We currently anticipate adoption of the new standard effective January 1, 2018 under the modified retrospective method. The Company is in the process of determining the impact of the Revenue Recognition ASUs on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)". Under the amendments in ASU 2016-02 lessees will be required to recognize (i) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term for all leases (with the exception of short-term leases) at the commencement date. This guidance is effective for fiscal years beginning after December 15, 2019 including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the potential impact the adoption of this standard will have on its financial statements and related disclosures.

Pieris has considered other recent accounting pronouncements and concluded that they are either not applicable to the business, or that the effect is not expected to be material to the unaudited condensed consolidated financial statements as a result of future adoption.

### **10. Subsequent Events**

#### *License and Collaboration Agreement and Non-Exclusive Anticalin Platform Technology License Agreement with AstraZeneca*

On May 2, 2017, the Company and wholly-owned subsidiaries Pieris Pharmaceuticals GmbH and Pieris Australia Pty Ltd. entered into a License and Collaboration Agreement (the "AstraZeneca Collaboration Agreement") and a Non-Exclusive Anticalin<sup>®</sup> Platform Technology License Agreement (the "License Agreement" and together with the AstraZeneca Collaboration Agreement, the "Agreements") with AstraZeneca AB ("AstraZeneca"), pursuant to which the parties will advance several novel inhaled biologic molecules leveraging the unique properties of Pieris' Anticalin<sup>®</sup> proteins, including Pieris' lead inhaled drug candidate, PRS-060.

Under the Agreements, Pieris and AstraZeneca will pursue up to five therapeutic programs, including PRS-060, a first-in-class inhaled IL-4Ra receptor antagonist for the treatment of asthma. Pieris will receive \$57.5 million in up-front and near-term milestone payments, including \$45 million of up-front payments and \$12.5 million for the initiation of the PRS-060 Phase 1 trial. Pieris may receive development, regulatory and sales-based milestone payments not exceeding \$2.1 billion if all five programs are successfully commercialized. In addition, Pieris will be entitled to receive tiered royalties up to the mid-teens, depending on the product, on sales of products commercialized by AstraZeneca or royalties up to the high teens or a gross margin share on worldwide sales, determined by the level of investment to which Pieris commits, for any co-developed programs. For co-developed programs, the milestone payments are structured to provide Pieris with income in stages in order to contribute to the ensuing phases of development.

Pieris will be responsible for advancing PRS-060 into clinical trials in the second half of 2017 and will conduct a Phase 1 trial, with clinical development costs covered by AstraZeneca. The parties will collaborate thereafter to conduct a Phase 2a clinical trial in asthma patients, with AstraZeneca continuing to fund development costs. After completion of the Phase 2a trial, Pieris has the option to co-develop and subsequently co-commercialize the program in the United States with AstraZeneca. For the other four programs, Pieris will be responsible for the initial discovery of novel Anticalin proteins, after which AstraZeneca will take the lead on continued development. Pieris has the option to co-develop two of these programs beginning at a pre-defined preclinical stage and would also have the option to co-commercialize these programs in the United States, while AstraZeneca will be responsible for development and commercialization of the other programs worldwide.

The term of each Agreement ends upon the expiration of all of AstraZeneca's payment obligations under such Agreement. The AstraZeneca Collaboration Agreement may be terminated by AstraZeneca in its entirety for convenience beginning 12 months after its effective date upon 90 days' notice or, if Pieris has obtained marketing approval for the marketing and sale of a product, 180 days' notice. Each program may be terminated at AstraZeneca's option; if any program is terminated by AstraZeneca, Pieris will have full rights to such program. The AstraZeneca Collaboration Agreement may also be terminated by AstraZeneca or Pieris for material breach upon 180 days' notice of a material breach (or 30 days with respect to payment breach), provided that the applicable party has not cured such breach by the permitted cure period (including an additional 180 days if the breach is not susceptible to cure during the initial 180-day period) and dispute resolution procedures specified in the applicable Agreement have been followed. The AstraZeneca Collaboration Agreement may also be terminated due to the other party's insolvency and may in certain instances be terminated on a product-by-product and/or country-by-country basis. Each party may also terminate the agreement if the other party challenges the validity of patents related to certain intellectual property licensed under the Agreements, subject to certain exceptions for infringement suits, acquisitions and newly-acquired licenses. The License Agreement will terminate upon termination of the AstraZeneca Collaboration Agreement, on a product-by-product and/or country-by-country basis.

The Agreements are conditioned upon the expiration or early termination of the applicable waiting period (and any extension thereof) under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

#### *Pieris' Collaboration Agreement with Daiichi Sankyo.*

In May 2011, the Company entered into a definitive collaboration research and technology licensing agreement with Daiichi Sankyo, under which we agreed to use our proprietary Anticalin<sup>®</sup> scaffold technologies to discover novel drug candidates against two targets chosen by

Daiichi Sankyo under two separate collaboration projects.

The first therapeutic comprises an Anticalin protein targeting PCSK9, DS-9001a. Daiichi Sankyo completed a Phase 1 single dose study in healthy subjects for DS-9001a in December 2016. Due to strategic and commercial reasons related to the market for PCSK9 inhibitors, Daiichi Sankyo provided notice to Pieris on May 8, 2017 of its termination of the DS-9001a program.

---

## [Table of Contents](#)

### **Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations**

*The interim financial statements and this Management’s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2016, and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on March 30, 2017. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under the caption “Risk Factors” in the Annual Report on Form 10-K for the year ended December 31, 2016.*

*As used in this Quarterly Report on Form 10-Q, unless the context indicates or otherwise requires, “our Company”, “the Company”, “Pieris”, “we”, “us”, and “our” refer to Pieris Pharmaceuticals, Inc., a Nevada corporation, and its consolidated subsidiaries.*

*We have registered trademarks for Pieris®, Anticalin® and Pocket Binding®. All other trademarks, trade names and service marks included in this Quarterly Report on Form 10-Q are the property of their respective owners. Use or display by us of other parties’ trademarks, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owner.*

### **Company Overview**

We are a clinical-stage biopharmaceutical company that discovers and develops Anticalin® protein-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immuno-oncology multi-specifics tailored for the tumor micro-environment, an inhaled Anticalin to treat uncontrolled asthma and a half-life-optimized Anticalin to treat anemia. Proprietary to Pieris, Anticalin proteins are a novel class of low molecular-weight therapeutic proteins derived from lipocalins, which are naturally occurring low-molecular weight human proteins typically found in blood plasma and other bodily fluids.

Each of our development programs focus on the following:

- *300-Series oncology drug candidates* are multispecific Anticalin®-based proteins designed to engage immunomodulatory targets and consist of a variety of multifunctional biotherapeutics that genetically link antibody with one or more Anticalin proteins, thereby constituting a multispecific protein;
  - *PRS-343* our lead immune-oncology program is a 4-1BB/HER2 bispecific, comprised of a HER2-targeting antibody genetically linked to a 4-1BB-targeting Anticalin, in which tumor-targeted drug clustering mediated by HER2 expressed on certain solid tumors is intended to drive tumor localized T cell activation for patient unresponsive to current standard of care.
  - *PRS-332* is a bispecific Anticalin-antibody fusion protein comprising an anti-PD-1 antibody genetically fused to an Anticalin targeting an undisclosed checkpoint target. In order to improve on existing PD-1 therapies, we are developing PRS-332 with the intent to simultaneously block PD-1 and another immune checkpoint co-expressed on exhausted T cells.
- *PRS-080* is an Anticalin protein that binds to hepcidin, a natural regulator of iron in the blood. It has been designed to target hepcidin for the treatment of functional iron deficiency in anemic patients with chronic kidney disease particularly in end-stage renal disease patients requiring dialysis.
- *PRS-060* is a drug candidate that binds to the IL-4RA receptor, thereby inhibiting the signaling of IL-4 and IL-13, two cytokines, small proteins mediating signaling between cells within the human body), known to be key mediators in the inflammatory cascade that causes asthma and other inflammatory diseases.

Our programs are in varying stages:

- *300-Series*—We are conducting activities relating to lead candidate identification, lead candidate optimization, preclinical evaluation and IND filing preparation on several of our 300-Series lead candidates.
  - Our lead candidate, PRS-343, has been advanced through IND-enabling studies in 2016. Preclinical safety and efficacy studies were performed. A Master Cell bank was generated and GMP material to support initial clinical trials has been produced. We intend to initiate a Phase I clinical trial in HER2 positive solid tumor for PRS-343 in the first half of 2017; and
  - PRS-332—We expect to nominate a development candidate and initiate IND-enabling activities in the second half of 2017.
- *PRS-080*—We completed a Phase Ia single-ascending dose clinical trial with PRS-080 in healthy volunteers in 2015. Based on the data we obtained in the Phase Ia clinical trial, we initiated a Phase Ib clinical study in CKD5 patients requiring hemodialysis.

---

## Table of Contents

The clinical part was complete in March 2017 and the final clinical report is expected by the second quarter of 2017. The company plans to initiate in the second quarter of 2017 a multi-dose clinical study in CKD patients requiring hemodialysis, which will assess the ability of PRS-080 to elevate hemoglobin over a period of approximately four weeks.

- PRS-060—We have formulated PRS-060 for pulmonary delivery by inhalation and we have developed a bioprocess that has generated GMP material for use in safety and tolerability studies and First in Human clinical studies. We intend to pursue a first-in-human clinical trial for PRS-060 in the second half of 2017.

Our core Anticalin<sup>®</sup> technology and platform was developed in Germany, and we have partnership arrangements with major multi-national pharmaceutical companies headquartered in the U.S., Europe and Japan and with regional pharmaceutical companies headquartered in India. These include existing agreements with Daiichi Sankyo Company Limited, (“Daiichi Sankyo”), and Sanofi Group, (“Sanofi”), pursuant to which our Anticalin platform has consistently achieved its development milestones. Furthermore, we established a collaboration with F.Hoffman – La Roche Ltd. and Hoffmann – La Roche Inc., (“Roche”) in December 2015, a collaboration with Les Laboratoires Servier and Institut de Recherches Internationales Servier (“Servier”) in January 2017, and a collaboration with AstraZeneca AB (“AstraZeneca”) in May 2017. We have discovery and preclinical collaboration and service agreements with both academic institutions and private firms in Australia.

Since inception, we have devoted nearly all of our efforts and resources to our research and development activities. We have incurred significant net losses since inception. For the three months ended March 31, 2017 we reported a net loss of \$8.0 million. For the three months ended March 31, 2016 we reported a net loss of \$4.2 million. As of March 31, 2017, we had an accumulated deficit of \$110.7 million.

We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. Our operating expenses are comprised of research and development expenses and general and administrative expenses.

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for at least the next several years. Our revenues for the periods presented were primarily from license and collaboration agreements with our partners, and, to a lesser extent, from grants from government agencies.

A significant portion of our operations are conducted in countries other than the United States. Since we conduct our business in U.S. dollars, our main exposure, if any, results from changes in the exchange rates between the euro and the U.S. dollar. All assets and liabilities denominated in euros are translated into U.S. dollars at the exchange rate on the balance sheet date. Revenues and expenses are translated at the average rate during the period. Equity transactions are translated using historical exchange rates. Adjustments resulting from translating foreign currency financial statements into U.S. dollars are included in accumulated other comprehensive loss. We may incur negative foreign currency translation changes as a result of changes in currency exchange rates.

### **Financial Operations Overview**

The following discussion summarizes the key factors our management believes are necessary for an understanding of our consolidated financial statements.

#### ***Revenues***

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for the foreseeable future. Our revenues for the last two years have been primarily from the license and collaboration agreements with Sanofi, Daiichi Sankyo, Roche and Servier.

The revenues from our collaborations have been comprised primarily of upfront payments, research and development services and, to a lesser extent, milestone payments. We recognized revenues from upfront payments under these agreements based on multiple-element arrangement guidance as we have determined that the licenses to which the payments related did not have standalone value. Research service revenue is recognized when the costs are incurred and the services have been performed. Revenue from milestone payments is recognized when all of the following conditions are met: (1) the milestone payments are non-refundable, (2) the probability of the achievement of the milestone is near certain, (3) substantive effort on our part is involved in achieving the milestone, (4) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (5) a reasonable amount of time passes between the up-front license payment and the first milestone payment.

We expect our revenues for the next several years to consist of upfront payments, research funding, and milestone payments from strategic collaborations we currently have or may establish in the future.

---

## [Table of Contents](#)

### Research and Development Expenses

The process of researching and developing drugs for human use is lengthy, unpredictable, and subject to many risks. We expect to continue incurring substantial expenses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. We are unable with any certainty to estimate either the costs or the timelines in which those costs will be incurred. Our current development plans focus on three lead drug programs: PRS-080, PRS-060 and 300-series. These programs consume a large proportion of our current, as well as projected, resources.

Our research and development costs include costs that are directly attributable to the creation of certain of our Anticalin<sup>®</sup> drug candidates and are comprised of:

- internal recurring costs, such as labor and fringe benefits, materials and supplies, facilities and maintenance costs; and
- fees paid to external parties who provide us with contract services, consulting services, such as preclinical testing, manufacturing and related testing, and clinical trial activities.

### General and Administrative Expenses

General and administrative expenses consist primarily of payroll, employee benefits, equity compensation, and other personnel-related costs associated with executive, administrative and other support staff. Other significant general and administrative expenses include the costs associated with professional fees for accounting, auditing, insurance costs, consulting, and legal services.

### Results of Operations

#### Comparison of the three months ended March 31, 2017 and March 31, 2016

The following table sets forth our revenues and operating expenses for the periods presented (in thousands):

	Three months ended March 31, 2017	Three months ended March 31, 2016
Revenues	\$ 1,343	\$ 1,247
Research and development expenses	5,360	3,659
General and administrative expenses	3,989	1,968
Non-operating income, net	12	219
Net profit loss	\$ 7,994	\$ 4,161

## [Table of Contents](#)

### Revenues

The following table provides a comparison of revenues for three months ended March 31, 2017 and 2016, respectively (in thousands):

	Three months ended March 31, 2017	Three months ended March 31, 2016	\$ Change	% Change
Upfront payments	\$1,008	\$ 836	\$ 172	21%
Research and development services	335	411	(76)	(18%)
<b>Total Revenue</b>	<b>\$1,343</b>	<b>\$1,247</b>	<b>\$ 96</b>	<b>8%</b>

- The \$0.2 million increase in revenues from upfront payments in the three months ended March 31, 2017 compared to the three months ended March 31, 2016 relates to the recognition of an upfront payment under our collaboration with Servier, which commenced in January 2017, offset by slightly lower revenues from upfront payments under our collaboration with Roche due to less full-time equivalents used in Q1 2017 compared to Q1 2016.
- The \$0.1 million decrease in revenues from research and development services in the three months ended March 31, 2017 compared to the three months ended March 31, 2016 relates to less research and development services being provided to Roche pursuant to the Roche Agreement.

### Research and Development expenses

Total research and development expenses were \$5.4 million for the three months ended March 31, 2017 as compared to \$3.7 million for the three months ended March 31, 2016.

The following table provides a comparison of the research and development expenses for our drug candidates and projects for the three months ended March 31, 2017 and 2016, respectively (in thousands):

	Three months ended March 31,		\$-	%-Change
	2017	2016	Change	
Other R&D activities	\$ 2,163	\$ 1,870	\$ 293	16%
PRS-300 series	1,978	1,093	885	81%
PRS-060	816	347	469	135%
PRS-080	403	349	54	15%
<b>Total</b>	<b>\$ 5,360</b>	<b>\$ 3,659</b>	<b>\$1,701</b>	<b>46%</b>

The increase in total research and development expenses in the three months ended March 31, 2017 compared to the three months ended March 31, 2016 is primarily due to:

- the \$0.5 million increase for PRS-060 is mainly due to a \$0.6 million increase in chemistry, manufacturing, controls, or CMC, costs and \$0.1 million in expenses for toxicology studies, which started in late 2016. Other costs also increased by \$0.1 million. These amounts are offset by a decrease of \$0.3 million in preclinical costs;
- the \$0.1 million increase for PRS-080 is due to higher clinical costs related to the phase Ib study commencing in the first quarter of 2016 and the clinical part of this study was completed in the first quarter of 2017;
- the \$0.9 million increase for our PRS-300 series is due to a \$0.2 million increase in preclinical costs, as we carry out our IND enabling studies for PRS-343, \$0.3 million increase in clinical costs as well as a \$0.3 million increase in license fees to TUM in connection with the platform license under the agreement with Servier. Expenses for general lab supplies increased by \$0.1 million;



---

## Table of Contents

- the \$0.3 million increase in other R&D is mainly due to a \$0.2 million increase in payroll expenses, including stock-based compensation expense, an increase of \$0.2 million for preclinical and CMC costs, and a \$0.1 million increase for general lab costs. Other costs, such as recruiting and travel costs, increased by \$0.1 million. These increases were offset by a decrease of \$0.3 million in license fees the Company paid to TUM in early 2016.

### *General and Administrative expenses*

General and administrative expenses were \$4.0 million for the three months ended March 31, 2017 compared to \$2.0 million for the three months ended March 31, 2016. The Company noted an increase of \$0.8 million in higher personnel related costs, including stock compensation, and \$0.9 million increase for professional services including success fees paid in the first quarter of 2017. Additionally, expenses for audit, tax, services, other expenses, specifically travel, recruiting fees increased by \$0.3 million.

### *Non-operating income, net*

Non-operating other income decreased to approximately \$12,000 for three months ended March 31, 2017 from \$0.2 million of non-operating income for the three months ended March 31, 2016. This decrease is mainly a result of net foreign currency transaction losses related to the weakness of the Euro against the U.S. dollar in the periods presented.

## **Liquidity and Capital Resources**

Through March 31, 2017, we have funded our operations with \$230.0 million of cash, obtained from the following main sources: \$117.9 million from sales of equity; \$91.3 million in total payments received under license and collaboration agreements, including \$13.6 million for research and development services costs received from our collaboration partners; \$14.2 million from government grants and \$6.5 million from loans.

As of March 31, 2017, we had a total of \$55.2 million in cash.

We have experienced operating losses since our inception and had a total accumulated deficit of \$110.7 million as of March 31, 2017. We expect to incur additional costs and will require additional future capital. We have incurred losses in nearly every period since inception including the three months ended March 31, 2017. These losses have primarily resulted in significant cash used in operations. Due to the upfront payment received from Servier and the option payment received from ASKA during the three months ended March 31, 2017 offset with our net losses for the period, our net cash used in operating activities is \$25.8 million. We have several research and development programs underway in varying stages of development and we expect they will continue to require increasing amounts of cash for development, conducting clinical trials, and testing and manufacturing of product material. As we continue to conduct these activities necessary to pursue governmental regulatory approval of our 300-Series, including PRS-343, PRS-342, PRS-332, and PRS-080 and PRS-060, and our other product candidates, we expect the cash necessary to fund operations will increase significantly over the next several years.

In June 2016, we entered into a securities purchase agreement for a private placement with a select group of institutional investors. The private placement, referred to as the 2016 PIPE, consisted of the sale of 8,188,804 units at a price of \$2.015 per unit for gross proceeds to us of approximately \$16.5 million. After deducting for placement agent fees and offering expenses, the aggregate net proceeds from the 2016 PIPE was approximately \$15.3 million.

In August 2016, our shelf registration statement in the amount of \$100 million was declared effective by the SEC. This registration allows us to offer for sale various unspecified classes of equity and debt securities. As circumstances warrant, we may issue debt and/or equity securities from time to time on an opportunistic basis, dependent upon market conditions and available pricing. We make no assurance that we can issue and sell such securities on acceptable terms or at all.

In January 2017, we entered into a License and Collaboration Agreement and a Non-Exclusive Anticalin Platform Technology License Agreement with Les Laboratoires Servier and Institut de Recherches Internationales Servier (collectively, "Servier"). Under the agreements, we received an upfront payment of \$32.3 million. The total development, regulatory and sales-based milestone payment to the Company could exceed \$1.8 billion over the life of the collaboration. We believe the signing of the agreements with Servier improves the Company's liquidity profile.

In May 2017, we entered into a License and Collaboration Agreement (the "Collaboration Agreement") and a Non-Exclusive Anticalin<sup>®</sup> Platform Technology License Agreement (the "License Agreement" and together with the Collaboration Agreement, the "Agreements") with AstraZeneca AB ("AstraZeneca"). Under the agreements, the Company will receive \$57.5 million in up-front and near-term milestone payments, including \$45 million of up-front payments and \$12.5 million for the initiation of the PRS-060 Phase 1 trial. The Company may receive development, regulatory and sales-based milestone payments up to



---

## **Table of Contents**

approximately \$2.1 billion. The Company believes the signing of the agreements with AstraZeneca improves the Company's liquidity profile. We will need to obtain additional funding in order to continue our operations and pursue our business plans. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts.

We expect that our existing cash and cash equivalents will enable us to fund our operations and capital expenditure requirements for at least the next twelve months. Our requirements for additional capital will depend on many factors, including the following:

- the scope, rate of progress, results, timing and cost of our clinical studies, preclinical testing and other related activities;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our drug candidates and any products that we may develop;
- the number and characteristics of drug candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our potential products;
- the cost of preparing, filing, prosecuting, defending, and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

We cannot be sure that future funding will be available to us on acceptable terms, or adequate enough at all. Due to the often volatile nature of the financial markets, equity and debt financing may be difficult to obtain. In addition, any unfavorable development or delay in the progress of our 300-Series programs, including PRS-343, PRS-342, PRS-332, and PRS-080 and PRS-060 could have a material adverse impact on our ability to raise additional capital.

We may seek to raise any necessary additional capital through a combination of private or public equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our drug candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we raise additional capital through private or public equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. We believe that our existing cash as of March 31, 2017 will be sufficient to enable us to continue as a going concern through at least the day of filing in May 2018.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

### **Critical Accounting Policies and Estimates**

Refer to Part II, Item 7, "Critical Accounting Policies and Estimates" of our Annual Report on Form 10-K for the fiscal year ended on December 31, 2016 for a discussion of our critical accounting policies and estimates. There were no significant changes to our Critical Accounting Policies and Estimates for the three months ended March 31, 2017.

### **Recently Issued Accounting Pronouncements**

We review new accounting standards to determine the expected financial impact, if any, that the adoption of each such standard will have. For the recently issued accounting standards that we believe may have an impact on our consolidated financial statements, see "Note 9—Recently Issued Accounting Pronouncements" in our consolidated financial statements.

---

## [Table of Contents](#)

### **Emerging Growth Company and Smaller Reporting Company Status**

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, establishes a class of company called an “emerging growth company,” which generally is a company whose initial public offering was completed after December 8, 2011 and had total annual gross revenues of less than \$1 billion during its most recently completed fiscal year. Additionally, Section 12b-2 of the Exchange Act establishes a class of company called a “smaller reporting company,” which generally is a company with a public float of less than \$75 million as of the last business day of its most recently completed second fiscal quarter or, if such public float is \$0, had annual revenues of less than \$50 million during the most recently completed fiscal year for which audited financial statements are available. We currently qualify as both an emerging growth company and a smaller reporting company.

As an emerging growth company and a smaller reporting company, we are eligible to take advantage of certain exemptions from various reporting requirements that are not available to public reporting companies that do not qualify for those classifications, including without limitation the following:

- An emerging growth company is exempt from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and financial statements, commonly known as an “auditor discussion and analysis.”
- An emerging growth company is not required to hold a nonbinding advisory stockholder vote on executive compensation or any golden parachute payments not previously approved by stockholders.
- Neither an emerging growth company nor a smaller reporting company is required to comply with the requirement of auditor attestation of management’s assessment of internal control over financial reporting, which is required for other public reporting companies by Section 404 of the Sarbanes-Oxley Act.
- A company that is either an emerging growth company or a smaller reporting company is eligible for reduced disclosure obligations regarding executive compensation in its periodic and annual reports, including without limitation exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures.
- A company that is either an emerging growth company or a smaller reporting company is eligible for reduced financial statement disclosure in registration statements, which must include two years of audited financial statements rather than the three years of audited financial statements that are required for other public reporting companies. Smaller reporting companies are also eligible to provide such reduced financial statement disclosure in annual reports on Form 10-K.

For as long as we continue to be an emerging growth company and/or a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. We will remain an emerging growth company until the earlier of (i) December 31, 2019, the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act; (ii) the last day of the fiscal year in which we have total annual gross revenues of \$1 billion or more; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under applicable SEC rules. We expect that we will remain an emerging growth company for the foreseeable future, but cannot retain our emerging growth company status indefinitely and will no longer qualify as an emerging growth company on or before December 31, 2019. We will remain a smaller reporting company until we have a public float of \$75 million or more as of the last business day of our most recently completed second fiscal quarter, and we could retain our smaller reporting company status indefinitely depending on the size of our public float.

Emerging growth companies may elect to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Not applicable.

---

## [Table of Contents](#)

### **Item 4. Controls and Procedures**

#### *Evaluation of Disclosure Controls and Procedures*

Our management is responsible for establishing and maintaining “disclosure controls and procedures”, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as well as for establishing and maintaining “adequate internal control over financial reporting” as such term is defined in Rule 13a-15(f) under the Exchange Act. The Company’s system of internal controls over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements in accordance with generally accepted accounting principles.

Because of the inherent limitations surrounding internal controls over financial reporting, our disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Our management, under the supervision of and with the participation of the Chief Executive Officer and Acting Chief Financial Officer, assessed the effectiveness of the Company’s internal control over financial reporting and disclosure controls and procedures as of March 31, 2017. In making this assessment, management used the updated criteria set forth in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on our assessment under the COSO Internal Control-Integrated Framework, management believes that, as of March 31, 2017, our internal control over financial reporting was effective.

Notwithstanding the remediation described below, we have concluded that the financial statements and other financial information included in this Quarterly Report on Form 10-Q, fairly represent in all material respects our financial condition, results of operations, and cash flows as of, and for, the periods presented.

#### *Changes in Internal Control over Financial Reporting*

During the period, the Company remediated a previously identified material weakness with regard to technical accounting for complex transactions, specifically accounting for a previous equity transaction. Except for this remediation, there are no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the quarter ended March 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II — OTHER INFORMATION**

### **Item 1. Legal Proceedings**

Claims and lawsuits are filed against our Company from time to time. Although the results of pending claims are always uncertain, we believe that we have adequate reserves or adequate “insurance coverage” in respect of these claims, but no assurance can be given as to the sufficiency of such reserves or insurance coverage in the event of any unfavorable outcome resulting from these actions.

### **Item 1A. Risk Factors**

There have been no material changes from the risk factors previously disclosed in Part I, Item 1A (Risk Factors) of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

### **Item 3. Defaults upon Senior Securities**

None.

---

## [Table of Contents](#)

### **Item 4. Mine Safety Disclosures**

Not applicable.

### **Item 5. Other Information**

#### *Pieris' Collaboration Agreement with Daiichi Sankyo.*

Daiichi Sankyo Company Limited (“Daiichi Sankyo”) partnered with Pieris to research, develop and commercialize two Anticalin therapeutics pursuant to a May 31, 2011 Collaboration Research and Technology Licensing Agreement (the “Collaboration Agreement”).

The first therapeutic comprises an Anticalin protein targeting PCSK9, DS-9001a. Daiichi Sankyo completed a Phase 1 single dose study in healthy subjects for DS-9001a in December 2016. The results of the Phase 1 Study did not show any safety concerns precluding DS-9001a’s continued development. The results of the Phase 1 Study also show that DS-9001a is a potent inhibitor of PCSK9; the product decreased LDL-C levels in the phase 1 study healthy subjects.

Due to strategic and commercial reasons related to the market for PCSK9 inhibitors, however, Daiichi Sankyo provided notice to Pieris on May 8, 2017 of its termination of the DS-9001a program. In connection with a termination of the development of DS-9001a, and under the terms of the Collaboration Agreement, Daiichi Sankyo is obligated to carry out certain activities to facilitate transfer of activities, regulatory filings, materials, data, agreements and other matters to Pieris in connection with the return to Pieris of the development program related to DS-9001a. Pieris intends to diligently review the clinical data associated with the program and consider its strategic options thereafter.

Daiichi Sankyo’s termination is only with respect to DS-9001a, and the Collaboration Agreement remains in effect with respect to the second Anticalin protein against an undisclosed target. Pieris previously reported Daiichi Sankyo’s decision to initiate GLP toxicology studies with respect to that product and Pieris’ receipt of the associated milestone in October 2016.

The foregoing summary of the terms relating to the Collaboration Agreement, including with respect to Daiichi Sankyo’s termination of such Agreement with respect to DS-9001a, is qualified in its entirety by the terms of the Collaboration Agreement, which were filed with the SEC as exhibit 10.7 to the Form 10-K filed on March 30, 2017. The contents of such exhibit are hereby incorporated by reference.

---

## Table of Contents

### Item 6. Exhibits

#### EXHIBIT INDEX

10.1±	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 Annual Report on Form 10-K filed March 30, 2017 (File No. 001-37471))
10.2±	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 Annual Report on Form 10-K filed March 30, 2017 (File No. 001-37471))
10.3±	Exclusive Option Agreement by and among the Registrant, Pieris Pharmaceuticals GmbH and ASKA Pharmaceutical Co., Ltd., dated as of February 27, 2017
10.4	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))
10.5*	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))
10.6*	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))
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Principal Executive Officer.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Principal Financial Officer.
32.1	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.
32.2	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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document

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

\* Indicates management contract or compensatory plan.

---

[Table of Contents](#)

**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.

**PIERIS PHARMACEUTICALS, INC.**

Date: May 15, 2017

By: /s/ Stephen S. Yoder

Stephen S. Yoder  
President, Chief Executive Officer and Director

Date: May 15, 2017

By: /s/ Lance Thibault

Lance Thibault  
Acting 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, 9<sup>th</sup> 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<sup>®</sup> 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 contract or otherwise, to direct the management and policies of a Party or such other person or entity, as applicable.

*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**

- 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 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.

*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**

- 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 Patent 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 jointly developed, or owned by Pieris as of the Effective Date and thereafter during 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.

*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**

- 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 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.

*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**

- 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 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.

*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**

- 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 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.

*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**

- 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 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.

*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**

- 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 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.

***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**

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) [\*\*\*] ([\*\*]) 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**”).
- 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.

*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**

- 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.
- 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.

*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**

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.

**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: [\*\*\*]

*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**

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

Pieris Pharmaceuticals  
255 State Street, 9<sup>th</sup> 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 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.

*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**

- 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.
- 10.2 Choice of Law. This Agreement shall be governed by and construed in accordance with the laws of [\*\*\*], 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

*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**

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, 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]*

*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 \_\_\_\_\_  
Name Stephen Yoder  
Title President and CEO  
Date \_\_\_\_\_

**PIERIS PHARMACEUTICALS GMBH**

Signature \_\_\_\_\_  
Name Stephen Yoder  
Title Managing Director  
Date \_\_\_\_\_

**ASKA PHARMACEUTICAL CO., LTD.**

Signature \_\_\_\_\_  
Name Takashi Yamaguchi, Ph.D.  
Title President and Representative Director  
Date \_\_\_\_\_

*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 A**

**Patent Rights within the Licensed Platform IP**

[\*\*\*]

*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.*

Page 16 of 23

**CONFIDENTIAL TREATMENT REQUESTED**

**EXHIBIT B**

**Patent Rights within the Licensed Product IP**

[\*\*\*]

*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 C**

**Success Criteria for Phase 2a Study**

[\*\*\*]

*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.

*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**

- (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
Up to [***] USD	[***]%
Between \$[***] and \$[***] USD	[***]%
Between \$[***] and \$[***]0 USD	[***]%
In excess of \$[***] USD	[***]%

*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**

- (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 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.

*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**

- (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 ([\*\*\*]%).

*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 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.

*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.*

**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 quarterly report on Form 10-Q of Pieris Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. paragraph omitted in accordance with Exchange Act Rule 15d-14(a);
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2017

/s/ Stephen S. Yoder

Stephen S. Yoder

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

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

I, Lance Thibault, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pieris Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. paragraph omitted in accordance with Exchange Act Rule 15d-14(a);
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2017

/s/ Lance Thibault

Lance Thibault

Title: Acting Chief Financial Officer  
(principal financial officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER UNDER SECTION 906**

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Pieris Pharmaceuticals, Inc. (the “Company”) hereby certifies, to his knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2017 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2017

/s/ Stephen S. Yoder

Stephen S. Yoder

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



**CERTIFICATION OF CHIEF FINANCIAL OFFICER UNDER SECTION 906**

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Pieris Pharmaceuticals, Inc. (the “Company”) hereby certifies, to her knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2017 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2017

/s/ Lance Thibault

Lance Thibault  
Title: Acting Chief Financial Officer  
(principal financial officer)