# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549** 

	FORM 10-Q
(Mark One)  ☑ QUARTERLY REPORT PURSUANT TAGENT OF 1934	TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
For the qu	uarterly period ended March 31, 2016
	OR
☐ TRANSITION REPORT PURSUANT TACT OF 1934	TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
For the transiti	ion period from to
Com	nmission file number: 001-37471
(Exact name Nevada	e of registrant as specified in its charter)  30-0784346
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
255 State Street, 9th Floor Boston, MA	
United States (Address of principal executive offices)	02109 (Zip Code)
(Registran	857-246-8794 nt's telephone number, including area code)
	has filed all reports required to be filed by Section 13 or 15(d) of the Securities (or for such shorter period that the registrant was required to file such reports), and past 90 days.   Yes  No
	submitted electronically and posted on its corporate Web site, if any, every ed 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).

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-acc reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company. Exchange Act (check one):		
Large accelerated filer □	Accelerated filer	
Non-accelerated filer	Smaller reporting company	X
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 N	May 9, 2016 was 39,833,023.	
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#### **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  $\{0.00\}$  to U.S.  $\{0.00\}$  to U.S.  $\{0.00\}$  to  $\{0.00$ 

#### **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," "suggests," "future," "likely," "goal," "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 U.S. 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 Form 10-K filed on March 23, 2016 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.

# PART I — FINANCIAL INFORMATION CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2016	December 31, 2015
	(unaudited)	
Assets		
Current assets:		
Cash	\$ 31,188,527	\$ 29,349,124
Trade accounts receivable	70,259	_
Prepaid expenses and other current assets	3,608,102	2,311,385
Total current assets	34,866,888	31,660,509
Property and equipment, net	2,210,389	2,162,771
Other non-current assets	128,020	126,781
Total assets	\$ 37,205,297	\$ 33,950,061
Liabilities and Stockholders' Equity		
Current liabilities:		
Trade accounts payable	\$ 1,711,028	\$ 1,058,536
Accrued expenses and other current liabilities	2,322,044	1,739,380
Deferred revenues, current portion	2,464,722	
Total current liabilities	6,497,794	2,797,916
Deferred revenue, net of current portion	3,491,690	_
Other long-term liabilities	39,742	23,852
Total liabilities	10,029,226	2,821,768
Stockholders' equity:		
Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 39,833,023 shares		
issued and outstanding at March 31, 2016 and December 31, 2015	39,833	39,833
Additional paid-in capital	112,595,106	112,226,723
Accumulated other comprehensive loss	(1,432,125)	(1,272,574)
Accumulated deficit	(84,026,743)	(79,865,689)
Total stockholders' equity	27,176,071	31,128,293
Total liabilities and stockholders' equity	\$ 37,205,297	\$ 33,950,061

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three months er	nded March 31,
	2016	2015
Revenue	\$ 1,246,644	\$ 217,621
Operating expenses		
Research and development	3,659,435	1,524,631
General and administrative	1,967,883	2,394,323
Total operating expenses	5,627,318	3,918,954
Loss from operations	(4,380,674)	(3,701,333)
Interest (expense), net	_	(4,170)
Other income, net	219,620	769
Loss before income taxes	(4,161,054)	(3,704,734)
Provision for income tax	<u> </u>	
Net Loss	\$ (4,161,054)	\$ (3,704,734)
Net loss per share		
Basic and diluted	\$ (0.10)	\$ (0.13)
Weighted average number of common shares outstanding		
Basic and diluted	39,833,023	29,292,855

# CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)

	Three months	Three months ended March 31,	
	2016	2015	
Net loss	\$ 4,161,054	\$ 3,704,734	
Other comprehensive loss components:			
Foreign currency translation	163,340	602,732	
Total other comprehensive loss	163,340	602,732	
Comprehensive loss	\$ 4,324,394	\$ 4,307,466	

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Three months ended March 31,	
	2016	2015
Operating activities:		
Net loss	\$ (4,161,054)	\$ (3,704,734)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	94,521	78,117
Stock-based compensation	368,383	217,335
Non-cash restricted shares	_	311,066
Changes in operating assets and liabilities:		
Trade accounts receivable	(68,870)	
Prepaid expenses and other assets	(1,185,384)	(727,475)
Deferred Revenue	5,838,737	
Trade accounts payable	597,189	440,649
Accrued expenses and other current liabilities	543,037	(208,047)
Net cash provided by (used in) operating activities	2,026,559	(3,593,089)
Investing activities:		
Purchase of property and equipment	(67,919)	(40,648)
Net cash used in investing activities	(67,919)	(40,648)
Financing activities:		
Repayment of debt		(1,127,805)
Net cash used in financing activities		(1,127,805)
Effect of exchange rate change on cash and cash equivalents	(119,236)	(545,633)
Net increase (decrease) in cash and cash equivalents	1,839,403	(5,307,175)
Cash and cash equivalents at beginning of year	29,349,124	18,474,211
Cash and cash equivalents at end of year	\$31,188,527	<u>\$13,167,036</u>
Supplemental cash flow disclosures:		
Cash paid for interest	<u>\$</u>	\$ 4,224

# 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 Securities and Exchange Commission rules and regulations. Accordingly, they 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, 2015 filed with the SEC on March 23, 2016 (the "2015 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, 2015, 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, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016 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. Revenues

#### General

Pieris, to date has not generated revenues from product sales. Pieris has generated revenues pursuant to (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.

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 generally accepted accounting principles, or 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 or joint research 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.

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 relative performance method provided that 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-efforts basis. Full-time equivalents are typically used as the measure of performance.

If the Company cannot reasonably estimate when its performance obligation either ceases or becomes inconsequential and perfunctory, then revenue is deferred until the Company can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period 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.

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

In December 2015, the Company entered into a Research Collaboration and License 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 Anticalins that bind to a specific target for an expected period of 20 months, which may be extended by Roche for up to an additional 12 months. Roche has the ability to continue exclusivity rights for up to an additional 5 years. Both Roche and the Company will participate in a joint research committee. Following the research program, Roche will be responsible for subsequent preclinical 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. Roche will pay Pieris additional amounts related to 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 well as royalties on any future product sales.

In addition to the upfront payment, the Company is eligible to receive additional research funding, development and regulatory and sales based milestone payments up to approximately \$423.9 million, plus royalties on the sales of any commercial products. The total potential milestones are categorized as follows: development and regulatory milestones - \$294.0 million; and sales milestones - \$124.6 million. Management has determined that the development milestones are substantive because they relate solely to past performance of the Company. The milestones, will be recognized under the milestone method, when achieved to the extent the Company has no remaining performance obligations under the arrangement.

The Company identified the research and commercial licenses, performance of R&D services and participation in the joint research committee as deliverables under the 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.

Pieris recorded \$1.2 million in revenue for the three months ended March 31, 2016, 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. The revenue for the upfront payment is recognized under the proportional performance method as research services are provided over the potential research term of 32 months. No revenues were recorded for the three months ended March 31, 2015.

#### 3. Net Loss per Common Share

Basic net loss per share was determined by dividing net loss by the weighted average common 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 was the same because any increase in the number of shares of common stock equivalents for any period presented would be antidilutive based on the net loss for the period.

For the three months ended March 31, 2016 and 2015, approximately 3.5 million and 0.8 million potential weighted average shares subject to stock options respectively, as calculated using the treasury stock method, were excluded from the calculation of diluted weighted average common shares outstanding as their effect would have been antidilutive.

#### 4. 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. The standard describes the following fair value hierarchy based on three levels of input, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

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

# 5. Related-Party Transactions

#### Research and License Agreement with Technische Universität München ("TUM")

On July 4, 2003, the Company entered into a research and licensing agreement with TUM, which was subsequently renewed and, on July 26, 2007, superseded and replaced. The agreement established a joint research effort led by Prof. Arne Skerra, Chair of Biological Chemistry of TUM, to optimize Anticalin technologies for use in therapeutic, prophylactic and diagnostic applications and as research reagents, and to gain fundamental insights in lipocalin scaffolds. Prof. Dr. Skerra was a member of the Company's supervisory board when the parties entered into such agreement and during the period covered by the consolidated financial statements in this report. The Company provided certain funding for TUM research efforts performed under the agreement.

As a result of research efforts to date under the agreement, the Company holds a worldwide exclusive license under its license agreement with TUM to multiple patents and patent applications, including an exclusive license to an issued U.S. patent, which patent will expire in 2027 (subject to a possible term adjustment period). The Company also holds an exclusive license to an issued U.S. patent No. 8,420,051, which patent is expected to expire in 2029. The Company bears the costs of filing, prosecution and maintenance of patents assigned or licensed to the Company under the agreement.

As consideration for the assigned patents and licenses above, the Company is required to pay certain development milestones to TUM. The Company also is obliged to pay low-single-digit royalties, including annual minimum royalties, on sales of such products incorporating patented technologies. If the Company grants licenses or sublicenses to those patents to third parties, the Company will be obliged to pay a percentage of the resulting revenue to TUM. The Company's payment obligations are reduced by the Company's proportionate contribution to a joint invention. Payment obligations terminate on expiration or annulment of the last patent covered by the agreement. The Company can terminate the licenses to any or all licensed patents upon specified advance notice to TUM. TUM may terminate the license provisions of the agreement only for cause. Termination of the agreement does not terminate the rights in patents assigned to the Company.

Effective as of the fourth quarter of 2015, the Company no longer deems TUM a related party due to Prof. Dr. Skerra no longer having a supervisory board position in Pieris GmbH or other direct relationship with the Company since its initial public offering in December 2014. Therefore no expenses to TUM as a related party were incurred during the three months ended March 31, 2016. The Company incurred expenses related to TUM as a related party of approximately \$14,000 for the three months ended March 31, 2015.

### Consulting Contract between Prof. Dr. Arne Skerra and Pieris AG

In 2001, the Company entered into a Consulting Agreement with Prof. Dr. Arne Skerra, pursuant to which Prof. Dr. Arne Skerra provides advice regarding the use of new proteins, in particular Anticalin proteins and antibodies, for the purpose of research and development. As of the fourth quarter of 2015, Pieris no longer deems Prof. Dr. Skerra a related party due to Prof. Dr. Skerra no longer having a supervisory board position in Pieris GmbH or other direct relationship with the Company after its initial public offering in December 2014. The Company incurred and paid to Prof. Dr. Skerra consulting fees of approximately \$6,000 for the three months ended March 31, 2015.

#### 6. Accrued expenses

The Company has recorded the following accrued expenses as of March 31, 2016 and December 31, 2015, respectively:

	March 31, 2016	December 31, 2015
Accrued expenses	<u> </u>	
Accrued compensation expense	\$ 449,376	\$ 704,597
Accrued audit and tax fees	183,081	179,223
Accrued professional fees	733,221	194,790
Accrued R&D expense	873,666	466,076
Accrued other	82,700	194,694
Total amount of accrued expenses	\$2,322,044	\$1,739,380

#### 7. Stock-based compensation

Stock-based compensation expense for the three months ended March 31, 2016 and 2015 was \$0.4 million and \$0.2 million, 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 end	Three months ended March 31,		
	2016	2015		
Research and development	\$ 126,441	\$ 50,837		
General and administrative	241,942	166,498		
Total stock-option expense	\$_368,383	\$ 217,335		

There were no options exercised during the three months ended March 31, 2016 and 2015, respectively.

Pieris granted 1,068,881 and 25,000 options to employees, consultants, and directors under the 2014 Employee, Director and Consultant Equity Incentive Plan, (the "Plan") during the three months ended March 31, 2016 and 2015, 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 during the three months ended March 31, 2016 and 2015 was \$1.00 and \$1.86, respectively based on the following assumptions:

	Three months ended	Three months ended March 31,		
	2016	2015		
Dividend yield	0.0%	0.0%		
Expected volatility	75.53 - 76.00%	75.07%		
Risk-free interest rate	1.35% - 1.61%	1.66%		
Expected term	5.0 - 5.7 years	5.8 years		

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's estimated expected stock price volatility is based on the average volatilities of other guideline companies in the same industry. Pieris's expected term of options granted during the three months ended March 31, 2016 and 2015, 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.

#### 8. Consulting Shares

In March 2015, the Company entered into an independent consulting agreement (the "Consulting Agreement") with the Del Mar Consulting Group, Inc. and Alex Partners, LLC (the "Consultants"), pursuant to which the Company issued 150,000 shares of its common stock (par value \$0.01 per share) to the Consultants (the "Consulting Shares"). The Company agreed to retain the Consultants to provide investor relations consulting to the Company for a period commencing on March 6, 2015 (the "Commencement Date") and ending thirteen months after the Commencement Date (such period, the "Term"). The shares issued in

connection with the Consulting Agreement were deemed to be exempt from registration in reliance upon Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving any public offering.

The Company recognized expenses in connection with the Consulting Shares of \$0.3 million for the three months ended March 31, 2015 in general and administrative expenses. No expenses were recognized in 2016 as the remaining shares vested on September 2, 2015 and the remaining expense was recorded based on the fair value of the shares on that date.

#### 9. Recent Accounting Pronouncements

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. If this standard had been adopted as of March 31, 2016, the Company believes that it would have concluded there was no substantial doubt about its ability to continue as a going concern.

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.

In March 2016, the FASB issued ASU No. 2016-08, "Revenues from Contract with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)". The amendments are intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations by amending certain existing illustrative examples and adding additional illustrative examples to assist in the application of the guidance. This guidance is effective for fiscal years beginning after December 15, 2018 including interim periods within those fiscal years. The Company is currently evaluating the potential impact the adoption of this standard will have on its financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation – Stock Compensation (Topic 718): Improvement to Employee Share-Based Payment Accounting". Under the amendments in ASU 2016-09 several aspects of the accounting for share-based payment award transactions are simplified, including (i) income tax consequences, (ii) classification of awards as either equity or liabilities and (iii) classification on the statement of cash flows and (iv) estimation of forfeiture rates. This guidance is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for any interim or annual period. The Company is currently evaluating the potential impact the adoption of this standard will have on its financial statements and related disclosures.

In April 2016, the FASB issued ASU. No. 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing". The amendments in ASU 2016-10 add further guidance on identifying performance obligations and also to improve the operability and understandability of the licensing implementation guidance. The amendments do not change the core principle of the guidance in Topic 606. This guidance is effective for annual periods beginning after December 15, 2018, including interim reporting periods therein. 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

On April 18, 2016 the Company entered into a license and transfer agreement (the "Enumeral Agreement") with Enumeral Biomedical Holdings, Inc. ("Enumeral"), pursuant to which the Company acquired a non-exclusive worldwide license to use specified patent rights and know-how owned by Enumeral to research, develop and market fusion proteins.

Under the terms of the Enumeral Agreement, the Company agreed to pay Enumeral an upfront license fee of \$250,000 and a \$750,000 maintenance fee which is due on May 31, 2016. Under the initial license, the Company also agreed to pay Enumeral development milestones up to an aggregate of \$37.8 million and sales milestones up to an aggregate of \$67.5 million. The Company also agreed to pay Enumeral royalties within a range in the low to lower-middle single digits as a percentage of net sales depending on the amount of net sales in the applicable years. In the event that the Company is required to pay a license fee or royalty to any third party related to the licensed products, the royalty payment due to Enumeral shall be reduced by the amount of such third party fees or payments, up to 50% of the royalty payment for each calendar year due to Enumeral.

Under the terms of the Enumeral Agreement, the Company has an option that can be exercised at its discretion for twelve months after the date of the Agreement to license from Enumeral one of a specified set of antibodies owned by Enumeral for use in developing such fusion Anticalin proteins for use in the oncology area. In this case the Company must pay to Enumeral an additional undisclosed upfront payment and any resulting fusion protein products will be subject to additional royalties and development and sales milestones in the same amounts applicable to the fusion proteins under the initial license.

The term of the Enumeral Agreement ends upon the expiration of the last to expire patent covered under the license. The Enumeral Agreement may be terminated by the Company on 30 days' notice and by Enumeral upon 60 days' notice of a material breach by the Company (or 30 days with respect to a breach of payment obligations by the Company), provided that the Company has not cured such breach and dispute resolution procedures specified in the Enumeral Agreement have been followed. The Enumeral Agreement will also automatically terminate if the Company fails to make the maintenance fee payment described above.

#### 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, 2015, 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, 2015, filed with the SEC on March 23, 2016. 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, 2015.

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® based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immune-oncology multi-specifics tailored for the tumor microenvironment, 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 two distinct Anticalin proteins together or an antibody with one or more Anticalin proteins, thereby constituting a multispecific protein;
- *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; and
- *PRS-060* is a drug candidate that binds to the IL-4RA receptor, thereby inhibiting 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.

Each of our programs are in varying stages:

- 300-Series—We are conducting preclinical experiments on a number of 300-Series lead candidates and expect to complete preclinical phase in 2016. For our lead candidate, PRS-343, we expect to complete IND enabling studies in 2017 and plan a Phase I clinical study to begin in 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 obtained we are now continuing further development of PRS-080 in a Ib clinical study in CKD5 patients requiring hemodialysis and which we expect to complete by the end of 2016; and
- PRS-060—We have formulated PRS-060 for pulmonary delivery by inhalation, and we are actively preparing to carry out bioprocess optimization in preparation for cGMP ("current Good Manufacturing Practice"), manufacturing and preclinical safety and tolerability studies. We intend to begin a Phase I clinical trial with this program in 2017.

Our core Anticalin® 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. 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 periods ended March 31, 2016 and 2015, we reported a net loss of \$4.2 million and \$3.7 million, respectively. As of March 31, 2016, we had an accumulated deficit of \$84.0 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 period ended March 31, 2016 and 2015 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, to a much lesser extent, grants from government agencies.

The revenues from Sanofi, Daiichi Sankyo and Roche 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.

#### **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 candidates: 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 ® 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, 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, 2016 and March 31, 2015

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

	months ended ch 31, 2016	Three months ended March 31, 2015	
Revenues	\$ 1,247	\$	218
Research and development expenses	(3,659)		(1,525)
General and administrative expenses	(1,968)		(2,394)
Non-operating income (expense), net	 219		(3)
Net loss	\$ (4,161)	\$	(3,705)

#### Revenues

The following table provides a comparison of revenues for the periods presented (in thousands):

	nonths ended h 31, 2016	onths ended a 31, 2015	\$ Change	% Change
Upfront payments	\$ 837	\$ 	\$ 837	100%
Research and development services	410	_	410	100%
Government Grants	 <u> </u>	 218	(218)	(100%)
<b>Total Revenue</b>	\$ 1,247	\$ 218	\$ 1,029	472%

- The \$0.8 million increase in revenues from upfront payments in the period ended March 31, 2016 compared to the period ended March 31, 2015 relates to the recognition of a portion of the upfront payment under our collaboration with Roche, which commenced in January 2016. The revenue for the upfront payment is recorded based on the proportionate performance method using the full-time equivalents as a measure to spread the upfront payment over the research term. No upfront payments were recognized for the three months ended March 31, 2015.
- The \$0.4 million increase in revenues from research and development services in the three months ended March 31, 2016 compared to the three months ended March 31, 2015 relates to research and development services being provided to Roche pursuant to the Roche Agreement. No research and development services were recognized for the three months ended March 31, 2015.
- The decrease in revenues from grants in the three months ended March 31, 2016 compared to the three months ended March 31, 2015 results from the end of the Seventh Research Framework Program ("FP7") under which the Company recognized \$0.2 million in the three months ended March 31, 2015. No grant revenues were recognized for the three months ended March 31, 2016 as the Company received the last tranche under the FP7 program in November 2015 and no other programs under which the Company could receive government grants are currently in place.

#### Research and Development

The following table provides a comparison of the research and development expenses for our drug candidates and projects for the periods presented (in thousands):

	eı	e months nded 31, 2016	eı	e months nded 31, 2015	\$ (	Change	% Change
PRS-060	\$	347	\$	22	\$	325	1477%
PRS-080		349		613		(264)	(43)%
PRS-300 series		1,093		429		664	155%
Other R&D activities		1,870		461		1,409	306%
Total	\$	3,659	\$	1,525	\$	2,134	140%

Total research and development expenses were \$3.7 million for the three months ended March 31, 2016 as compared to \$1.5 million for the three months ended March 31, 2015.

The \$2.1 million increase in total research and development expenses in the three months ended March 31, 2016 compared to the three months ended March 31, 2015 is primarily due to:

- increased preclinical efforts associated with PRS-060, as we carry out for process optimization efforts;
- increased preclinical and CMC efforts for PRS-300 series as certain CMO agreements are put in place;
- offset by decreased preclinical and CMC expenses for PRS-080, as the Phase Ia trial has been completed; and
- increase in other R&D activities of \$1.4 million. This increase is due to a \$0.6 million increase in personnel-related expenses, including stock-based compensation expense due to the hiring of additional R&D staff, as well as a 5% license fee of \$0.3 million to TUM in relation to the Roche upfront payment. General lab supplies increased \$0.1 million as well as consulting costs of \$0.2 million and various facility costs allocated to research and development of \$0.2 million, primarily associated with the opening of our Boston office.

As of March 31, 2016, we employed 29 full-time and 2 consultants in our research and development group compared to 23 full-time, 5 part-time personnel in our research and development group as of March 31, 2015.

#### General and Administrative

General and administrative expenses were \$2.0 million for the three months ended March 31, 2016 compared to \$2.4 million for the three months ended March 31, 2015. The decrease resulted primarily from a \$0.8 million decrease in legal, consulting and audit costs. These amounts are offset by an increase of \$0.2 million in higher personnel-related costs, \$0.1 million increase in stock compensation expense and \$0.1 million increase for investor relation expenses.

#### Non-operating income (expenses), net

Non-operating other income increased to \$0.2 million in the three months ended March 31, 2016 from a deficit approximately of \$3,000 of non-operating expenses for the three months ended March 31, 2015. This increase is a result of net foreign currency transaction gains related to the strengthening of the Euro against the U.S. dollar at the end of the first quarter of 2016.

# **Liquidity and Capital Resources**

Through March 31, 2016, we have funded our operations with \$176.7 million of cash that has been obtained from the following main sources: \$102.7 million from sales of equity; \$6.5 million from loans; \$14.2 million from grants from government agencies; and \$53.3 million in total payments received under license and collaboration agreements, including \$12.2 million for research and development services costs we received from our collaboration partners. We expect that reimbursements of our development costs by Daiichi Sankyo and Sanofi will decline going forward, and we do not expect such reimbursements to be a significant source of funding in the future.

As of March 31, 2016, we had a total of \$31.2 million in cash.

We have experienced operating losses since our inception and had a total accumulated deficit of \$84.0 million as of March 31, 2016. We expect to incur additional costs and require additional capital. We have incurred losses in nearly every period since inception including the three months ended March 31, 2016. These losses have primarily resulted in significant cash used in operations. Due to the upfront payment received from Roche during the three months ended March 31, 2016 offset with our net losses for the period, our cash provided by operating activities was \$2.0 million. During the three months ended March 31, 2015, our cash used in operations was \$3.6 million. We have several research and development programs underway in varying stages of development and we expect they will continue to consume increasing amounts of cash for development, conducting clinical trials and the testing and manufacturing of product material. As we continue to conduct these activities necessary to pursue FDA approval of our 300-Series, including PRS-343, PRS-080 and PRS-060 and our other product candidates, we expect the cash needed to fund operations to increase significantly over the next several years.

On July 6, 2015 we closed a public offering of an aggregate of 9,090,909 shares of our common stock at a purchase price of \$2.75 per share. On July 28, 2015 the underwriters exercised their option to purchase an additional 1,211,827 shares of common stock at the public offering price of \$2.75 per share. Gross proceeds from the offering, including the over-allotment option, were \$28.3 million and net proceeds were approximately \$25.8 million. 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 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 for our 300-Series programs, including PRS-343, 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.

#### **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, 2015 for a discussion of our critical accounting policies and estimates. There were no significant changes to our Critical Accounting Policies and Estimates in the three months ended March 31, 2016.

#### **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.

#### **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.

#### 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, as well as for establishing and maintaining "adequate internal control over financial reporting" as such term is defined in Rule 13a-15(f). 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 Chief Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting and disclosure controls and procedures as of March 31, 2016. 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, 2016, our internal control over financial reporting is effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended March 31, 2016 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, 2015.

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

None

#### Item 3. Defaults Upon Senior Securities

None.

# Item 4. Mine Safety Disclosures

Not applicable.

# Item 5. Other Information

None.

# Item 6. Exhibits

# EXHIBIT INDEX

10.1*	License and Transfer Agreement by and between the Company and Enumeral Biomedical Holdings, Inc dated as of April 18, 2016.
10.2	Non-Employee Director Compensation Policy
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

<sup>\*</sup> Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC.

#### **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 12, 2016 By: /s/ Stephen S. Yoder

Stephen S. Yoder

President, Chief Executive Officer and Director

Date: May 12, 2016 By: /s/ Darlene Deptula-Hicks

Darlene Deptula-Hicks

Chief Financial Officer, Secretary and Treasurer

#### LICENSE AND TRANSFER AGREEMENT

This license and transfer agreement (the "Agreement") is entered into with effect as of April 18, 2016 (the "Effective Date") by and between Pieris Pharmaceuticals, Inc., a Nevada corporation with a place of business at 255 State Street, 9th Floor, Boston, MA 02109 and Pieris Pharmaceuticals GmbH, a German company with a place of business at Lise-Meitner-Strasse 30, 85354 Freising, Germany (collectively and together with their Affiliates, "Pieris") and Enumeral Biomedical Holdings, Inc., a Delaware corporation with a place of business at 200 CambridgePark Drive, Suite 2000, Cambridge, MA 02140 (together with its Affiliates, "Enumeral").

Whereas, Enumeral possesses proprietary technology and intellectual property rights related to certain antibodies; and

Whereas, Pieris wishes to obtain one or more of such antibodies for development and commercialization and a license to intellectual property related to such antibodies; and

Whereas, Enumeral is willing to provide such antibodies and license such intellectual property to Pieris for development and commercialization of novel compounds comprising fusion proteins based on such antibodies in oncology; and

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

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

Affiliate. The term "Affiliate" shall mean any individual, corporation, association or other business entity that directly or indirectly controls, is controlled by, or is under common control with the Party in question. As used in this definition of "Affiliate" only, the term "control" shall mean the direct or indirect ownership of more than fifty percent (>50%) of the stock having the right to vote for directors thereof or the ability to otherwise control the management of the corporation or other business entity whether through the ownership of voting securities, by contract, resolution, regulation or otherwise.

Anticalin<sup>®</sup>. The term "Anticalin<sup>®</sup>" shall mean, whether in nucleic acid or protein form, any mutein of any lipocalin. The term "mutein" shall mean a protein arising as a result of a mutation or a recombinant DNA procedure.

Commercially Reasonable Efforts. The term "Commercially Reasonable Efforts" shall mean 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 their product life taking into account the existence of other competitive products in the market place or under development, the proprietary position of the product, the regulatory structure

involved, 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. For avoidance of any doubt, Commercially Reasonably Efforts do not require Pieris to seek to market any therapeutic product in every country or seek to obtain regulatory approval in every country or for every potential indication.

Confidential Information. The term "Confidential Information" means all nonpublic information disclosed in oral, written, electronic or other form or otherwise learned by the Party receiving such information (the "Recipient"), including but not limited to information regarding the activities of the party disclosing such information (the "Discloser"), such as research, development, preclinical and clinical programs, data and results; pharmaceutical or biologic candidates and products; inventions, works of authorship, trade secrets, processes, conceptions, formulas, patents, patent applications, and licenses; business, product, marketing, sales, scientific and technical strategies, programs and results, including costs and prices; suppliers, manufacturers, customers, market data, personnel, and consultants; and other confidential matters related to Discloser. Pieris' Confidential Information shall specifically include any and all non-public sequence information provided by Pieris to Enumeral of Anticalin® proteins and/or lipocalin muteins, any and all therapeutic or diagnostic information of Anticalin® proteins and/or lipocalin muteins including any therapeutic drug programs derived therefrom, any and all information disclosed by Pieris to Enumeral relating to target molecules of Anticalin® proteins; provided however that Pieris shall not disclose any information related to the target molecules of any Anticalin® to Enumeral without the prior written consent of Enumeral. "Enumeral Confidential Information" shall be Confidential Information disclosed by Enumeral and "Pieris Confidential Information" shall be Confidential Information disclosed by Pieris.

Calendar Quarter. The term "Calendar Quarter" means each three-month period in any year commencing with January 1 of such year.

Definitive Agreement. The term "Definitive Agreement" shall have the meaning set forth in Section 4.

<u>Developed IP</u>. The term "Developed IP" shall have the meaning set forth in Section 6.

Effective Date. The term "Effective Date" shall have the meaning set forth in the first paragraph of the Agreement.

Enumeral IP. The term "Enumeral IP" shall mean (i) Know-How Enumeral owns or controls with respect to the First Antibody as of the Effective Date, (ii) Know-How Enumeral owns or controls with respect to the Subsequent Antibody as of the Option Exercise Date (as defined in Section 4.7) and (iii) the, Patent Rights Enumeral owns or controls claiming the First Antibody and, upon the Option Exercise Date, the Subsequent Antibody (including, without limitation, any patents issuing on such patent applications, and any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, division, continuation or continuation-in-part with respect thereto during the Term); and in the case of each clause (i), (ii) and (iii) only as such Know How and Patent Rights relate to the First Antibody and/or Subsequent Antibody, methods of using, administrating, manufacturing or formulating said First or Subsequent Antibody, useful or necessary for Pieris to develop and commercialize Products under this Agreement. The Patent Rights as of the Effective Date are listed in Exhibit A.

Exclusive Field. The term "Exclusive Field" shall mean the uses within the Field that employ a First Antibody and/or a Subsequent Antibody fused with or linked to one or more Anticalin® proteins.

<u>Field</u>. The term "Field" shall mean, all therapeutic, prophylactic, diagnostic and palliative uses for the diagnosis and treatment of cancer, provided that, subject to Section 4.8, any diagnostic uses shall be limited to Products and shall not include services until a Definitive Agreement is reached, which the Parties intend will provide for the inclusion of diagnostic services within the Field.

<u>First Antibody</u>. The term "First Antibody" shall mean, individually and collectively, the antibodies against PD-1 described in Exhibit B.

<u>GLP Tox Study</u>. The term "GLP Tox Study" means, with respect to a Product, a study conducted in accordance with GLP for the purposes of assessing the efficacy, safety or the onset, severity, and duration of toxic effects and their dose dependency to establish a profile sufficient to support the filing of an investigational new drug application.

Good Laboratory Practice or GLP. The term "Good Laboratory Practice" or "GLP" means the then-current Good Laboratory Practice Standards promulgated or endorsed by the U.S. Food and Drug Administration or in the case of any other country in the Territory, comparable regulatory standards promulgated or endorsed by that country, including those procedures expressed in or contemplated by any Regulatory Filings.

Infringed Patent. The term "Infringed Patent" shall mean an issued and unexpired patent (a) that has not been abandoned, held invalid, revoked, held or rendered unenforceable or lost through interference and (b) the claims of which would be infringed by Pieris' making, using, selling, offering for sale or importing of the First Antibody, Subsequent Antibody, or any portion or component thereof, as the case may be.

Know-How. The term "Know-How" shall mean data, knowledge and information, including chemical manufacturing data, toxicological data, pharmacological data, preclinical data, formulations, specifications, quality control testing data, that are necessary or useful for the discovery, manufacture, development or commercialization of any Product existing as of the date of this Agreement. For avoidance of doubt, Know-How does not include the antibody screening technology licensed by Enumeral from the Massachusetts Institute of Technology ("MIT") and further does not require Enumeral to provide samples of the First Antibody. The Parties will agree in writing whether and to what extent samples of any Subsequent Antibody are required in connection with the Definitive Agreement.

Maintenance Fee. The term "Maintenance Fee" shall have the meaning set forth in Section 4.

Major Markets. The term Major Markets means the territories of North America, European Union and Japan.

<u>Marketing Authorization</u> or <u>MA</u>. The term "Marketing Authorization" or "MA" shall mean shall mean any approvals, licenses, registrations or authorizations, including any pricing approvals, necessary for the sale of a Product on the market in any country of the Territory as granted by a competent regulatory authority.

<u>Modifications</u>. The term "Modifications" means an alteration, mutation or derivative of the First Antibody or any Subsequent Antibody invented, conceived or reduced to practice by or on behalf of Pieris, its Affiliates or its Sublicensees. For avoidance of doubt, Modification shall not mean the First Antibody or the Subsequent Antibody fused with or linked to an Anticalin.

Net Sales. The term "Net Sales" shall mean shall mean for a Product in a particular period, the sum of (1) and (2):

- (1) the gross amount invoiced by Pieris for sale of Products to Third Parties in the Field and Territory, excluding transactions transferring a Product to a Pieris Affiliate, Sublicensee, distributor and/or agent for resale, less the sum of the following items:
  - (a) customary trade, prompt payment, quantity or cash discounts to the extent actually allowed and taken;
  - (b) amounts repaid or credited by reason of rejection, recalls or returns;
  - (c) to the extent separately stated on purchase orders, invoices or other documents of sale, any taxes, duties, tariffs or other governmental charges levied on the production, sale, transportation, delivery or use of a Product;
  - (d) outbound transportation costs prepaid or allowed and costs of insurance of transit;
  - (e) discounts or rebates or other payments required by law to be made under Medicaid, Medicare or other governmental special medical assistance programs to the extent actually allowed and taken; and
  - (f) amounts written off by reason of uncollectible bad debt, but not to exceed [\*\*\*] ([\*\*\*]) of the Net Sales per calendar year.

No other deductions shall be made for commissions paid to individuals whether they be with independent sales agencies or regularly employed by Pieris and on its payroll, or for the cost of collections. Products shall be considered "sold" ninety (90) days after billing or invoicing, or upon receipt of payment, whichever comes first, provided, however, that Products are actually shipped to customers.

(2) for Sublicensees, the net sales amounts reported on a calendar quarterly basis to Pieris in accordance with the Sublicensee contractual terms and their then-currently used accounting standards (provided, however, that such accounting standards are consistent with the US GAAP and/or IFRS or such other internationally recognized accounting standards as may be agreed by the Parties).

Party. The term "Party" shall mean Pieris or Enumeral, as the case may be, and "Parties" shall mean Pieris and Enumeral collectively.

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

<u>Phase I Clinical Trial</u>. The term "Phase I Clinical Trial" means a human clinical trial for any Product in any country that would satisfy the requirements of 21 CFR 312.21(a).

<u>Phase II Clinical Trial</u>. The term "Phase II Clinical Trial" means a human clinical trial conducted in any country that would satisfy the requirements of 21 CFR 312.21(b) and is intended to explore one or more doses, dose response, and duration of effect, and to generate initial evidence of clinical activity and safety, for any Product in the target patient population.

<u>Phase III Clinical Trial</u>. The term "Phase III Clinical Trial" means a clinical trial in an extended human patient population designed to obtain data determining efficacy and safety of any Product to support regulatory approvals in the proposed therapeutic indication, as more fully defined in 21 C.F.R. §312.21(c), or its successor regulation, or the equivalent in any foreign country.

Product. The term "Product" shall mean a fusion protein, or formulations containing such fusion protein, that constitutes a First Antibody, Subsequent Antibody and/or Modification, which First Antibody, Subsequent Antibody, or any component or portion thereof, and/or Modification is fused with or linked to at least one Anticalin®. For avoidance of doubt, Product may also include a First Antibody, Subsequent Antibody and/or Modification that is fused with or linked to an Anticalin® and one or more additional proteins. The term "Product" expressly includes bi- and multi-specific fusion proteins against at least two and up to an unlimited number of targets.

Royalty Term. The term "Royalty Term" shall mean, with respect to a Product and for a given country, the period of time commencing on the date of first commercial sale of the Product in such country and ending on the later of the date that is (a) [\*\*\*] years after the date of the first commercial sale of the Product in such country, or (b) the expiration of the last to expire or lapse of any valid claims of Patent Rights owned by Enumeral and filed as of the Effective Date in such country covering the use, import, offering for sale, or sale of the Product.

Sublicensee. The term "Sublicensee" shall mean an entity to which Pieris has licensed any right (through one or multiple tiers) pursuant to this Agreement.

<u>Subsequent Antibody</u>. The term "Subsequent Antibody" shall mean the antibody or antibodies which principally and specifically bind(s) to one of the target sites known as [\*\*\*] owned by Enumeral other than the First Antibody that is licensed by Pieris pursuant to Section 4.7, as will be more specifically described in Exhibit C included in the Definitive Agreement.

Territory. The term "Territory" shall mean all countries of the world.

Term. The term "Term" shall have the meaning set forth in Section 9.1.

Third Party. The term "Third Party" shall mean any party other than Pieris or Enumeral.

#### 2. Grant of License and Transfer

- 2.1 <u>License to Pieris</u>. Subject to the terms and conditions hereof, Enumeral hereby grants to Pieris during the Term a currently effective, royalty bearing, non-exclusive (except as to the Exclusive Field) right and license (including the right to sublicense through multiple tiers), under Enumeral IP, to research, have researched, develop, have developed, register, have registered, use, have used, make, have made, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sold and have sold Products in the Field and in the Territory.
- 2.2 <u>Transfer</u>. Within ten (10) days of payment of the Initial Fee, Enumeral shall provide to Pieris the full sequence information for the First Antibody and relevant Know-How related to the First Antibody as described in the definition of Enumeral IP.
- 2.3 Exclusive Field. Until the completion of all royalty payments under Section 4.5, Enumeral hereby covenants and agrees it shall not practice in the Exclusive Field. For avoidance of any doubt, during such period of time, Enumeral shall not conduct any research or development efforts in the Exclusive Field and shall not file any patent applications claiming any invention in the Exclusive Field or assist Third Parties in doing so. Enumeral further shall not out-license any Enumeral IP for use in the Exclusive Field to any party other than Pieris and shall, if applicable, include in any out-license or other agreement a restriction prohibiting the use of a First Antibody and/or Subsequent Antibody in the Exclusive Field. Enumeral shall remain responsible for enforcement of this Section and shall by liable for any breach of this Section by any licensee or sublicensee of Enumeral that violate this Section. Notwithstanding the foregoing, nothing herein shall be deemed to prevent any Third Party from acquiring Enumeral, even if it is engaged in the research, development or sale of lipocalins, provided it does not use such lipocalins with any Enumeral IP during the period herein.
- 2.4 <u>Sublicenses</u>. Pieris shall have the right to sublicense or subcontract (through multiple tiers) without the prior consent of Enumeral; provided, however, that in the event of such sublicensing, (a) such Sublicensees will be subject to at least the same confidentiality and diligence obligations Pieris has hereunder, and (b) Pieris will remain liable for all the terms and conditions of this Agreement and for any breach by the Sublicensee of these terms, (c) Pieris promptly notifies Enumeral of any Sublicense along with the identity of the applicable Sublicensee(s), and (d) all Sublicenses shall be in writing. Pieris shall not sublicense the First Antibody, any Subsequent Antibody or a Modification unless it is part of a Product.

#### 3. Diligence.

3.1 <u>Diligence</u>. During the Term of the Agreement, Pieris shall use Commercially Reasonable Efforts to develop at least one Product for sale in at least each of the Major Markets.

#### 4. Payments.

4.1 <u>Initial Fee</u>. Pieris shall pay to Enumeral an initial fee of \$250,000, which shall be due upon execution of this Agreement and paid within fifteen (15) days of the Effective Date.

- 4.2 Maintenance Fee. By May 31, 2016 Pieris shall pay to Enumeral a maintenance fee of \$750,000 ("Maintenance Fee"). In the event that Pieris does not pay this Maintenance Fee, the Agreement shall terminate and the license under Section 2.1 shall automatically terminate. For the avoidance of doubt, the non-payment of the Maintenance Fee shall not be deemed a breach of this Agreement and other than the initial fee set forth in Section 4.1, Pieris shall have no further financial obligation to Enumeral. Simultaneous with the payment of the Maintenance Fee by Pieris, the Parties shall execute a full license and transfer agreement including customary contractual terms that set forth all rights and obligations of the Parties ("Definitive Agreement") and superseding this Agreement, which the Parties hereby agree to diligently negotiate in good faith upon execution of the Agreement. If the Parties fail to agree on a Definitive Agreement by the due date for payment of the Maintenance Fee specified in this Section, Pieris may elect, upon its sole discretion, to pay the Maintenance Fee and this Agreement shall continue to govern the rights and obligations of the Parties. For avoidance of any doubt, Enumeral shall not have the right to terminate this Agreement for failure to execute the Definitive Agreement. Moreover, failure to execute a Definitive Agreement shall not affect any of Pieris' or Enumeral's rights under this Agreement.
- 4.3 Development Milestone Payments. With respect to each of the First Antibody and the Subsequent Antibody, Pieris shall pay the following milestone payments to Enumeral by the later of (i) [\*\*\*] days of the occurrence of [\*\*\*] Product (and [\*\*\*] and [\*\*\*] Product) to achieve each of the following events and (ii) [\*\*\*] days of the occurrence of the following events for any corresponding milestone payment with respect to any payment from Sublicensee to Pieris:

	[***] Product,	[***] Product or	[***] Product or
Development Event	[***] indication	indication	indication
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]		
[***]	[***]		
[***]	[***]		
[***]	[***]		
[***]	[***]	[***]	[***]
[***]	[***]		
[***]	[***]		
[***]	[***]		
Total	[***]		
Grand Total	\$37,750,000 (thir	ty seven million sever	n hundred and
	fifty they send del	llowa)	

fifty thousand dollars)

For avoidance of any doubt, in no event shall milestone payments paid by Pieris under this Section 4.3 exceed \$37,750,000 (thirty-seven million seven hundred and fifty thousand dollars) for the First Antibody and \$37,750,000 (thirty-seven million seven hundred and fifty thousand dollars) for the Subsequent Antibody.

4.4 <u>Sales Milestone Payments</u>. With respect to each of the First Antibody and the Subsequent Antibody, Pieris shall pay the following sales milestone payments to Enumeral by the later of (i) [\*\*\*] days of the occurrence of [\*\*\*] and [\*\*\*] Product to achieve each of the following events and (ii) [\*\*\*] days of the occurrence of the following events for any corresponding milestone payment with respect to any payment from Sublicensee to Pieris:

Net sales threshold	[***] Product	[***] Product
1st year with Net Sales [***]	[***]	[***]
1st year with Net Sales [***]	[***]	[***]
1st year with Net Sales [***]	[***]	[***]
Total	[***]	[***]
Grand Total	\$67,500,000 (sixty	y seven million
	five hundred thou	sand dollars)

For avoidance of any doubt, in no event shall milestone payments paid by Pieris under this Section 4.4 exceed \$67,500,000 (sixty-seven million five hundred thousand dollars) for the First Antibody and \$67,500,000 (sixty-seven million five hundred thousand dollars) for the Subsequent Antibody. Net Sales shall be calculated on a worldwide basis.

4.5 <u>Royalty Payments.</u> During the Royalty Term, Pieris shall pay the following royalty payments to Enumeral within the time set forth in Section 5.2(b):

Royalty Tier	Royalty Rate on incremental annual Net Sales
[***] in Net Sales	[***]

Royalty payments under this Section 4.5 shall be incremental and calculated and paid on a Product-by-Product and on a worldwide basis. For avoidance of doubt, the Royalty Term shall be on a country-by country basis and a royalty under this Section 4.5 shall not be paid for Net Sales in countries where the Royalty Term has expired.

#### 4.6 Royalty Payment Reduction.

- 4.6(a) In the event that Pieris is required to enter into a license or other agreement and pay a license fee or royalty to any Third Party for an Infringed Patent, the royalty payment described in Section 4.5 shall be reduced by the amount of such Third Party payment, up to fifty percent (50%) of the royalty payment for each calendar year. For the avoidance of doubt, in no event shall the royalty rate under Section 4.5 be reduced by more than fifty percent (50%) in any period.
- 4.6(b) In the event that no valid patent claim issues from the Enumeral IP covering the First Antibody or Subsequent Antibody in a country or that all claims of the Enumeral IP covering the First Antibody or Subsequent Antibody are subsequently invalidated in a country, then the royalty shall be reduced by [\*\*\*] ([\*\*\*]) for the duration of the Royalty Term on a country-by-country basis. For the avoidance of doubt, in no event shall the royalty rate under Section 4.5 be reduced by more than [\*\*\*] ([\*\*\*]) in any period.
- 4.7 <u>Subsequent Antibody Payment</u>. Enumeral hereby grants to Pieris an exclusive option, for a period ending 12 months after the Effective Date, to license one (1) Subsequent Antibody owned or controlled by Enumeral in order to develop and commercialize one or more additional Products within the Field. Such Subsequent Antibody shall be identified by Pieris to Enumeral in writing no later than the time the Maintenance Fee is paid pursuant to Section 4.2. If Pieris wishes to exercise the option, Pieris shall pay Enumeral [\*\*\*] within [\*\*\*] days of Pieris' written notice to Enumeral of its election to exercise the option ("<u>Option Exercise Date</u>") described in this section and within [\*\*\*] days of such payment, Enumeral shall provide to Pieris the full sequence information and any related Know-How for the Subsequent Antibody useful or necessary for Pieris to develop and commercialize Products under this Agreement. In the event that Pieris makes such an election, the Definitive Agreement (or this Agreement, in the event that there is no Definitive Agreement) shall apply to the Subsequent Antibody *mutatis mutandis* as if the Subsequent Antibody was a new First Antibody, meaning all terms shall apply to it in addition to the application of the terms to the First Antibody.
- 4.8 <u>Diagnostic Services Payment</u>. For a Product used in connection with a diagnostic service, the Parties shall negotiate in good faith a payment structure for such services in the Definitive Agreement by Pieris to Enumeral. Such payment structure shall be in view of Enumeral's Third Party obligations to the Massachusetts Institute of Technology and shall take into account the Parties' desire to maintain the same overall economic structure as set forth in this Agreement.

4.9 <u>Development and Commercialization</u>. Pieris shall be solely responsible for development and commercialization of all Products under this Agreement, and shall have no obligation to consult with Enumeral regarding such development or commercialization activities.

#### 5. Reports; Payments; Records.

#### 5.1 Reports and Payments.

- (a) Reports. Within [\*\*\*] days after the conclusion of each Calendar Quarter commencing with the first Calendar Quarter in which Net Sales are generated, Pieris shall deliver to Enumeral a report containing the following information (in each instance, on a Product-by-Product basis):
  - (i) the amount of Products sold, leased or otherwise transferred or performed by Pieris, its Affiliates and Sublicensees for the applicable Calendar Quarter;
  - (ii) the gross amount billed or invoiced for Products sold, leased or otherwise transferred or performed by Pieris, its Affiliates and Sublicensees during the applicable Calendar Quarter;
  - (iii) a calculation of Net Sales for the applicable Calendar Quarter;
  - (v) the total amount payable to Enumeral in U.S. Dollars on Net Sales for the applicable Calendar Quarter, together with the exchange rates used for conversion.

Each such quarterly report shall be certified on behalf of Pieris by its chief financial officer as true, correct and complete in all material respects. If no amounts are due to Enumeral for a particular Calendar Quarter, the report shall so state. To the extent that any of the information described in this Section 5.1(a) is not received from a Sublicensee, Pieris shall not be required to provide such information to Enumeral but shall take actions to obtain such information.

- (b) Payment. Within the later of (i) [\*\*\*] days after the end of each Calendar Quarter and (ii) [\*\*\*] days after the end of each Quarter with respect to any payment from any Sublicensee, Pieris shall pay Enumeral all amounts due with respect to Net Sales for the applicable Calendar Quarter.
- 5.2. <u>Payment Currency</u>. All payments due under this Agreement will be paid in U.S. Dollars. Conversion of foreign currency to U.S. Dollars will be made at the conversion rate existing in the United States (as reported in the Wall Street Journal) on the last working day of the applicable Calendar Quarter. Such payments will be without deduction of exchange, collection or other charges.
- 5.3. Records. Pieris shall maintain, and shall, if applicable, cause its Affiliates to maintain, complete and accurate records of Products that are sold, leased or transferred under this Agreement, any amounts payable to Enumeral in relation to such Products, which records shall contain sufficient information to permit Enumeral to confirm the accuracy of any reports or notifications delivered to Enumeral under Section 5.1. Pieris and its Affiliates, as applicable, shall retain such records relating to a given Calendar Quarter for at least [\*\*\*]

years after the conclusion of that Calendar Quarter, during which time Enumeral will have the right, at its expense, to cause an independent, certified public accountant to inspect such records of Pieris during normal business hours for the purposes of verifying the accuracy of any reports and payments delivered under this Agreement and Pieris' compliance with the terms hereof. Such accountant or other auditor, as applicable, shall not disclose to Enumeral any information other than information relating to the accuracy of reports and payments delivered under this Agreement. The Parties shall reconcile any underpayment or overpayment within [\*\*\*] days after the accountant delivers the results of the audit. If any audit performed under this Section 5.3 reveals an underpayment in excess of [\*\*\*] in any calendar year, Pieris shall reimburse Enumeral for all amounts incurred in connection with such audit. For avoidance of doubt, Enumeral shall not have the right to audit or inspect Sublicensee(s) directly but may audit or inspect any applicable materials received from Sublicensee and in the possession of Pieris. Pieris, however, shall audit Sublicensees and require royalty and milestone reports in connection with any Sublicense. Enumeral may exercise its rights under this Section 5.3 only once every 12-month period and only with reasonable prior notice.

- 5.4. <u>Late Payments</u>. Any payments by Pieris that are not paid on or before the date such payments are due under this Agreement will bear interest at [\*\*\*] percent ([\*\*\*]%) per month. Interest will accrue beginning on the first day following the due date for payment and will be compounded quarterly. Payment of such interest by Pieris shall not limit, in any way, Enumeral's right to exercise any other remedies Enumeral may have as a consequence of the lateness of any payment.
- 5.5. <u>Payment Method</u>. Each payment due to Enumeral under this Agreement shall be paid by check or wire transfer of funds to Enumeral's account in accordance with written instructions provided by Enumeral. If made by wire transfer, such payments shall be marked so as to refer to this Agreement.
- 5.6. Withholding and Similar Taxes. If Pieris is required to withhold any amounts payable hereunder to Enumeral due to the applicable laws of any country, such amount will be deducted from the payment to be made by Pieris and remitted to the appropriate taxing authority for the benefit of Enumeral. Pieris will withhold only such amounts as are required to be withheld by applicable law in the country from which payment is being made. Pieris shall submit to Enumeral originals of the remittance voucher and the official receipt evidencing the payment of the corresponding taxes with the applicable royalty report. Pieris will cooperate with Enumeral to provide such information and records as Enumeral may require in connection with any application by Enumeral to the tax authorities in any country, including attempt to obtain an exemption or a credit for any withholding tax paid in any country.

#### 6. Intellectual Property.

6.1 <u>Product Intellectual Property</u>. Pieris shall have the right to file patent applications on inventions developed by, at the direction of, or under the sponsorship of Pieris (including but not limited to inventions conceived or reduced to practice by Pieris employees, contractors, consultants, and/or Sublicenses) related to any Product, materials, processes or other intellectual property generated under this Agreement including any manufacture,

formulation or use thereof ("**Developed IP**"). For avoidance of doubt, Developed IP includes but is not limited to IP directed to the sequence for any Product and formulations, methods of use, and methods of manufacture thereof. In the event of termination of this Agreement, Pieris shall continue to own such intellectual property.

6.2 <u>License to Enumeral</u>. For any Developed IP that falls outside of the scope of the Product and Developed IP related to the Product (including but not limited to the Product formulations, methods of use of the Product, methods of manufacture of the Product, target-based claims including the Product, and the Exclusive Field) (collectively, the "Grantback IP"), Pieris hereby grants to Enumeral, on a claim-by-claim basis, a royalty free, fully paid up, non-exclusive license (with the right to sublicense) to any such claims from the Grantback IP; for the sake of clarity, nothing in the license granted under this Section 6.2 shall affect the scope of the Exclusive Field or the covenant by Enumeral under Section 2.3. Without limiting the foregoing, if Pieris files patent application and/or obtains a patent containing a claim or claims directed to a Modification (other than a Modification fused with or linked to an Anticalin), whether singly or one or more of many claims under a broader patent, then it (or such claims, as the case may be) shall be part of the Grantback IP licensed hereunder, including but not limited to a composition of matter and method of use or manufacture, and any vectors or host cells related thereto.

#### 7. Liability and Indemnification.

7.1 <u>Indemnity by Enumeral</u>. Enumeral shall indemnify, defend and hold harmless Pieris, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, the "Pieris Indemnitees") from and against all liabilities, damages, losses and expenses (including reasonable attorneys' fees and expenses of litigation) (collectively, "Losses") (i) incurred by or imposed upon the Pieris Indemnitees, or any of them, as a result of any claim by MIT, Whitehead Institute for Biomedical Research, the General Hospital Corporation (d/b/a Massachusetts General Hospital), the President and Fellows of Harvard College, and Howard Hughes Medical Institute (collectively the "MIT Agreement Parties") in connection with any agreement between the MIT Agreement Parties and Enumeral, or (ii) incurred by or imposed upon the Pieris Indemnitees, or any of them, as a direct result of claims, suits, actions, demands or judgments of Third Parties arising out of or resulting from a breach of the representations and warranties hereunder (collectively, the "Pieris Indemnity Claims").

7.2 <u>Indemnity by Pieris</u>. Pieris shall indemnify, defend and hold harmless Enumeral, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, the "Enumeral Indemnitees") against any Losses incurred by or imposed upon the Enumeral Indemnitees, or any of them, as a direct result of claims, suits, actions, demands or judgments of Third Parties arising out of or resulting from (i) the development, commercialization, manufacture or use of any Product either before or after the receipt of any MA or (ii) any breach of the representations and warranties hereunder (collectively, the "Enumeral Indemnity Claims").

- 7.3 Conditions for Indemnification. A Person seeking recovery under this Section 7 (the "Indemnified Party") in respect of a Claim shall give prompt notice of such Claim to the Party from whom indemnification is sought (the "Indemnifying Party"); and provided that the Indemnifying Party is not contesting its obligation under this Section 7, shall permit the Indemnifying Party to control any litigation relating to such Claim and the disposition of such Claim; and further provided, that the Indemnifying Party shall (a) act reasonably and in good faith with respect to all matters relating to the settlement or disposition of such Claim as the settlement or disposition relates to such Indemnified Party and (b) not settle or otherwise resolve such claim without the prior written consent of such Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). Each Indemnified Party shall cooperate with the Indemnifying Party in its defense of any such Claim in all reasonable respects and shall have the right to be present in person or through counsel at all legal proceedings with respect to such Claim. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Section 7.
- 7.4 <u>Insurance</u>. Each Party shall procure and maintain insurance, including, as applicable to Pieris and any of its Affiliates, product liability insurance, or shall self-insure, in each case in a manner adequate to cover its obligations under this Agreement and consistent with normal business practices of prudent companies similarly situated at all times during the Term and for a period of five (5) years thereafter. Each Party shall procure insurance or self-insure at its own expense. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Section 7. Each Party shall provide the other Party with written evidence of such insurance or self-insurance upon request. Each Party shall provide the other Party with prompt written notice prior to the cancellation, non-renewal or material change in such insurance.

# 8. Confidentiality.

8.1 <u>Treatment of Confidential Information</u>. With respect to Confidential Information of Discloser, Recipient agrees to: (a) use such Confidential Information solely as contemplated by this Agreement (including by Pieris for the development and commercialization of one or more Products) and for no other purpose; (b) hold such Confidential Information in confidence and not to disclose such Confidential Information to others, except to its employees, consultants and representatives who require Confidential Information in order to carry out the Purpose and who are subject to binding obligations of confidentiality and restricted use at least as protective as those of this Agreement; (c) protect the confidentiality of such Confidential Information using at least the same level of efforts and measures used to protect its own valuable confidential information, and at least commercially reasonable efforts and measures; and (d) notify Discloser as promptly as practicable of any unauthorized use or disclosure of such Confidential Information of which Recipient becomes aware.

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

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- 8.2 Exceptions to Confidential Treatment. The obligations of Section 8.1 shall not apply to any Confidential Information that:
  (a) Recipient knew before learning it under this Agreement, as demonstrated by written records predating the date it was learned under this Agreement; (b) is now, or becomes in the future, publicly available except by an act or omission of Recipient; (c) a Third Party discloses to Recipient without any restriction on disclosure or breach of confidentiality obligations to which such Third Party is subject; or (d) Recipient independently develops without use of or reference to Confidential Information, as demonstrated by Recipient's written records contemporaneous with such development.
- 8.3 <u>Required Disclosures</u>. Notwithstanding Section 8.1, Recipient may disclose Discloser's Confidential Information to the extent and to the persons or entities required under applicable governmental law, rule, regulation or order provided that Recipient (a) first gives prompt written notice of such disclosure requirement to Discloser so as to enable Discloser to seek any limitations on or exemptions from such disclosure requirement and (b) reasonably cooperates at Discloser's request in any such efforts by Discloser.
- 8.4 Ownership of Confidential Information. Subject to Section 8.6, Discloser retains all right, title and interest in and to its Confidential Information.
- 8.5 <u>Publicity</u>. Upon execution of this Agreement, the Parties may file the Form 8-K statements attached as Exhibit D. No disclosure of the existence, or the terms, of this Agreement may be made by either Party, and no Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as otherwise set forth herein and/or to the extent as may be required by law or regulation (including, but not limited to, federal and state securities laws), for which prior written permission is not required. With respect to any filing of this Agreement with the U.S. Securities and Exchange Commission, each Party will provide the other Party with reasonable advance notice and a copy of the portion of such proposed filing to which the Agreement directly relates. Each Party may provide comments and/or requests regarding any proposed confidential treatment of the Agreement or the terms and conditions of the Agreement, as the case may be, and the other Party will consider any reasonable comments and requests made with respect to such filing, provided that such comments and requests are consistent with applicable law and regulation. The Parties will agree to propose redaction of the same information on any confidential treatment application for this Agreement (and, if applicable, the Definitive Agreement). Notwithstanding this Section 8.5, each Party shall be permitted to issue, at a later date, public filings, presentations and press releases regarding this Agreement or the Definitive Agreement that contain information from the Parties' Form 8-K statements attached as Exhibit D and, as applicable, the Enumeral press release attached as Exhibit E.

- 8.6 Ownership of Information and Data. All information generated by Pieris using Enumeral Confidential Information including but not limited to all data and information related to the Product shall be the sole property of Pieris and Pieris shall have the unlimited right to use and disclose such information. All information related to the Product, whether generated using Enumeral Confidential Information or otherwise, shall be the sole property of Pieris. Pieris shall have no obligation to disclose the information described in this Section 8.6 to Enumeral.
- 8.7 <u>Third Party Disclosure</u>. Notwithstanding anything in this Section 8, either Party may share the existence and terms of this Agreement and Enumeral Confidential Information related to the First Antibody with Third Parties under an obligation of confidentiality at least as restrictive as those of this Agreement and the CDA (as defined below) without the prior consent of the other Party. This includes the right to provide such information to potential investors in order to facilitate investment financing in connection with the development of one or more Products by Pieris. In all events, each Party remains subject to its obligations set forth herein and in the CDA.
- 8.8 <u>Prior Agreements</u>. The parties have previously entered into a Mutual Confidential Disclosure Agreement, dated October 9, 2015 (the "CDA") and the Material Transfer and Non-Disclosure Agreement, dated January 27, 2016 (the "MTA"). Confidential Information under this Agreement includes all non-public information disclosed in connection with the CDA and the MTA. To the extent that there are any inconsistencies, this Agreement shall supersede the CDA and the MTA.

#### 9. Term and Termination.

- 9.1 <u>Term</u>. The Term of this Agreement shall be from the Effective Date and, in the absence of early termination as provided for below, shall expire upon the expiration of the last to expire patent claim from the Enumeral IP covering the use, import, offering for sale or sale of any Product.
- 9.2 Termination by Pieris. Pieris may terminate this Agreement at any time upon thirty (30) days' notice.
- 9.3 <u>Termination by Enumeral</u>. Enumeral may terminate this Agreement if Pieris breaches any of its material obligations under this Agreement and fails to cure such breach within sixty (60) days (or thirty (30) days with respect to a breach of payment obligations by Pieris) following its receipt of written notice thereof from Enumeral if such breach is curable within the aforesaid period; *provided*, *however*, that, without limiting the application of Section 11.3 to this Agreement, if there is a dispute between the Parties in connection with such termination under this Section 9.3 shall be subject to the dispute resolution procedures of Section 11.3.
- 9.4 <u>Termination for Insolvency</u>. A Party shall have the right to terminate this Agreement in its entirety upon immediate written notice if the other Party (i) applies for or consents to the appointment of, or the taking of possession by, a receiver, custodian, trustee or liquidator of itself or of all of a substantial part of its property, (ii) makes a general assignment for the benefit of its creditors, (iii) commences a voluntary case under the Bankruptcy Code (as defined below) of any country, (iv) fails to controvert in a timely and appropriate manner, or acquiesce in writing to, any petition filed against it in any involuntary case under the Bankruptcy Code of any country, (v) takes a corporate action for the purpose of effecting

any of the foregoing, or (vi) has an order for relief against it entered in an involuntary case under the Bankruptcy Code of any country and, in any of (i) through (v) above, the application, assignment, commencement, filing, or corporate action continues unstayed for, and/or is not otherwise discharged or withdrawn on or before, a period of sixty (60) days.

- 9.5 Effect of Termination. In the event of a termination of this Agreement, (a) Pieris may retain and shall not be required to provide Enumeral with information or materials related to any Products created or developed in connection with this Agreement, including the material described in Section 8.6 and (b) all licenses to Enumeral IP shall terminate and, until a Definitive Agreement is reached to more distinctly set forth the Parties' rights post-termination, Pieris shall no longer have the right to develop and commercialize Products.
- 9.6 <u>Survival</u>. The following Sections shall survive termination or expiration of this Agreement:1, 4 (to the extent any payments are or will be earned as of or after termination), 5 (to the extent any payments are or will be earned as of or after termination), 6.1, 7, 8, 9, 10, 11.2, 11.3, 11.4, 11.5, 11.6, 11.7 and 11.8.

# 10. Representations and Warranties.

- 10.1 No Notice of Infringement. Enumeral warrants and represents that it has not received a cease and desist letter or otherwise been informed by a Third Party that it may be infringing intellectual property related to the First Antibody or that would otherwise adversely impair Pieris' ability to develop and commercialize Products under this Agreement.
- 10.2 No Conflicting Obligation. Enumeral warrants and represents that it has the ability to enter into this Agreement and that no agreement with any Third Party, including MIT, conflicts with this Agreement.
- 10.3 <u>Mutual Representations and Warranties</u>. Pieris and Enumeral each represents and warrants to the other, as of the Effective Date (except as otherwise noted), as follows:
  - (a) <u>Organization</u>. 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.
  - (b) <u>Authorization</u>. 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.
  - (c) <u>Binding Agreement</u>. This Agreement is a legal, valid and binding obligation of such Party, enforceable against it in accordance with its terms and conditions.
  - (d) 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.

(e) <u>Compliance with Law</u>. 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, including, with respect to Pieris, those laws and regulations relating to the development, manufacture, use, sale and importation of Products.

# 11. Miscellaneous.

- 11.1 <u>Bankruptcy</u>. All licenses (and to the extent applicable rights) granted under or pursuant to this Agreement by Enumeral to Pieris are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, United States Code (the "Bankruptcy Code") licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The Parties agree that Pieris, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.
- 11.2 <u>Limitation on Damages</u>. Other than the representations and warranties set forth herein, Pieris and Enumeral disclaim all other warranties, whether express or implied, with respect to each of their obligations hereunder, including whether one or more Products can be successfully developed or marketed. In no event shall either Pieris or Enumeral be liable for special, indirect, incidental or consequential damages arising out of this Agreement based on contract, tort or any other legal theory.
- 11.3 <u>Dispute Resolution.</u> In the event of any controversy, claim or counterclaim arising out of or in relation to this Agreement, the Parties will first attempt to resolve such controversy or claim through good-faith negotiation between Pieris' CEO and Enumeral's CEO, for a period of not less than thirty (30) days following written notification of such controversy or claim to the other Party. If such controversy or claim cannot be resolved by means of such negotiations during such period, then it will be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with such rules. The place of arbitration will be New York, the language to be used in the arbitration proceedings will be English. Notwithstanding the foregoing, nothing shall prevent either Party from seeking injunctive or other similar equitable relief in in the venue permitted by Section 11.4.
- 11.4 <u>Governing Law</u>. This Agreement shall be governed by and construed in accordance with the laws of New York, without reference to its conflict of laws principles. Subject to Section 11.3, the Parties consent to the exclusive jurisdiction of the state and federal courts of New York in the event that there is a dispute related to this Agreement.
- 11.5 <u>Assignment</u>. This Agreement may not be assigned or transferred by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, either Party shall have the right to assign this Agreement to its Affiliates or to a Third Party in connection with: (i) an acquisition (of or by), a consolidation with, or merger into, any other corporation or other entity or person; (ii) any corporate reorganization wherein there is a change of control; or (iii) the sale of its business to which this Agreement is related; *provided, however, that* in any such transaction the assignee expressly obligates itself in a

written instrument delivered to the non-assigning Party to this Agreement, on or before the date of closing of such transaction, to fully perform all of the obligations of the assigning Party under this Agreement. This right of assignment shall likewise be available to the assignee in the same manner as it is to the assigning Party, and subsequent assignees in like manner, provided that in each instance of assignment, the assignee provides the writing specified above to the non-assigning Party to this Agreement prior to the date of closing of such transaction.

- 11.6 Entire Understanding. This Agreement contains the entire understanding between the Parties hereto with respect to the within subject matter and supersedes any and all prior agreements, understandings and arrangements, whether written or oral.
- 11.7 <u>Unenforceable Provisions and Severability</u>. If any of the provisions of this Agreement are held to be void or unenforceable, then such void or unenforceable provisions shall be replaced by valid and enforceable provisions that will achieve as far as possible the economic business intentions of the Parties. However, the remainder of this Agreement will remain in full force and effect, provided that the material interests of the Parties are not affected, i.e. the Parties would presumably have concluded this Agreement without the unenforceable provisions.
- 11.8 Waiver and Amendment. This Agreement may be amended, modified, superseded or canceled, and any of the terms of this Agreement may be waived, only by a written instrument executed by each Party or, in the case of waiver, by the Party or Parties waiving compliance. The delay or failure of either Party at any time or times to require performance or to exercise any right arising out of any provisions shall in no manner affect the rights at a later time to enforce the same. Any waiver by a party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such party. No single or partial exercise of any right, power or privilege will preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege. No waiver by either Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement. Except as expressly set forth in this Agreement, all rights and remedies available to a party, whether under this Agreement or afforded by applicable laws or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such party.

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

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In Witness Whereof, the Parties hereto have executed this Agreement as of the Effective Date.

Pieris Pharmaceuticals Inc.

**Enumeral Biomedical Holdings Inc.** 

By: <u>/s/ Stephen Yoder</u> By: <u>/s/ John J. Rydzewski</u>

Name: Stephen Yoder Name: John J. Rydzewski

Title: President and CEO Title: Executive Chairman of the Board

Date: 18 April 2016 Date: April 18, 2016

Pieris Pharmaceuticals GmbH

By: /s/ Stephen Yoder

Name: Stephen Yoder
Title: President and CEO
Date: 18 April 2016

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

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# Exhibit A

# Patent Rights as of the Effective Date

The subject matter that pertains to the First Antibody in the claims (but not, for example, subject matter that would apply to a different antibody even if contained in the same claim) of the following patent applications:

Patent Application No.

Filing Date

[\*\*\*, 1 page]

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

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# Exhibit B

First Antibody Description

[\*\*\*, 1 page]

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

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# Exhibit C

Subsequent Antibody Descriptions

[to be completed with the Definitive 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.

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# Exhibit D

# Pieris and Enumeral Form 8-K Filings

# Pieris Form 8-K Disclosure:

On April 18, 2016, Pieris Pharmaceuticals, Inc. (the "Company") and Pieris Pharmaceuticals GmbH, a wholly-owned subsidiary of the Company (together with the Company, "Pieris"), entered into a license and transfer agreement (the "Agreement") with Enumeral Biomedical Holdings, Inc. ("Enumeral"), pursuant to which Pieris acquired a non-exclusive (except in the exclusive field described below) worldwide license to use specified patent rights and know-how owned by Enumeral to research, develop and market fusion proteins consisting of PD-1 antibodies linked to one or more Anticalin proteins for use in the oncology area. Enumeral also agreed not to practice or assist third parties in practicing in the exclusive field, consisting of licensed antibodies fused to Anticalin proteins in the oncology area.

Under the Agreement, Pieris agreed to pay Enumeral an upfront license fee of \$250,000 and, on May 31, 2016, a \$750,000 maintenance fee. Under the initial license, Pieris also agreed to pay to Enumeral development milestones of up to an aggregate of \$37.8 million for all products and indications and sales milestones of up to an aggregate of \$67.5 million for all products and indications. Pieris also agreed to pay Enumeral royalties within a range in the low to lower-middle single digits as a percentage of net sales depending on the amount of net sales in the applicable years. In the event that Pieris is required to pay a license fee or royalty to any third party related to the licensed products, the royalty payment due to Enumeral shall be reduced by the amount of such third party fees or payments, up to 50% of the royalty payment for each calendar year due to Enumeral.

Under the Agreement, Pieris has an option for twelve months after the date of the Agreement to license from Enumeral one of a specified set of antibodies owned by Enumeral for use in developing such fusion Anticalin proteins for use in the oncology area. If Pieris licenses an additional antibody pursuant to the option described above, Pieris must pay to Enumeral an additional undisclosed upfront payment, and any resulting fusion protein products will be subject to additional royalties and development and sales milestones in the same amounts applicable to the fusion proteins linking PD-1 and Anticalins under the initial license.

The term of the Agreement ends upon the expiration of the last to expire patent covered under the license. The Agreement may be terminated by Pieris on 30 days' notice and by Enumeral upon 60 days' notice of a material breach by Pieris (or 30 days with respect to a breach of payment obligations by Pieris), provided that Pieris has not cured such breach and dispute resolution procedures specified in the Agreement have been followed. The Agreement will also automatically terminate if Pieris elects to not make the maintenance fee payment described above.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, which Pieris intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ended March 31, 2016.

# Enumeral Form 8-K Disclosure:

On April 18, 2016, Enumeral Biomedical Holdings, Inc. (with its subsidiaries, "Enumeral" or the "Company") entered into a License and Transfer Agreement (the "Agreement") with Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals GmbH (collectively, "Pieris"). Pursuant to the terms of the Agreement, Enumeral is granting Pieris a non-exclusive, royalty-bearing worldwide license to use specified Enumeral patent rights and know-how to research, develop and market fusion proteins consisting of Enumeral's 388D4 family of anti-PD-1 antibodies linked to one or more Pieris Anticalin proteins for use in the oncology area. Enumeral has agreed not to practice or assist third parties in practicing in an exclusive field consisting of licensed antibodies fused to Anticalin proteins in the oncology area.

Pursuant to the Agreement, Pieris has agreed to pay Enumeral an upfront initial license fee of \$250,000. The Agreement also provides that Pieris has an option to continue the license by paying Enumeral an additional maintenance fee in the amount of \$750,000 by May 31, 2016. In the event that Pieris does not pay this maintenance fee by May 31, 2016, the Agreement expires and the license granted thereunder automatically terminates.

If Pieris elects to continue the license and pays Enumeral the maintenance fee, the Agreement provides that Pieris shall also receive an option for twelve months following the date of the Agreement to license from Enumeral one of a specified set of antibodies owned by Enumeral on the same terms and conditions as for Enumeral's 388D4 family of anti-PD-1 antibodies (the "Subsequent Option"). In the event that Pieris exercises the Subsequent Option, Pieris will pay Enumeral an additional undisclosed license fee.

The terms of the Agreement provide for Pieris to pay Enumeral development milestones of up to an aggregate of \$37.8 million upon the achievement of specified events, as well as net sales milestone payments of up to an aggregate of \$67.5 million upon the achievement of specified net sales thresholds. Pieris also agrees to pay Enumeral royalties in the low-to-lower middle single digits as a percentage of net sales depending on the amount of net sales in the applicable years. In the event that Pieris is required to pay a license fee or royalty to any third party related to the licensed products, the royalty payment due to Enumeral shall be reduced by the amount of such third party fees or payments, up to 50% of the royalty payment for each calendar year due to Enumeral.

The Agreement also provides that in the event Pieris licenses an additional antibody pursuant to the Subsequent Option, any resulting fusion protein products will be subject to additional royalties and development and sales milestones in the same amounts applicable to the fusion proteins linking PD-1 and Anticalins under the initial license.

Pursuant to the terms of the Agreement, Enumeral will indemnify Pieris Indemnitees (as defined in the Agreement) against certain claims specified therein, including with respect to breaches of representations and warranties, as well as claims by the Massachusetts Institute of Technology and other specified entities who are parties to an agreement with Enumeral. In addition, Pieris

will indemnify Enumeral Indemnitees (as defined in the Agreement) against certain claims specified therein, including with respect to breaches of representations and warranties, as well as with respect to the development, commercialization, manufacture or use of any Product before or after Marketing Authorization (as such terms are defined in the Agreement). The Agreement also contains customary representations and warranties for both Enumeral and Pieris.

The term of the Agreement ends upon the expiration of the last to expire patent covered under the license. The Agreement may be terminated by Pieris on 30 days' notice and by Enumeral upon 60 days' notice of a material breach by Pieris (or 30 days with respect to a breach of payment obligations by Pieris), provided that Pieris has not cured such breach and that dispute resolution procedures specified in the Agreement have been followed. The Agreement will also automatically terminate if Pieris elects to not make the maintenance fee payment described 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.

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# Exhibit E

# Enumeral Press Release

# Enumeral and Pieris Pharmaceuticals Enter into License and Transfer Agreement

**CAMBRIDGE, Mass.**—April 18, 2016—Enumeral Biomedical Holdings, Inc. (OTCQB: ENUM) ("Enumeral" or the "Company"), a biotechnology company focused on discovering and developing novel antibody-based immunotherapies to help the immune system fight cancer and other diseases, today announced that it has entered into a License and Transfer Agreement (the "License Agreement") with Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals GmbH (collectively, "Pieris").

Pursuant to the terms and conditions of the License Agreement, Pieris is licensing from Enumeral specified intellectual property related to Enumeral's anti-PD-1 antibody program ENUM 388D4 for the potential development and commercialization by Pieris of novel multispecific therapeutic proteins comprising fusion proteins based on Pieris' Anticalins® class of therapeutic proteins and Enumeral antibodies in the field of oncology.

Under the License Agreement, Pieris has agreed to pay Enumeral a \$250,000 initial license fee, and Enumeral is providing Pieris with sequence and related information for Enumeral's 388D4 family of anti-PD-1 antibodies. The License Agreement provides that Pieris may continue the license by paying Enumeral an additional maintenance fee in the amount of \$750,000 by May 31, 2016. In the event that Pieris does not pay this maintenance fee by May 31, 2016, the License Agreement expires and the license granted thereunder automatically terminates.

If Pieris elects to continue the license and pays Enumeral the maintenance fee, the License Agreement provides that Pieris shall also receive an exclusive twelve-month option to license Enumeral intellectual property related to an additional antibody program on the same terms and conditions as for the ENUM 388D4 family of anti-PD-1 antibodies (the "Subsequent Option"). The antibody subject to the Subsequent Option will be selected by Pieris from a specified list of antibodies owned by Enumeral. In the event that Pieris exercises the Subsequent Option, Pieris will pay Enumeral an additional undisclosed license fee.

The terms of the License Agreement provide for Pieris to pay Enumeral development milestones of up to an aggregate of \$37.8 million upon the achievement of specified events, as well as net sales milestone payments of up to an aggregate of \$67.5 million upon the achievement of specified net sales thresholds. Under the License Agreement, Pieris also agrees to pay Enumeral royalties in the low-to-lower middle single digits as a percentage of net sales depending on the amount of net sales in the applicable years. In the event that Pieris licenses an additional antibody pursuant to the Subsequent Option, any resulting fusion protein products will be subject to the same royalties and development and sales milestones applicable to the fusion proteins linking PD-1 and Anticalins under the initial license.

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

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"We are excited that Pieris has decided to work with our antibody sequences, and we are encouraged that these sequences could become part of a novel class of therapeutic based on Pieris' Anticalin platform," said Cokey Nguyen, Ph.D., Enumeral's Vice President of Research and Development. "Enumeral has been able to generate antibodies using our proprietary platform technology in a very efficient manner, and this transaction is further validation for the Enumeral approach. We look forward to working with Pieris as we pursue our mutual interests under the License Agreement."

"Gaining access to Enumeral's valuable PD-1 antibody IP not only enables Pieris to leverage its antibody-Anticalin multispecifics capabilities with a cornerstone immune checkpoint inhibitor, but also brings a high level of intra-pipeline synergy, including with Pieris' lead CD137 bispecific immune costimulator candidate PRS-343," commented Pieris President and CEO, Stephen S. Yoder. "This license gives Pieris an opportunity to independently develop anti-PD-1 antibody-Anticalin multispecific immune checkpoint inhibitors as next generation cancer immunotherapeutics."

# **About Enumeral**

Enumeral is a biopharmaceutical company discovering and developing novel antibody immunotherapies that help the immune system fight cancer and other diseases. The Company is building a pipeline focused on next-generation checkpoint modulators, with initial targets including PD-1, TIM-3, LAG-3, OX40, and VISTA. In developing these agents, Enumeral's researchers apply a proprietary immune profiling technology platform that measures functioning of the human immune system at the level of individual cells, providing key insights for candidate selection and validation. For more information on Enumeral, please visit <a href="https://www.enumeral.com">www.enumeral.com</a>.

# **About Pieris**

Pieris Pharmaceuticals is a clinical-stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in a unique and transformative way. Pieris' 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, Anticalins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin®, Anticalins® are registered trademarks of Pieris. For more information visit <a href="https://www.pieris.com">www.pieris.com</a>.

# Forward Looking Statements Disclosure

This press release contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Such statements reflect current beliefs of Enumeral Biomedical Holdings, Inc. ("Enumeral") with respect to future events and involve known and unknown risks, uncertainties, and other factors affecting operations, market growth, Enumeral's stock price, services, products and licenses. No assurances can be given regarding the achievement of future results, and although Enumeral believes that the expectations reflected in these forward-looking statements are based on reasonable assumptions,

actual results may differ from the assumptions underlying the statements that have been made regarding anticipated events. Factors that may cause actual results, performance or achievements, or industry results to differ materially from those contemplated by such forward-looking statements include, among others, the risks that (a) Enumeral's expectations regarding market acceptance of the Company's business in general and the Company's ability to penetrate the antibody discovery and development fields in particular, as well as the timing of such acceptance, (b) Enumeral's ability to attract and retain management with experience in biotechnology and antibody discovery and similar emerging technologies, (c) the scope, validity and enforceability of Enumeral's and third party intellectual property rights, (d) Enumeral's ability to raise capital when needed and on acceptable terms and conditions, (e) Enumeral's ability to comply with governmental regulation, (f) the intensity of competition, (g) changes in the political and regulatory environment and in business and fiscal conditions in the United States and overseas and (h) general economic conditions.

More detailed information about Enumeral and risk factors that may affect the realization of forward-looking statements, including forward-looking statements in this press release, is set forth in Enumeral's filings with the Securities and Exchange Commission. Enumeral urges investors and security holders to read those documents free of charge at the Commission's website at <a href="http://www.sec.gov">http://www.sec.gov</a>. Forward-looking statements speak only as to the date they are made, and except for any obligation under the U.S. federal securities laws, Enumeral undertakes no obligation to publicly update any forward-looking statement as a result of new information, future events or otherwise.

# Contact

Enumeral Biomedical Holdings, Inc. Kevin Sarney, (617) 945-9146 kevin@enumeral.com

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

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# PIERIS PHARMACEUTICALS, INC.

#### NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The Board of Directors of Pieris Pharmaceuticals, Inc. (the "<u>Company</u>") has approved the following Non-Employee Director Compensation Policy (this "<u>Policy</u>") which establishes compensation to be paid to non-employee directors of the Company, effective as of January 1, 2016 ("<u>Effective Time</u>"), to provide an inducement to obtain and retain the services of qualified persons to serve as members of the Company's Board of Directors.

# **Applicable Persons**

This Policy shall apply to each director of the Company who is not an employee of the Company or any Affiliate (each, a "Non-Employee Director"). "Affiliate" shall mean an entity which is a direct or indirect parent or subsidiary of the Company, as determined pursuant to Section 424 of the Internal Revenue Code of 1986, as amended.

# **Stock Option Grants**

All stock option amounts set forth herein shall be subject to automatic adjustment in the event of any stock split or other recapitalization affecting the Company's common stock.

# **Annual Stock Option Grants**

Annually, each Non-Employee Director shall be granted a non-qualified stock option to purchase 20,000 shares of the Company's common stock under the Company's 2014 Stock Incentive Plan (the "Stock Plan"), or any future stock incentive plans, on January 25 of each year.

# Initial Stock Option Grant For Newly Appointed or Elected Directors

Each new Non-Employee Director shall be granted a non-qualified stock option to purchase 30,000 shares of the Company's common stock under the Stock Plan on his or her initial appointment or election to the Board of Directors.

# **Terms for Option Grants**

Unless otherwise specified by the Board of Directors or the Compensation Committee at the time of grant, all Annual Stock Options granted under this Policy shall (i) vest in equal quarterly installments at the end of each quarter following the grant date until the end of the fiscal year in which the grant was made, subject to the Non-Employee Director's continued service on the Board of Directors; (ii) have an exercise price equal to the fair market value of the Company's common stock as determined in the Stock Plan on the grant date; (iii) terminate ten years after the grant date and (iv) contain such other terms and conditions as set forth in the form of option agreement approved by the Board of Directors or the Compensation Committee prior to the grant date.

Unless otherwise specified by the Board of Directors or the Compensation Committee at the time of grant, all Initial Stock Option Grants for Newly Appointed or Elected Directors granted under this Policy shall (i) vest in equal quarterly amounts over a one year period, beginning on the grant date, subject to the Non-Employee Director's continued service on the Board of Directors; (ii) have an exercise price equal to the fair market value of the Company's common stock as determined in the Stock Plan on the grant date; (iii) terminate ten years after the grant date and (iv) contain such other terms and conditions as set forth in the form of option agreement approved by the Board of Directors or the Compensation Committee prior to the grant date.

# **Annual Fees**

Each Non-Employee Directors serving on the Board of Directors and the Audit Committee, Compensation Committee and/or Nominating and Corporate Governance Committee, as applicable, shall be entitled to the following annual amounts (the "Annual Fees"):

Board of Directors or				
Committee of Board of	Annual Retainer Amount for Member		Annual Retainer Amount for Chair	
Directors				
Board of Directors	\$	25,000	•	
Audit Committee	\$	7,500	\$	15,000
Compensation Committee	\$	5,000	\$	10,000
Nominating and Corporate Governance				
Committee	\$	3,750	\$	7,500

Except as otherwise set forth in this Policy, all Annual Fees shall be paid for the period from January 1 through December 31 of each year. Such Annual Fees shall be paid quarterly in cash or a grant of an option to purchase common stock under the Stock Plan, at the election of each Non-Employee Director annually, as follows:

- · cash in the amount of each Non-Employee Director's Annual Fees, paid quarterly in arrears; or
- an option to purchase such number of shares of the Company's common stock as is equal to the full dollar amount of each Non-Employee Director's Annual Fees, paid quarterly in arrears (as calculated below under "Calculation of Shares and Grant Terms"); or

# Election

Each Non-Employee Director shall make an annual election, on a form provided by the Company, indicating their election for that year of cash or common stock, at the beginning of each fiscal year. If no election has been made, then the Non-Employee Director shall receive all Annual Fees in cash. Each newly elected or appointed Non-Employee Director shall make an election prior to the beginning of or at the time of his or her initial appointment or election.

# **Payments**

Payments payable to Non-Employee Directors, who have elected to receive cash fees, shall be paid quarterly in arrears promptly following the end of each fiscal quarter, provided that (i) the amount of such payment shall be prorated for any portion of such quarter that such director was not serving on the Board or a committee and (ii) no fee shall be payable in respect of any period prior to the date such director was elected to the Board or a committee.

# Calculation of Shares and Grant Terms

If an option to purchase shares of common stock are to be received as payment, the number of shares underlying such option shall equal the Black Scholes value of the options computed in accordance with FASB Topic 718 on the 25th day of the month following the end of each fiscal quarter (the "Calculation Date") (rounded down to the nearest whole number so that no fractional shares shall be issued). The option shall be automatically and without any further action required by the Board of Directors issued as of the Calculation Date.

# **Expenses**

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each Non-Employee Director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board of Directors and committees thereof or in connection with other business related to the Board of Directors.

# Amendments

The Compensation Committee shall periodically review this Policy to assess whether any amendments in the type and amount of compensation provided herein should be made and shall make recommendations to the Board of Directors for its approval of any amendments to this Policy.

# 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 12, 2016 /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, Darlene Deptula-Hicks, 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:
  - 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);
  - 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 12, 2016 /s/ Darlene Deptula-Hicks

Darlene Deptula-Hicks

Title: Chief Financial Officer (principal accounting and 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, 2016 (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 12, 2016 /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, 2016 (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 12, 2016 /s/ Darlene Deptula-Hicks

Darlene Deptula-Hicks

Title: Chief Financial Officer (principal accounting and financial officer)