# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

		FORM 10-Q		
(Mark	One)			
$\boxtimes$	QUARTERLY REPORT PURS 1934	UANT TO SECTION 13 OR 15(d) OF THE	SECURITIES EXCHANGE ACT	OF
		For the quarterly period ended September 30, 2018 OR		
	TRANSITION REPORT PURS 1934	UANT TO SECTION 13 OR 15(d) OF THE	SECURITIES EXCHANGE ACT	OF
		For the transition period from to to		
	PIERIS	PHARMACEUTICA	LS, INC.	
		(Exact name of registrant as specified in its charter)		
	Nevada (State or other jurisdiction o incorporation or organization		EIN 30-0784346 (I.R.S. Employer Identification No.)	
	255 State Street, 9th Floo Boston, MA United States		02109	
	(Address of principal executive of	857-246-8998	(Zip Code)	
		Registrant's telephone number, including area code		
orecedi		as filed all reports required to be filed by Section 13 or 15(d) or registrant was required to file such reports), and (2) has been s		
submitt	9	submitted electronically and posted on its corporate Web site, in S-T during the preceding 12 months (or for such shorter periods).	J. J	ost
		arge accelerated filer, an accelerated filer, a non-accelerated fil r reporting company" in Rule 12b-2 of the Exchange Act. (Che		ions o
Large a	accelerated filer		Accelerated filer	$\boxtimes$
Non-ac	celerated filer $\Box$ [Do not check if a small	ller reporting company]	Smaller reporting company	$\boxtimes$
Emergi	ng growth company ⊠			
	an emerging growth company, indicate by check al accounting standards provided pursuant to Sec	mark if the registrant has elected not to use the extended transition 13(a) of the Exchange Act. $\square$	tion period for complying with any new or revised	l
	• • •	shell company (as defined in Rule 12b-2 of the Exchange Act).	Yes □ No ⊠	
Δα	of November 5, 2018, the registrant had 54,149	719 shares of common stock outstanding		

The registrant is a smaller reporting company. The aggregate market value of the registrant's common stock held by non-affiliates of the registrant based upon the closing price of common stock of \$5.07 per share as of June 29, 2018, the last trading day of the registrant's second fiscal quarter, was approximately \$273,283,424. Pieris had annual revenues of \$25,275,000 during its previous fiscal year.

## TABLE OF CONTENTS

	Page
PART I: FINANCIAL INFORMATION	
Item 1. Financial Statements (unaudited)	<u>1</u>
Condensed Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017	<u>1</u>
Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months ended September 30, 2018	
and 2017	<u>2</u>
Condensed Consolidated Statements of Cash Flows for the Nine Months ended September 30, 2018 and 2017	<u>3</u>
Notes to the unaudited Condensed Consolidated Financial Statements	<u>4</u>
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>15</u>
Item 3. Quantitative and Qualitative Disclosures about Market Risk	<u>23</u>
Item 4. Controls and Procedures	<u>23</u>
PART II: OTHER INFORMATION	
Item 1. Legal Proceedings	<u>25</u>
Item 1A. Risk Factors	<u>25</u>
Item 6. Exhibits	<u>25</u>
<u>SIGNATURES</u>	<u>27</u>

#### **Special Note Regarding Forward-Looking Statements**

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

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

You should not place undue reliance on any forward-looking statement(s), each of which applies only as of the date of this Quarterly Report on Form 10-Q. Before you invest in our securities, you should be aware that the occurrence of the events described in Part I, Item 1A (Risk Factors) of our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 15, 2018, 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.

#### **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 " $\in$ " 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 our operations is primarily 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 accumulated other comprehensive income/loss.

Where in this Quarterly Report we refer to amounts in euros, we have for your convenience also, in certain cases, provided a conversion of those amounts to U.S. dollars in parentheses. Where the numbers refer to a specific balance sheet account date or financial statement account period, we have used the exchange rate that was used to perform the conversions in connection with the applicable financial statement. In all other instances, unless otherwise indicated, the conversions have been made using the noon buying rate of €1.00 to U.S. \$1.1607 based on Thomson Reuters as of September 30, 2018.

## PIERIS PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited, in thousands, except share and per share data)

	September 30,		December 31,		
		2018		2017	
Assets	-				
Current assets:					
Cash and cash equivalents	\$	89,482	\$	37,878	
Short term investments		47,822		34,751	
Accounts receivable		5,338		15,546	
Prepaid expenses and other current assets		4,207		1,615	
Total current assets		146,849		89,790	
Property and equipment, net		4,687		4,034	
Long term investments		_		9,922	
Other non-current assets		121		130	
Total assets	\$	151,657	\$	103,876	
Liabilities and stockholders' equity					
Current liabilities:					
Accounts payable	\$	2,693	\$	2,452	
Accrued expenses and other current liabilities		5,981		6,170	
Deferred revenues, current portion		31,920		37,153	
Total current liabilities		40,594		45,775	
Deferred revenue, net of current portion		60,770		46,542	
Other long-term liabilities		32		37	
Total liabilities		101,396		92,354	
Stockholders' equity:					
Preferred stock, \$0.001 par value per share, 10,000,000 shares authorized and 2,907 and 4,963 issued and outstanding at September 30, 2018 and December 31, 2017, respectively		_		_	
Common stock, \$0.001 par value per share, 300,000,000 shares authorized and 54,149,719 and 45,017,062 issued and outstanding at September 30, 2018 and December 31, 2017, respectively		54		45	
Additional paid-in capital		188,644		136,484	
Accumulated other comprehensive loss		(3,053)		(4,695)	
Accumulated deficit		(135,384)		(120,312)	
Total stockholders' equity		50,261		11,522	
Total liabilities and stockholders' equity	\$	151,657	\$	103,876	

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

## PIERIS PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited, in thousands, except per share data)

	Three Months Ended September 30,			Nine Mo Septe				
		2018 2017		2018			2017	
Revenue	\$	8,345	\$	3,927	\$	24,187	\$	7,123
Operating expenses								
Research and development		11,401		6,259		28,492		17,015
General and administrative		4,748		2,852		13,878		11,190
Total operating expenses		16,149		9,111		42,370		28,205
Loss from operations		(7,804)		(5,184)		(18,183)		(21,082)
Interest income		504		_		1,491		_
Other income (expense), net		1,147		(1,729)		1,472		(3,097)
Loss before income taxes		(6,153)		(6,913)		(15,220)		(24,179)
Provision for income tax		_		146		(148)		959
Net loss	\$	(6,153)	\$	(7,059)	\$	(15,072)	\$	(25,138)
Other comprehensive income (loss):								
Foreign currency translation		27		(395)		546		(986)
Unrealized (loss) gain on available-for-sale securities		(506)		_		1,096		_
Comprehensive loss	\$	(6,632)	\$	(7,454)	\$	(13,430)	\$	(26,124)
Net loss per share								
Basic and diluted	\$	(0.11)	\$	(0.16)	\$	(0.29)	\$	(0.58)
Weighted average number of common shares outstanding					-			
Basic and diluted		54,089		44,387		52,721		43,624

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

## PIERIS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited, in thousands)

	N	Nine Months Ended September				
		2018		2017		
Operating activities:						
Net loss	\$	(15,072)	\$	(25,138)		
Adjustments to reconcile net loss to net cash provided by operating activities:						
Depreciation		405		268		
Stock-based compensation		3,665		1,962		
Other		(376)		87		
Changes in operating assets and liabilities		19,370		77,269		
Net cash provided by operating activities		7,992		54,448		
Investing activities:						
Purchases of property and equipment		(1,133)		(1,131)		
Proceeds from maturity of investments		64,490		_		
Purchases of investments		(67,015)				
Net cash used in investing activities		(3,658)		(1,131)		
Financing activities:						
Proceeds from exercise of stock options		983		366		
Proceeds from exercise of warrants		314		3,127		
Issuance of common stock, net of issuance costs		47,207		_		
Net cash provided by financing activities		48,504		3,493		
Effect of exchange rate change on cash and cash equivalents		(1,234)		3,755		
Net increase in cash and cash equivalents		51,604		60,565		
Cash and cash equivalents at beginning of period		37,878		29,356		
Cash and cash equivalents at end of period	\$	89,482	\$	89,921		
Supplemental cash flow disclosures:						
Cash paid for income taxes	\$	902	\$	_		
Net unrealized loss on investments	\$	1,096	\$	_		
Property and equipment included in accounts payable	\$	222	\$	121		

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

## PIERIS PHARMACEUTICALS, INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

#### 1. Corporate Information

Pieris Pharmaceuticals, Inc., was founded in May 2013, and acquired 100% interest in Pieris Pharmaceuticals GmbH (formerly Pieris AG, a German company which was founded in 2001) in December 2014. Pieris Pharmaceuticals, Inc. and its wholly-owned subsidiaries (collectively "Pieris" or the "Company") is a clinical-stage biopharmaceutical company that discovers and develops Anticalin®-based drugs to target validated disease pathways in unique and transformative ways. Pieris' corporate headquarters is located in Boston, MA and its research facility is located in Freising-Weihenstephan, Germany.

Pieris' clinical pipeline includes an immuno-oncology bispecific targeting HER2 and 4-1BB, an inhaled IL-4 receptor alpha antagonist Anticalin protein to treat uncontrolled asthma, and a half-life-optimized hepcidin antagonizing Anticalin protein to treat anemia.

The Company's core Anticalin technology and platform was developed in Germany, and the Company has partnership arrangements with several major multinational pharmaceutical companies.

As of September 30, 2018, the Company had cash, cash equivalents, and investments of \$137.3 million. The Company expects that its existing cash, cash equivalents, and investments are sufficient to support operating expense and capital expenditure requirements for at least 12 months from the date of filing.

#### 2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies", within the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017. There have been no material changes to the significant accounting policies during the three and nine months ended September 30, 2018.

#### **Unaudited Interim Financial Information**

The accompanying unaudited condensed consolidated financial statements included herein have been prepared by the Company in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustment, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the three and nine months ended September 30, 2018 are not necessarily indicative of results that may be expected for the year ending December 31, 2018. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on March 15, 2018.

## **Basis of Presentation and Use of Estimates**

The accompanying condensed consolidated financial statements of Pieris Pharmaceuticals, Inc. and its wholly-owned subsidiaries were prepared in accordance with U.S. GAAP. The condensed consolidated financial statements include the accounts of all subsidiaries. All intercompany balances and transactions have been eliminated.

The preparation of the financial statements in accordance with U.S. GAAP requires management to make estimates, judgments, and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and the related disclosures at the date of the financial statements and during the reporting period. Significant estimates are used for, but are not limited to, revenue recognition; deferred tax assets, deferred tax 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.

## Cash, Cash Equivalents and Investments

The Company determines the appropriate classification of its investments at the time of purchase. All liquid investments with original maturities of 90 days or less from the purchase date and for which there is an active market are considered to be cash equivalents. The Company's current and non-current investments are comprised of money market, asset backed securities,

government treasuries, and corporate bonds that are classified as available-for-sale in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 320, *Investments—Debt and Equity Securities*. The Company classifies investments available to fund current operations as current assets on its balance sheets. Investments are classified as non-current assets on the balance sheets if (i) the Company has the intent and ability to hold the investments for a period of at least one year and (ii) the contractual maturity date of the investments is greater than one year.

Available-for-sale investments are recorded at fair value, with unrealized gains or losses included in accumulated other comprehensive loss on the Company's balance sheets. Realized gains and losses are determined using the specific identification method and are included as a component of other income. Realized gains of approximately \$0.8 million and \$0.7 million were recognized for the three and nine months ended September 30, 2018, respectively. No realized gains or losses were recorded for the three and nine months ended September 30, 2017.

The Company reviews investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than temporary, the Company considers its intent to sell, or whether it is more likely than not that the Company will be required to sell the investment before recovery of the investment's amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, the severity and the duration of the impairment, and changes in value subsequent to period end. As of September 30, 2018, there were no investments with a fair value that was significantly lower than the amortized cost basis or any investments that had been in an unrealized loss position for a significant period.

#### Concentration of Credit Risk and Off-Balance Sheet Risk

The Company has no financial instruments with off-balance sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that subject Pieris to concentrations of credit risk include cash and cash equivalents, investments, and accounts receivable. The Company's cash, cash equivalents, and investments are held in accounts with financial institutions that management believes are creditworthy. The Company's investment policy includes guidelines on the quality of the institutions and financial instruments, and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. These amounts, at times, may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. Accounts receivable primarily consist of amounts due under strategic partnership and other license agreements with major multi-national pharmaceutical companies for which the Company does not obtain collateral.

#### **Fair Value Measurement**

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, *Fair Value Measurement and Disclosures*, ("ASC 820") established a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the financial instrument based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the financial instrument and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported or disclosed fair value of the financial instruments and is not a measure of the investment credit quality. Fair value measurements are classified and disclosed in one of the following three categories:

- 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.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Financial instruments measured at fair value on a recurring basis include cash equivalents and investments (Note 4).

An entity may elect to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in net loss. The Company did not elect to measure any additional financial instruments or other items at fair value.

#### **Revenue Recognition**

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

#### **Multiple-Element Arrangements**

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

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

Multiple element arrangements, such as license arrangements, are analyzed to determine whether the deliverables, which often include licenses and performance obligations such as research and development services and governance committee services, can be separated or whether they must be accounted for as a combined unit of accounting in accordance with U.S. GAAP. The Company recognizes the arrangement consideration allocated to licenses as revenue upon delivery of the license only if the license has stand-alone value. If the license is considered not to have stand-alone value, the license would then be combined with other undelivered elements into a combined unit of accounting and the license payments and payments for performance obligations would be recognized as revenue when the revenue recognition criteria have been satisfied for the last deliverable within the unit of accounting. In the case of combined units of accounting that include delivered licenses and undelivered services to be provided over time, revenue would be recognized over the estimated period during which services will be provided. For units of accounting that include licenses to be delivered upon satisfactory completion of certain research services, revenue is deferred until the license is delivered and the performance obligation is satisfied.

If the Company is involved in a governance committee, as part of a multiple element arrangement, it assesses whether its involvement constitutes a performance obligation or a right to participate. When governance committee services are determined to be performance obligations, the Company determines the fair value to be allocated to this deliverable and recognize the revenue over the expected term of the development period of the products. Otherwise, the fair value for participation is combined with other research services or performance obligations and is recognized over the term which the Company expects to complete its aggregate performance obligations.

The Company recognizes arrangement consideration allocated to each unit of accounting when all revenue recognition criteria in SEC Staff Accounting Bulletin No. 104, "Revenue Recognition in Financial Statements" ("SAB 104") are satisfied for that particular unit of accounting. For each unit of accounting, the Company must determine the period over which the performance obligations will be performed and revenue will be recognized. If there is no discernible pattern of performance or objectively

measurable performance measures do not exist, then the Company recognizes revenue under the arrangement on a straight-line basis over the period the Company is expected to complete its performance obligations. Conversely, if the pattern of performance over which the service is provided to the customer can be determined and objectively measurable performance measures exist, then the Company recognizes revenue under the arrangement using the proportional performance method. Revenue recognized cannot exceed the amount that has been earned and has been billed or is currently billable.

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

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

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

Payments or reimbursements resulting from Pieris' research and development efforts in multi-element arrangements, in which Pieris' research and development efforts are considered to be a deliverable, are included in allocable consideration and allocated to the units of accounting. These reimbursements are recognized as the services are performed and are presented on a gross basis, so long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is reasonably assured. Revenue recognized cannot exceed the amount that has been earned and has been billed or is currently billable. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets.

#### Milestone Payments and Royalties

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

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

For revenues from research, development, and commercial milestone payments, if the milestones are deemed substantive and the milestone payments are nonrefundable, such amounts are recognized entirely upon successful accomplishment of the milestones, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive are accounted for as contingent revenue and will be recognized when achieved to the extent the Company has no remaining

performance obligations under the arrangement. Revenues from sales milestone payments are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. Royalty payments are recognized in revenues based on the timing of royalty payments earned in accordance with the agreements, which typically is the period when the relevant sales occur, assuming all other revenue recognition criteria are met.

#### **Recent Accounting Pronouncements**

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

The Revenue ASUs provide an accounting standard for a single comprehensive model for use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The accounting standard is effective for public emerging growth companies ("EGC"), like Pieris, for interim and annual periods beginning after December 15, 2018, with an option to early adopt for interim and annual periods beginning after December 15, 2017. The guidance permits two methods of adoption: retrospectively to each prior reporting period presented (the full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). The Company expects to adopt this pronouncement commencing in the first quarter of 2019 using the modified retrospective approach and is in the process of reviewing our revenue arrangements and the anticipated effect the new standard will have on its consolidated financial statements, accounting policies and processes.

In February 2016, the FASB issued ASU No. 2016-2, *Leases (Topic 842)* ("ASU 2016-2"). Under the amendments in ASU 2016-2, 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, 2018 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 December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act*, or ("SAB 118"), which allows the recording of provisional amounts during a measurement period not to extend beyond one year of the enactment date. In accordance with SAB 118, we determined that our deferred tax asset value and associated valuation allowance reduction of \$3.7 million is a provisional amount and a reasonable estimate at December 31, 2017. The final impact may differ from this provisional amount due to, among other things, changes in interpretations and assumptions we have made thus far and the issuance of additional regulatory or other guidance. We expect to complete the final impact within the measurement period.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation - Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions when acquiring goods and services from nonemployees as part of the ongoing operations of the business. ASU 2018-07 will not apply in financing or revenue-based transactions. Upon adoption of ASU 2018-07, the requirements of Topic 718 will apply such that the Company must establish the value of nonemployee awards at the date of grant, rather than remeasure the value over the life of the award. ASU 2018-07 does not change either the inputs required when pricing the option or the attribution of cost (the vesting pattern and pattern of cost recognition over that period). This guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. As Topic 606 has not yet been adopted, early adoption of ASU 2018-07 is not permissible. The Company does not expect the adoption of this standard will have a material impact on its financial statements and related disclosures given the limited number of awards to non-employees.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). ASU 2018-13 modifies the disclosure requirements on fair value measurements by removing the requirement to disclose: the amount of and reasons for transfers

between Level 1 and Level 2 of the fair value hierarchy; the policy for timing of transfers between levels; and the valuation processes for Level 3 fair value measurements. ASU 2018-13 also requires disclosure of changes in unrealized gains and losses for the period included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. We are currently evaluating the effect that this guidance will have on our Consolidated Financial Statements.

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.

#### 3. Revenue

#### General

The Company has not generated revenue from product sales. The Company has generated revenue from (i) option, 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.

During the three and nine months ended September 30, 2018 and 2017, respectively, the Company recognized revenues as follows (in thousands):

	Three Months Ended September 30,			Nine Months Ended Septe			September	
		2018	2017		2017 2018			2017
License fees	\$	7,873	\$	3,650	\$	22,541	\$	6,166
Research and development services		472		263		1,555		943
Other revenues		_		14		91		14
Total Revenue	\$	8,345	\$	3,927	\$	24,187	\$	7,123

During the three and nine months ended September 30, 2018 and 2017, respectively, the Company recognized revenue from the following strategic partnerships and other license agreements (in thousands):

	Three Months Ended September 30,			Nine Months Ended Sept 30,			September			
		2018		2018 2017		2017		2018		2017
Seattle Genetics	\$	1,788	\$		\$	4,519	\$	_		
AstraZeneca		5,905		2,486		14,841		3,079		
Servier		652		474		3,279		1,163		
Other		_		967		1,548		2,881		
Total Revenue	\$	8,345	\$	3,927	\$	24,187	\$	7,123		

Under the Company's existing strategic partnerships, Pieris could receive the following potential milestone payments (in millions):

	Deve Co	esearch, Plopment & mmercial Tilestones	Sales Milestones		
Seattle Genetics	\$	769	\$	450	
AstraZeneca		1,111		960	
Servier		1,007		911	
Total potential milestone payments	\$	2,887	\$	2,321	

## Strategic Partnership with Seattle Genetics, Inc.

On February 8, 2018, the Company entered into a License and Collaboration Agreement and a Non-Exclusive Anticalin Platform Technology License Agreement (collectively the "Seattle Genetics Agreements") with Seattle Genetics, Inc. ("Seattle Genetics"), pursuant to which the parties will develop multiple targeted bispecific immuno-oncology treatments for solid tumors and blood cancers.

Under the terms of the Seattle Genetics Agreements, the companies will pursue multiple antibody-Anticalin fusion proteins during the research phase. The Seattle Genetics Agreements provides Seattle Genetics a base option to select up to three programs for further development. Prior to the initiation of a pivotal trial, Pieris may opt into global co-development and U.S. commercialization of the second program and share in global costs and profits on an equal basis. Seattle Genetics will solely develop, fund and commercialize the other two programs. In addition, Seattle Genetics will have an option to select up to three additional programs for further development.

The Non-Exclusive Anticalin Platform Technology License Agreement ("Seattle Genetics Platform License") grants Seattle Genetics a non-exclusive license to certain intellectual property related to the Anticalin platform technology.

Upon signing the Seattle Genetics Agreements, Seattle Genetics paid Pieris a \$30.0 million upfront fee and an additional \$4.9 million was estimated to be paid for research and development services as reimbursement to Pieris through the end of the research term. In addition, Pieris may receive tiered royalties on net sales up to the low double-digits and up to \$1.2 billion in total success-based research, development, commercial, and sales milestones payments across the product candidates, depending on the successful development and commercialization of those candidates. If Seattle Genetics exercises its option to select additional candidates from the initial research phase for further development, payment to Pieris of additional fees, milestone payments, and royalties would result.

The term of each of the Seattle Genetics Agreements ends upon the expiration of all of Seattle Genetics' payment obligations. The License and Collaboration Agreement may be terminated by Seattle Genetics on a product-by-product basis for convenience beginning 12 months after its effective date upon 90 days' notice or, for any program where a pivotal study has been initiated, upon 180 days' notice. If any program is terminated by Seattle Genetics after a pre-defined pre-clinical stage, Pieris will have full rights to continue such program. If any program is terminated by Seattle Genetics prior to such pre-defined pre-clinical stage, Pieris will have the right to continue to develop such program, but will be obligated to offer a co-development option to Seattle Genetics for such program. The License and Collaboration Agreement may also be terminated by Seattle Genetics or Pieris for an uncured material breach by the other party upon 90 days' notice, subject to extension for an additional 90 days if the material breach relates to diligence obligations and subject, in all cases, to dispute resolution procedures. The License and Collaboration Agreement may also be terminated due to the other party's insolvency and may in certain instances, including for reasons of safety, be terminated on a product-by-product basis. Each party may also terminate the Seattle Genetics Agreements if the other party challenges the validity of any patents licensed under the Seattle Genetics Agreements, subject to certain exceptions. The Seattle Genetics Platform License will terminate upon termination of the License and Collaboration Agreement, whether in its entirety or on a product-by-product basis.

The Company accounted for the Seattle Genetics Agreements as a multiple element arrangement under ASC 605-25. The arrangement with Seattle Genetics contains the following initial deliverables: (i) three candidate research licenses that each consist of a non-exclusive platform technology license, a coexclusive candidate research license, and research and development services, (ii) research, development and manufacturing services associated with each candidate research license, (iii) participation on various governance committees, and (iv) two antibody target swap options.

Management considered whether any of the deliverables could be considered separate units of accounting. The Company determined each license granted, at arrangement inception, did not have standalone value from the research and development services to be provided for the related antibody target programs due to the specific nature of the intellectual property and knowledge required to perform the research and development services. The Company determined that the participation on the various governance committees did have standalone value from the delivered licenses as the services could be performed by an outside party. The Company determined that the two antibody target swap options did have stand-alone value from the delivered licenses as the absence of delivering swap options does not impact the delivery of either the research licenses or the research, development and manufacturing services associated with each candidate research licenses.

As a result, management concluded there are six units of accounting at inception of the agreement: (i) three combined units of accounting each representing a non-exclusive platform technology license, a co-exclusive candidate research license, and research and development services for first three approved Seattle Genetics antibody target programs, (ii) two units of accounting each representing an antibody target swap right for first and the second approved Seattle Genetics antibody target, and (iii) one unit of accounting representing the participation of the various governance committees.

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

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

Allocable arrangement consideration at inception was comprised of the upfront fees of \$30.0 million and \$4.9 million of estimated research and development services to be reimbursed as research and development occurs through the research term. Therefore, the total allocable arrangement consideration at inception was \$34.9 million and was allocated among the separate units of accounting using the relative selling price method.

The amounts allocated to the combined units of accounting for the three research programs will be recognized on a proportional performance basis through the completion of each respective estimated research term for the individual research programs. However, for the first two programs that contain antibody target swap rights, if the antibody target swap right is exercised, any remaining deferred revenue associated with the two programs at the time of the exercise would be recognized immediately. The amounts allocated to the antibody target swap rights will be recognized either at the time the target right expires, or if exercised, on a proportional performance basis over the estimate research term for that program. The amounts allocated to the participation on each of the committees will be recognized ratably over the anticipated research term for all research programs.

Management determined that all research, development, commercial and sales milestones are deemed non-substantive as they are based solely on the performance of another party. Non-substantive milestones will be treated as contingent revenue and will be recognized when achieved, to the extent the Company has no remaining performance obligations under the arrangement. Milestone payments earned upon the achievement of sales events will be recognized when earned.

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

As of September 30, 2018, there is \$7.8 million and \$16.3 million of deferred revenue and non-current deferred revenue, respectively, related to the Seattle Genetics Agreements.

## 4. Cash, cash equivalents and investments

As of September 30, 2018 and December 31, 2017, cash, cash equivalents, and investments comprised of funds in depository, money market accounts, U.S. treasury securities, asset backed securities, and corporate bonds. The following table presents the cash equivalents and investments carried at fair value in accordance with the hierarchy defined in Note 2 (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2018				
Money market funds, included in cash equivalents	\$ 34,602	\$ 34,602	\$ —	\$ —
Investments - U.S. treasuries	2,694	2,694	_	_
Investments - Asset-backed securities	9,227	_	9,227	_
Investments - Corporate bonds	35,901	_	35,901	_
Total	\$ 82,424	\$ 37,296	\$ 45,128	\$
December 31, 2017				
Money market funds, included in cash equivalents	\$ 4,583	\$ 4,583	\$ —	\$
Corporate bonds, included in cash equivalents	13,595	_	13,595	_
Investments - U.S. treasuries	4,172	4,172	_	_
Investments - Asset-backed securities	6,384	_	6,384	<u> </u>
Investments - Corporate bonds	34,117	_	34,117	_
Total	\$ 62,851	\$ 8,755	\$ 54,096	\$ —

Cash equivalents and marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value. The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources, as needed. After completing its validation procedures, the Company did not adjust any fair value measurements provided by the pricing services as of September 30, 2018.

Cash equivalents and investments at September 30, 2018 consist of the following (in thousands):

	Contractual maturity (in days)	Am	ortized Cost	Unrealized gains	Unrealized losses	Fair Value
Investments						
U.S. treasuries	46-67	\$	2,702 \$	— \$	(8) \$	2,694
Asset-backed securities	15-319		9,228	7	(8)	9,227
Corporate bonds	1-207		35,615	319	(33)	35,901
Total		\$	47,545 \$	326 \$	(49) \$	47,822

The Company recorded \$0.8 million and \$0.7 million of realized gains from the maturity of available-for-sale securities during the three and nine months ended September 30, 2018, respectively. No realized gains or losses were recognized during the three and nine months ended September 30, 2017, respectively.

## 5. Property and equipment, net

Property and equipment are summarized as follows (in thousands):

	Sep	tember 30,	D	ecember 31,
		2018		2017
Laboratory equipment	\$	6,971	\$	6,101
Office and computer equipment		692		494
Leasehold improvements		323		318
Property and equipment at cost		7,986		6,913
Accumulated depreciation		(3,299)		(2,879)
Property and equipment, net	\$	4,687	\$	4,034

## 6. Accrued Expenses

Accrued expenses and other current liabilities consisted of the following (in thousands):

	Septem	ber 30,	D	ecember 31,	
	20	18	2017		
Compensation expense	\$	1,841	\$	2,325	
Professional fees		1,077		1,322	
Research and development fees		1,811		791	
Audit and tax fees		480		424	
Other current liabilities		772		1,308	
Total	\$	5,981	\$	6,170	

## 7. Stockholders' Equity

The Company had 54,149,719 shares of common stock and 2,907 shares of preferred stock outstanding as of September 30, 2018, both with a par value of \$0.001 per share. During the first quarter of 2018, 2,056 shares of preferred stock were converted into 2,056,000 shares of common stock. During the three and nine months ended September 30, 2018, respectively, the Company issued 75,634 and 594,769 shares of common stock upon option exercises, resulting in cash proceeds of \$0.1 million and \$1.0 million, respectively. For the three and nine months ended September 30, 2017, 142,555 and 232,017 options were exercised, resulting in cash proceeds of \$0.2 million and \$0.4 million, respectively. During the three and nine months ended September 30, 2018, respectively, the Company issued 66,029 and 156,888 shares of common stock upon exercise of warrants, resulting in cash proceeds of \$0.1 million and \$0.3 million, respectively. There were 721,385 and 1,364,878 warrants exercised during the corresponding 2017 periods, resulting in cash proceeds of \$1.8 million and \$3.1 million, respectively.

At our Annual Shareholder Meeting, held on July 24, 2018, the shareholders approved both the 2018 Employee, Director and Consultant Equity Incentive Plan, or the 2018 Plan, and the 2018 Employee Stock Purchase Plan, or the 2018 ESPP. Upon approval of the 2018 Plan, the 2016 Employee, Director and Consultant Equity Incentive Plan, or the 2016 Plan, was terminated and no additional awards will be made thereunder, however, all outstanding awards under the 2016 Plan will remain in effect. There were approximately 74,000 shares remaining and available for grant under the 2016 Plan that terminated pursuant to the approval of the 2018 Plan. The 2018 Plan permits the Company to issue up to 9,975,000 shares, including

3,000,000 shares reserved for issuance pursuant to the 2018 Plan and up to 6,975,000 additional shares which may be issued if awards outstanding under the Registrant's 2016 Employee, Director and Consultant Equity Incentive Plan and 2014 Employee, Director and Consultant Equity Incentive Plan are canceled or expire. The 2018 ESPP provides eligible employees with the opportunity to purchase shares of our common stock at a discount, on a tax-favored basis, through regular payroll deductions in compliance with federal tax regulations. The Company has reserved 500,000 shares of common stock for the administration of the 2018 ESPP.

#### **Underwritten Public Offering**

In February 2018, the Company completed an underwritten public offering of its common stock in which it sold 6,325,000 shares of common stock, including the exercise in full by the underwriters of their option to purchase an additional 825,000 shares of common stock, to the public at a price of \$8.00 per share (the "2018 Offering"). The 2018 Offering was completed under the Company's shelf registration statement that was filed on Form S-3 and declared effective by the SEC on August 3, 2016. Net proceeds of the 2018 Offering, after deducting the underwriting discounts and commissions, were \$47.6 million, excluding offering expenses of approximately \$0.4 million incurred by the Company.

## 8. Net Loss per Share

Basic net loss per share is calculated by dividing net income (loss) by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, preferred stock, stock options, and warrants are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

For the nine months ended September 30, 2018 and 2017, and as calculated using the treasury stock method, approximately 14.7 million and 15.7 million of weighted average shares, respectively, were excluded from the calculation of diluted weighted average shares outstanding as their effect was anti-dilutive.

#### 9. License Agreements

#### Pieris License and Collaboration Agreement with the Technical University of Munich

Pieris and the Technical University of Munich ("TUM") initiated discussions within the second quarter to clarify, expand and restructure their 2003 license agreement (the "TUM License"), including the parties' obligations under that License. The TUM License assigns or exclusively licenses to Pieris certain intellectual property related to Pieris' Anticalin platform technology. The parties' recent discussions relate to revised commercial terms and to re-initiate additional collaborations between faculty at TUM and Pieris. The Company believes it is reasonably possible that these discussions may lead to an increase in Pieris' financial obligations associated with the TUM License, including amounts due for 2017 and 2018 activities recorded as of September 30, 2018. These discussions may also lead to an increase in Pieris' collaborative research activities with TUM. An amended and restated license agreement has not yet been completed. The potential financial impact is estimated to be up to \$2.7 million for amounts related to 2017 and 2018 sub-licensing activities and will be recorded as additional research and development expense once the amounts become probable and estimable.

## 10. Subsequent Event

On October 24, 2018, Pieris Pharmaceuticals GmbH (the "Pieris GmbH"), a wholly-owned subsidiary of Pieris Pharmaceuticals, Inc. (the "Company"), entered into a lease agreement (the "Lease Agreement") with Hallbergmoos Grundvermögen GmbH (the "Lessor") pursuant to which Pieris GmbH has agreed to lease office and laboratory space located at Zeppelinstrasse 3, 85399 Hallbergmoos, Germany (the "Leased Property"). Under the Lease Agreement, 96,383 square feet of the Leased Property is expected to be delivered by the Lessor to Pieris GmbH by December 2019, 8,674 square feet of the Leased Property is expected to be delivered by the Lessor to Pieris GmbH by May 2020, and 22,284 square feet of the Leased Property is expected to be delivered by the Lessor to Pieris GmbH by October 2024. Pieris GmbH has a first right of refusal to lease an additional 13,440 square feet. Pieris GmbH intends to move its operations currently conducted at Lise-Meitner-Str. 30, 85354 Freising, Germany to the Leased Property.

The Lease Agreement is contingent on the Lessor obtaining appropriate building permits from governmental authorities and either party may rescind the Lease Agreement if the Lessor does not obtain such permits within a specified period of time. The Lease Agreement provides for an initial term of 150 months, commencing on the date the Lessor first delivers the Leased Property to Pieris GmbH as agreed under the Lease Agreement. Pieris GmbH also has an option to extend the term of the Lease Agreement for two additional 60-month periods. Pieris GmbH may sublease space within the Leased Property with Lessor's consent, which may not be unreasonably withheld.

Monthly base rent for the initial 105,057 square feet of the Leased Property, including parking spaces, will total approximately\$0.2M per month, which amount shall be adjusted starting on the second anniversary of the commencement date by an amount equal to the German consumer price index. In addition to the base rent, Pieris GmbH is also responsible for certain administrative and operational costs in accordance with the terms of the Lease Agreement. Pieris GmbH will maintain a security deposit in the amount of three months' rent. The Company will serve as a guarantor for the Lease Agreement.

Pieris GmbH and the Lessor are each entitled to terminate the Lease Agreement for due cause. Specifically, the Lessor may terminate for Pieris GmbH's default on rent payments beyond certain amounts, noncompliance with major obligations under the Lease Agreement, and certain bankruptcy and insolvency events

### 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, 2017, 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, 2017, filed with the SEC on March 15, 2018. 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, 2017.

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 others. All other trademarks, trade names and service marks included in this Quarterly Report on Form 10-Q are the property of their respective owners. Tecentriq® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group. 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.

#### Overview

We are a clinical-stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in unique and transformative ways. Our clinical pipeline includes an inhaled IL-4 receptor alpha antagonist Anticalin protein to treat uncontrolled asthma, an immuno-oncology bispecific targeting HER2 and 4-1BB and a half-life-optimized hepcidin antagonizing Anticalin protein to treat anemia. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and through partnerships with leading pharmaceutical companies. Our development programs include:

- *PRS-060*, our lead respiratory program partnered with AstraZeneca AB, or AstraZeneca, is a drug candidate that binds to IL-4Rα, thereby inhibiting IL-4 and IL-13, two cytokines known to be key mediators in the inflammatory cascade that causes asthma and other inflammatory diseases.
- *PRS-343*, our lead immuno-oncology program, is a fusion protein, comprising a HER2-targeting antibody genetically linked to 4-1BB-targeting Anticalin proteins. PRS-343 is designed to drive tumor localized T-cell activation through tumor-targeted drug clustering mediated by HER2 expressed on tumor cells. This program is the first bispecific T-cell costimulatory agonist to enter clinical development.
  - We are also developing additional immuno-oncology drug candidates that are multispecific Anticalin-based fusion proteins designed to engage immunomodulatory targets and consist of a variety of multifunctional biotherapeutics, including PRS-344, a bispecific Anticalin-antibody fusion protein comprising an anti-PD-L1 antibody genetically fused to Anticalin proteins specific for 4-1BB and PRS-332, a bispecific Anticalin-antibody fusion protein comprising an anti-PD-1 antibody genetically fused to an Anticalin protein specific for an undisclosed checkpoint target. PRS-344 and PRS-332 are being developed as part of our immuno-oncology collaboration with Servier.
- *PRS-080* is an Anticalin protein that binds to hepcidin, a natural regulator of iron in the blood. PRS-080 is 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.

Our programs are in varying stages:

• PRS-060, an inhaled IL-4 receptor alpha antagonist for moderate-to-severe asthma, was tested in 48 healthy volunteers at dose levels ranging from 0.25 mg to 400 mg in a single ascending dose Phase I study. The drug candidate was safe and well-tolerated in this study. We continue enrolling subjects in a multiple ascending dose (MAD) Phase I study of the drug candidate versus placebo in mild asthmatics. The MAD study will evaluate safety and tolerability as well as

exhaled nitric oxide, an inflammatory marker of inflamed lung epithelial cells. The data from the PRS-060 Phase I studies will be presented at a future medical meeting. PRS-060 is the lead candidate in Pieris' respiratory collaboration with AstraZeneca. We are sponsoring the Phase I studies and AstraZeneca is funding the costs. AstraZeneca will conduct and fund the Phase IIa study, after which we will have separate options to codevelop and co-commercialize the drug candidate in the United States.

- We continue to enroll and treat patients in a Phase I dose-escalation study of PRS-343, a 4-1BB/HER2 bispecific for HER2-positive solid tumors, and intend to report initial data from the study in the first half of 2019, after completing the dose escalation, in order to provide a more comprehensive data set. Our objective for the remaining enrollment will be to favor patient selection across a range of immunotherapy-responsive tumor types. In August, we initiated a trial with PRS-343 in combination with atezolizumab and intend to report data from this trial in 2019.
- For our other immuno-oncology drug candidates and programs, we are conducting activities relating to candidate identification, optimization, and preclinical evaluation. We intend to file two new INDs for immuno-oncology drug candidates in 2019, one that is proprietary to us and one that is directed to a partnered program with Servier.
- PRS-080 is currently in a Phase IIa study. We are planning to enroll and complete dosing of the final patient in this multiple ascending dose study by year end. In the ongoing trial, PRS-080 at both doses (4mg/kg and 8mg/kg) has not generated any observed drug-related serious adverse events and has demonstrated substantial iron mobilization and transferrin saturation (TSAT) increases versus placebo. To date, there has been no conclusive change in hemoglobin at either dose versus placebo. We remain committed to completing the study and sharing the data with ASKA and other potential partners for continued development. We intend to report the full data set from the study in the first half of 2019.

Our core Anticalin technology and platform were developed in Germany, and we have collaborations with major multi-national pharmaceutical companies. We entered into a License and Collaboration Agreement with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or Servier, in January 2017 in immuno-oncology and entered into an Exclusive Option Agreement with Aska, in February 2017 for PRS-080 in Japan and other Asian territories. In May 2017, we entered into an alliance with AstraZeneca to treat respiratory diseases and in February 2018 we entered into a License and Collaboration Agreement with Seattle Genetics, Inc., or Seattle Genetics in immuno-oncology.

Since inception, we have devoted nearly all of our efforts and resources to our research and development activities and have incurred significant net losses. For the three and nine months ended September 30, 2018, we reported a net loss of \$6.2 million and \$15.1 million, respectively. For the three and nine months ended September 30, 2017, we reported a net loss of \$7.1 million and \$25.1 million, respectively. As of September 30, 2018, we had an accumulated deficit of \$135.4 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.

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. At each period end, we re-measure assets and liabilities to the functional currency of that entity (for example, U.S. dollar payables recorded by Pieris GmbH). Re-measurement gains and losses are recorded in the statement of operations line item "Other income (expense), net". 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 weighted average rate during the period. Equity transactions are translated using historical exchange rates. All adjustments resulting from translating foreign currency financial statements into U.S. dollars are included in Accumulated other comprehensive loss.

#### **Key Financial Terms and Metrics**

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 Servier, AstraZeneca, and Seattle Genetics.

The revenues from Servier, AstraZeneca, and Seattle Genetics have been comprised primarily of upfront payments, research and development services, and 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. For revenues from research, development, and commercial milestone payments, if the milestones are deemed substantive and the milestone payments are nonrefundable, such amounts are recognized entirely upon successful accomplishment of the milestones, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive are accounted for as contingent revenue and will be recognized when achieved to the extent the Company has no remaining performance obligations under the arrangement. Revenues from sales milestone payments are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. Royalty payments are recognized in revenues based on the timing of royalty payments earned in accordance with the agreements, which typically is the period when the relevant sales occur, assuming all other revenue recognition criteria are met. 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 expenses will be incurred. Our current development plans focus on the following activities: Our immuno-oncology programs, or PRS-300 series, currently comprised of PRS-343 as well as multiple additional proprietary and partnered programs, PRS-060, and PRS-080. 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 personnel-related costs (salaries, employee benefits, equity compensation, and other costs), 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 salaries, 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 and nine months ended September 30, 2018 and 2017

The following table sets forth our revenues and operating expenses for the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ende 30,			d September	
		2018	2017		2018		2017
Revenues	\$	8,345	\$ 3,927	\$	24,187	\$	7,123
Research and development expenses		11,401	6,259		28,492		17,015
General and administrative expenses		4,748	2,852		13,878		11,190
Total operating expenses		16,149	9,111		42,370		28,205
Interest income		504	_		1,491		_
Other income (expense), net		1,147	(1,729)		1,472		(3,097)
Loss before income taxes		(6,153)	 (6,913)		(15,220)		(24,179)
Provision for income tax		_	146		(148)		959
Net loss	\$	(6,153)	\$ (7,059)	\$	(15,072)	\$	(25,138)

#### Revenues

The following table provides a comparison of revenues for the three months ended September 30, 2018 and 2017 (in thousands):

	Three Mo Septen			
	 2018	2017	Increas	e/(Decrease)
License fees	\$ 7,873	\$ 3,650	\$	4,223
Research and development services	472	263		209
Other	_	14		(14)
Total Revenue	\$ 8,345	\$ 3,927		4,418

- The \$4.2 million increase in revenues from license fees in the three months ended September 30, 2018 compared to the three months ended September 30, 2017 primarily relates to the increased level of activities with respect to our collaboration agreements with AstraZeneca, which commenced in June 2017 and Seattle Genetics which commenced in February 2018. These increases were partially offset by license fee revenue recorded in 2017 from our Roche collaboration agreement, which did not occur in the comparable period for 2018.
- The \$0.2 million increase in revenues from research and development services in the three months ended September 30, 2018 compared to the three months ended September 30, 2017 relates to increased research and development activities under our collaboration with Servier, partially offset by research and development activities that occurred during 2017 under our collaboration with Roche.

The following table provides a comparison of revenues for the nine months ended September 30, 2018 and 2017 (in thousands):

	Nine Months Ended September 30,					
		2018		2017	Incr	rease/(Decrease)
License Fees	\$	22,541	\$	6,166	\$	16,375
Research and development services		1,555		943		612
Other		91		14		77
Total Revenue	\$	24,187	\$	7,123		17,064

- The \$16.4 million increase in revenues from license fees in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 primarily relates to the recognition of revenue under our collaborations with AstraZeneca, Servier, and Seattle Genetics. License fee revenue from our Roche collaboration agreement recorded in 2018 upon termination of the Roche collaboration agreement by Roche decreased in comparison to the license fee revenue recorded as a result of services performed under the Roche collaboration agreement in 2017.
- The 0.6 million increase in revenues from research and development services in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 relates to increased research and development activities under our collaboration with Servier, partially offset by research and development activities that occurred during 2017 under our collaboration with Roche.

#### Research and Development Expenses

The following table provides a comparison of the research and development expenses for the three months ended September 30, 2018 and 2017 (in thousands):

	Three Mo Septer			
	 2018	2017	Increa	se/(Decrease)
PRS-300 series	\$ 4,225	\$ 525	\$	3,700
PRS-060	2,153	1,676		477
PRS-080	288	824		(536)
Other research and development activities	4,735	3,234		1,501
Total	\$ 11,401	\$ 6,259		5,142

- The \$3.7 million increase in our PRS-300 series expenses period-over-period is due to increases in clinical costs for the PRS-343 program which is currently in multiple Phase I clinical trials. In addition, preclinical and chemistry and manufacturing control, or CMC, costs increased for our other proprietary and partnered immuno-oncology programs as we are conducting activities relating to candidate identification, optimization, and preclinical evaluation.
- The \$0.5 million increase for our PRS-060 program expenses period-over-period is due primarily to an increase in our clinical costs as our first-in-human clinical trial for PRS-060 started in December 2017. These amounts were partially offset by a decrease in CMC costs to manufacture drug supply ahead of clinical trials and license fees we paid for the platform license under our collaboration with AstraZeneca in the 2017 period.
- The \$0.5 million decrease for PRS-080 program expenses period-over-period is mainly due to slightly lower clinical costs related to the Phase IIa study.
- The \$1.5 million increase in other research and development activities expenses is mainly due to higher personnel expenses, including bonus and stock compensation, due to an overall increase in headcount, and an increase in general lab supply, preclinical and other costs for our earlier stage programs.

The following table provides a comparison of the research and development expenses for the nine months ended September 30, 2018 and 2017 (in thousands):

	Nine Moi Septer			
	 2018	2017	Increa	se/(Decrease)
PRS-300 series	\$ 8,789	\$ 3,136	\$	5,653
PRS-060	5,400	3,790		1,610
PRS-080	1,591	1,727		(136)
Other research and development activities	12,712	8,362		4,350
Total	\$ 28,492	\$ 17,015		11,477

- The \$5.7 million increase in our PRS-300 series expenses period-over-period is due primarily to increases in clinical costs for the PRS-343 program which is currently in multiple Phase I clinical trials. In addition, preclinical costs increased for our other immuno-oncology programs as we are conducting activities relating to candidate identification, optimization, and preclinical evaluation.
- The \$1.6 million increase in our PRS-060 program expenses period-over-period is due primarily to an increase in our clinical costs as our first-in-human clinical trial for PRS-060 started in December 2017. These amounts are partially offset by lower CMC costs and a decrease in expenses for license fees we paid in the 2017 period for the platform license under our collaboration with AstraZeneca.
- The \$0.1 million decrease for PRS-080 program expenses period-over-period is mainly due lower clinical costs related to our Phase IIa study partially offset by an increase in license fees related to our collaboration with ASKA.
- The \$4.4 million increase in other research and development activities expenses is mainly due to increases of our personnel expenses including
  bonus and stock compensation due to an increase in overall headcount and an increase in general lab supply, preclinical and other costs for our
  earlier stage programs.

### General and Administrative Expenses

General and administrative expenses were \$4.7 million for the three months ended September 30, 2018 as compared to \$2.9 million for the three months ended September 30, 2017. The period-over-period increase is due to investments in our general and administrative functions, including approximately \$0.6 million in personnel costs, an increase of approximately \$0.3 million of audit and legal fees, an increase in consulting costs of approximately \$0.2 million, and an increase of investor relations costs of approximately \$0.2 million. The remainder of the increase in general administrative costs is spread across various expense types (such as rent and facility costs, insurance, travel, and IT infrastructure) to support our growing business.

General and administrative expenses were \$13.9 million for the nine months ended September 30, 2018 as compared to \$11.2 million for the nine months ended September 30, 2017. The period-over-period increase is due to investments in our general and administrative functions including approximately \$1.8 million in personnel costs, an increase of approximately \$0.7 million for audit and legal services, and approximately \$0.4 million for rent and facility costs. These amounts are partially offset by \$1.8 million of lower professional fees including transaction fees specific to our license and collaboration agreements recorded in the first three quarters of 2017 for which there were none in 2018. The remainder of the increase in general administrative costs is spread across various expense types (such as investor relations, insurance, travel, and IT infrastructure) to support our growing business.

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

Our non-operating income was \$1.7 million for the three months ended September 30, 2018 as compared to a net non-operating expense of \$1.7 million for the three months ended September 30, 2017. This increase in income is mainly a result of net foreign currency transaction gains due to the strengthening of the U.S. dollar against the euro, including foreign currency remeasurement of monetary assets, primarily U.S. dollar cash, investments and receivable balances in Germany. In addition, we earned interest income of \$0.5 million on our investments during the three months ended September 30, 2018. We did not hold investments during the corresponding 2017 period.

Our non-operating income was \$3.0 million for the nine months ended September 30, 2018 as compared to a net non-operating expense of \$3.1 million for the nine months ended September 30, 2017. This increase in income is a result of net foreign currency transaction gains due to the strengthening of the U.S. dollar against the euro, including foreign currency remeasurement of monetary assets, primarily U.S. dollar cash, investment and, receivable balances in Germany. In addition, we earned interest income of \$1.5 million on our investments during the first three quarters of 2018. We did not hold investments during the corresponding 2017 period.

## **Liquidity and Capital Resources**

Through September 30, 2018, we have funded our operations with \$379.2 million of cash that has been obtained from the following main sources: \$170.5 million from sales of equity; \$187.9 million in total payments received under license and collaboration agreements, including \$22.7 million for research and development services costs received from our collaboration partners; \$14.2 million from government grants and \$6.5 million from loans.

As of September 30, 2018, we had a total of \$137.3 million in cash, cash equivalents and investments. We have incurred losses in every period since inception including the three and nine months ended September 30, 2018 and 2017, respectively, and have a total accumulated deficit of \$135.4 million as of September 30, 2018.

In February 2018, we completed an underwritten public offering of our common stock in which we sold 6,325,000 shares of Common Stock, including the exercise in full by the underwriters of their option to purchase an additional 825,000 shares of Common Stock, to the public at a price of \$8.00 per share. The offering was completed under the shelf registration statement that was filed on Form S-3 and declared effective by the SEC on August 3, 2016. Net proceeds of the underwritten public offering, after deducting the underwriting discounts and commissions, were \$47.6 million, excluding our offering expenses of approximately \$0.4 million.

We have several research and development programs underway in varying stages of development and we expect they will continue to require increasing amounts of cash for development, conducting clinical trials, and testing and manufacturing of product material. We expect cash necessary to fund operations will increase significantly over the next several years as we continue to conduct these activities necessary to pursue governmental regulatory approval of clinical-stage programs and our other product candidates.

The following table provides a summary of operating, investing, and financing cash flows for the nine months ended September 30, 2018 and 2017 respectively (in thousands):

	Nine Months Ended	September 30,
	2018	2017
Net cash provided by operating activities	7,992	54,448
Net cash used in investing activities	(3,658)	(1,131)
Net cash provided by financing activities	48,504	3,493

Net cash provided by operating activities of 8.0 million for the nine months ended September 30, 2018 is comprised principally of aggregate receipts of \$46.2 million from Seattle Genetics and AstraZeneca, offset by operating expenses of \$35.7 million, net of non-cash items and a decrease in net working capital of \$2.5 million. Net cash provided by operating activities was 54.4 million for the nine months ended September 30, 2017, comprised principally of aggregate receipts of 82.7 million from AstraZeneca and Servier and an increase in net working capital of 0.7 million, offset by operating expenses amounting to 29.0 million, net of non-cash items.

The increase in net cash used in investing activities for the nine months ended September 30, 2018 compared to the same period in 2017 is mainly attributable to higher investing activities in 2018 for which there were none in 2017.

The increase in net cash provided by financing activities for the nine months ended September 30, 2018 was primarily due to the issuance of common stock under our 2018 Offering. In addition, proceeds from warrant exercises were slightly lower for the nine months ended 2018 compared to the same period in 2017.

We expect that our existing cash, cash equivalents, and investments will enable us to fund our operational and capital expenditure requirements for at least twelve months from the issuance date of these financial statements. Any requirements for additional capital will depend on many factors, including the following:

- the scope, rate of progress, results 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.

Due to the often-volatile nature of the financial markets, equity and debt financing(s) may be difficult to obtain. In addition, any unfavorable development or delay in the progress of our core clinical-stage programs including PRS-343 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, as defined under applicable SEC rules.

#### **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, 2017 for a discussion of our critical accounting policies and estimates. There were no significant changes to our Critical Accounting Policies and Estimates for the three and nine months ended September 30, 2018.

#### **Recently Issued Accounting Pronouncements**

We review new accounting standards to determine the expected financial impact, if any, that the adoption of each standard will have. For the recently issued accounting standards that we believe may have an impact on our consolidated financial statements, see "Note 2—Summary of Significant Accounting Policies" 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 \$1.07 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, effective September 10, 2018, was amended to include companies with a public float of less than \$250 million as of the last business day of its most recently completed second fiscal quarter or, if such public float is less than \$700 million, had annual revenues of less than \$100 million during the most recently completed fiscal year for which audited financial statements are available. Currently, we 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 and have taken advantage of certain exemptions from various reporting requirements that are not available to public reporting companies that do not qualify for those classifications, including, but not limited to, the following:

- 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."
- A requirement to hold a non-binding advisory stockholder vote on executive compensation or any golden parachute payments not previously approved by stockholders.
- A requirement 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.

- An opportunity 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.
- An opportunity 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.

Emerging growth companies may also 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.

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 expect that we will no longer qualify as an emerging growth company on December 31, 2019 as this is 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.

### Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

#### Item 4. Controls and Procedures.

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

Our management, with the participation of our principal executive officer and principal financial officer have evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our principal executive officer and principal financial officer have concluded that, based on such evaluation, our disclosure controls and procedures were not effective as of September 30, 2018 as a result of the previously reported material weakness discussed below.

In connection with the preparation of our financial statements for the year ended December 31, 2017, we concluded that we had a material weakness relating to the financial statement close process due to a combination of deficiencies. The deficiencies resulted from two separate errors that were not identified by management; one related to the classification of certain operating expenses and one related to the reporting of foreign currency re-measurements on investments. These errors were corrected in the financial statements for the year ended December 31, 2017 prior to their issuance.

In response to the identified material weaknesses, our management, with the oversight of the Audit Committee of our Board of Directors, has taken action on a number of different remediation initiatives to improve our internal control over financial reporting for the year ended December 31, 2018. We are committed to continuing to improve our internal control processes and we continue to review, optimize, and enhance our internal control environment. These material weaknesses will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded that these controls are operating effectively.

Notwithstanding this material weakness, management, including our principal executive officer and principal financial officer, has concluded that the financial statements and other financial information included in this Quarterly Report on Form 10-Q,

fairly present in all material respects our financial condition, results of operations and cash flows as of, and for, the periods presented.

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

There have been no changes in our internal control over financial reporting identified in connection with the evaluation of such internal control required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting other than the remediation efforts described above.

#### **PART II - OTHER INFORMATION**

## Item 1. Legal Proceedings.

As of the date of this Quarterly Report on Form 10-Q, we are not party to and our property is not subject to any material pending legal proceedings. However, from time to time, we may become involved in legal proceedings or subject to claims that arise in the ordinary course of our business activities. Regardless of the outcome, such legal proceedings or claims could have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

## 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, 2017.

#### 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 <u>Number</u>	Exhibit Description		Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
10.1	2018 Employee Stock Purchase Plan.		Exhibit 10.2 to the Registrant's Current Report on Form 8-K	July 26, 2018	001-37471
10.2	2018 Employee, Director and Consultant Equity Incentive Plan.		Exhibit 10.11 to the Registrant's Current Report on Form 8-K	July 26, 2018	001-37471
31.1	Certification of Principal Executive Officer Pursuant to Rules 12a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	*			
31.2	Certification of Principal Financial Officer and Principal Accounting Officer Pursuant to Rules 12a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	*			

Exhibit		
<u>Number</u>	Exhibit Description	
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	**
32.2	Certification of Principal Financial Officer and Principal Accounting Officer Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	**
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 Extension Presentation Linkbase Document	*
*	Filed herewith.	
**	The certifications furnished in Exhibit 32.1 and Exhibit 32.2 hereto are deemed to accompany this Quarterly Report and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.	

Incorporated by Reference herein from Form or Schedule

SEC File / Registration Number

Filing Date

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

## PIERIS PHARMACEUTICALS, INC.

November 7, 2018 By: /s/ Stephen S. Yoder

Stephen S. Yoder

Chief Executive Officer and President

(Principal Executive Officer)

November 7, 2018 By: /s/ Allan Reine

Allan Reine

Chief Financial Officer

(Principal Financial and Accounting Officer)

## CERTIFICATIONS UNDER 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 7, 2018

/s/ Stephen S. Yoder

Stephen S. Yoder

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

## CERTIFICATIONS UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

## I, Allan Reine, 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(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 7, 2018

/s/ Allan Reine

Allan Reine

Title: Chief Financial Officer (principal financial officer)

#### **CERTIFICATIONS 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 September 30, 2018 (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.

Dated: November 7, 2018 /s/ Stephen S. Yoder

Stephen S. Yoder

Title: Chief Executive Officer and President

(principal executive officer)

#### **CERTIFICATIONS 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 September 30, 2018 (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.

Dated: November 7, 2018 /s/ Allan Reine

Allan Reine

Title: Chief Financial Officer

(principal financial officer)