August 9, 2017



# Pieris Pharmaceuticals Reports Financial Results for the Second Quarter Ended June 30, 2017 and Provides Corporate Update

BOSTON, MA -- (Marketwired) -- 08/09/17 -- *Pieris Pharmaceuticals, Inc.* (NASDAQ: PIRS), a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary <u>Anticalin<sup>®</sup></u> technology platform for cancer, respiratory and other diseases, today reported financial results for the second quarter of 2017 and provided an update on the Company's recent developments, including:

- Strategic alliance in respiratory diseases with AstraZeneca: Announcement of a global and transformative alliance in one of the Company's core therapeutic areas, respiratory diseases, with AstraZeneca, anchored around lead respiratory program PRS-060. Pieris plans to dose healthy subjects in the fourth quarter of 2017 in a single-ascending dose trial, followed by a multi-ascending dose trial, under a clinical trial notification to the Therapeutic Goods Administration in Australia. The dosing of the first subject will trigger a milestone payment of \$12.5 million by AstraZeneca to Pieris.
- *IND approval for PRS-343:* Notification by FDA of acceptance of the Company's IND filing for its lead proprietary immuno-oncology (IO) program, PRS-343. The Company is diligently engaged with its clinical trial sites toward initiation of patient dosing in a Phase I study in patients with HER2-positive solid tumors. In April, at the Annual Meeting of the American Association for Cancer Research, Pieris presented preclinical data for PRS-343 that further validated the understanding of its differentiated bispecific mechanism of action in the treatment of HER2-positive tumors.
- Positive clinical data and progression of PRS-080: Advancement of the Company's anemia program, PRS-080, including the filing of separate clinical trial applications with the German and Czech Republic regulatory authorities to conduct a Phase IIa trial in functional iron deficient anemia patients with the intention, pending timely regulatory approval, to initiate enrollment of patients during this quarter. During the second quarter, the Company completed a Phase Ib single ascending dose study in anemic chronic kidney disease patients on hemodialysis and presented positive data at the 54<sup>th</sup> European Renal Association & European Dialysis and Transplant Association Congress in Spain.
- Advancing and broadening IO pipeline with Servier: Advancement of the

Company's IO partnership with Servier, including progression of our lead program PRS-332, through preclinical studies, while initiating activities for two of the collaboration programs beyond PRS-332.

"During the second quarter, we continued to build on the momentum with which we began the year, by announcing a global transformative alliance with AstraZeneca in one of our core therapeutic areas, respiratory diseases. We also advanced our strategic collaboration with Servier in immuno-oncology, while strengthening our relationship with ASKA Pharmaceutical, who holds an exclusive development and commercialization option in Japan for our anemia program, PRS-080. Our partnerships have generated nearly \$80 million in cash flow in 2017, and together could result in more than \$4.4 billion in potential milestone payments plus royalties from future product sales, not to mention opportunities for direct commercial sales for several products in the United States. This year's transactions are a significant step towards achieving our goal of becoming a fully integrated, immunologyfocused, commercial-stage biopharmaceutical company," said Stephen Yoder, President and CEO of Pieris. "We recently received FDA acceptance of our IND filing for our lead and wholly owned IO program, PRS-343, and soon expect to dose our first patient in HER2positive cancers. We remain on track to advance our lead respiratory program, PRS-060, into a first-in-human trial in the second half of this year in collaboration with AstraZeneca, while advancing PRS-080 into a Phase IIa study in anemia patients. Finally, our balance sheet remains strong, with a financial runway that extends through several critical, clinicalstage value inflection points."

## Second Quarter Financial Update:

<u>Cash Position</u> - Cash and cash equivalents totaled \$50.3 million as of June 30, 2017, compared to \$29.4 million as of December 31, 2016. The increase in cash was driven primarily by a EUR30.0 million (approximately \$32.0 million) upfront payment received from Servier and a \$2.8 million option payment received from ASKA, offset by \$15.2 million of operating cash expenditures during the first half of the year. In addition, in July 2017 the Company received \$45.0 million of upfront payments from AstraZeneca.

<u>*R&D Expense*</u> - Research and development expenses were \$5.4 million and \$10.8 million for the three and six-month periods ended June 30, 2017, respectively, as compared to \$4.5 million and \$8.2 million for the three and six-month periods ended June 30, 2016. The Company's increases in research and development expenses reflect advancement across its pipeline of programs.

<u>*G&A Expense*</u> - General and administrative expenses were \$4.3 million and \$8.3 million for the three and six-month periods ended June 30, 2017, respectively, as compared to \$2.4 million and \$4.3 million for the three and six-month periods ended June 30, 2016. The increase in the 2017 periods as compared to the corresponding periods in 2016 is largely attributable to \$1.8 million in transaction fees for the successful close of our license and collaboration agreement with AstraZeneca. Of a more recurring nature, recruiting and personnel related costs are increasing as we continue to build the organization and we increasingly require outside professional services, including for intellectual property and corporate legal work, auditing, finance, communications and in other facets of the business.

<u>Net Loss</u> - Net loss was \$10.1 million or (\$0.23) per share for the three-month period ended June 30, 2017, compared to a net loss \$5.9 million or (\$0.14) per share for the three-month

period ended June 30, 2016. Net loss was \$18.1 million or (\$0.42) per share for the sixmonth period ended June 30, 2017, compared to a net loss \$10.0 million or (\$0.25) per share for the six-month period ended June 30, 2016.

#### **Upcoming Milestones:**

- PRS-343: dose first patient in a Phase I multi-ascending dose study involving a range of HER2-positive solid cancers representing unmet medical needs, such as gastrointestinal, bladder and breast cancers.
- PRS-080: dose first patient in a Phase IIa trial enrolling FID anemia patients in Germany and the Czech Republic.
- PRS-060: complete first-in-human trial activities and dose first subject in a Phase I study, which will be funded by Pieris' partner, AstraZeneca.

## Conference Call

Pieris management will host a conference call beginning at 10:00 AM Eastern Daylight Time on Thursday, August 10, 2017, to discuss the first quarter financial results and provide a corporate update. To access the call, participants may dial 877-407-8920 (US & Canada) or 412-902-1010 (International) at least 10 minutes prior to the start of the call. An archived replay of the call will be available for 30 days by dialling (Toll Free US & Canada): 877-660-6853, (International): 201-612-7415, Conference ID #: 13661472.

## About Pieris Pharmaceuticals

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

## Forward Looking Statements

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to novel technologies and methods; our business and product development plans; the timing and progress of our studies, including the timing of enrollment and dosing of PRS-343 patients, the enrollment of patients in the PRS-080 multi-dose trial and dosing healthy subjects; our liquidity and ability to fund our future operations; our ability to achieve certain milestones and receive future milestone or royalty payments; or market information. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, our ability to raise the additional funding we will need to continue to pursue our business and product development plans; the inherent

uncertainties associated with developing new products or technologies and operating as a development stage company; our ability to develop, complete clinical trials for, obtain approvals for and commercialize any of our product candidates, including our ability to recruit and enroll patients in our studies; our ability to address the requests of the FDA; competition in the industry in which we operate and market conditions. These forward-looking statements are made as of the date of this press release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents we file with the SEC available at www.sec.gov, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and the Company's Quarterly Reports on Form 10-Q.

#### PIERIS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

		l	December	
	 June 30, 2017		31, 2016	
Assets:				
Cash and cash equivalents	\$ 50,325,193	\$	29,355,528	
Accounts receivable	48,470,309		57,582	
Prepaid expenses and other current assets	 3,947,997		3,259,503	
Total current assets	102,743,499		32,672,613	
Property and equipment, net	 3,085,063		2,264,477	
Other noncurrent assets	 128,211		125,741	
Total Assets	\$ 105,956,773	\$	35,062,831	
Liabilities and stockholders' equity:				
Accounts payable	\$ 4,646,270	\$	2,386,183	
Accrued expenses	6,350,841		3,719,457	
Deferred revenue, current portion	 24,798,649		2,274,514	
Total current liabilities	35,795,760		8,380,154	
Deferred revenue, net of current portion	 60,784,291		1,409,483	
Other long-term liabilities	42,862		46,667	
Total Liabilities	96,622,913		9,836,304	
Total stockholders' equity	 9,333,860		25,226,527	

## PIERIS PHARMACEUTICALS, INC CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

Three months ended June								
		30,			Six months ended June 30,			
		2017		2016		2017		2016
Revenues	\$	1,852,858	\$	1,072,862	\$	3,196,158	\$	2,319,506
<i>Operating expenses</i> Research and								
development General and		5,395,724		4,500,097		10,755,680		8,159,532
administrative		4,348,579		2,368,217		8,337,459		4,336,100
Total operating expenses		9,744,303		6,868,314		19,093,139		12,495,632
Loss from operations		(7,891,445)		(5,795,452)		(15,896,981)		(10,176,126)
Interest income								
(expense), net		67		-		167		-
Other income (expense),								
net		(1,379,779)		(87,801)	_	(1,368,077)		131,819
Loss before income taxes		(9,271,157)		(5,883,253)		(17,264,891)		(10,044,307)
Income tax expenses		813,710				813,710		-
Net loss	\$	(10,084,867)	\$	(5,883,253)	\$	<u>(18,078,601</u> )	\$	(10,044,307)
Basic and diluted net loss per share	\$	(0.23)	\$	(0.14)	\$	(0.42)	\$	(0.25)
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Basic and diluted weighted average shares outstanding		43,407,712		40,862,608		43,236,701		40,347,816
outstanding		70, <del>4</del> 07,71Z		-0,002,000	_	,	_	,

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Source: Pieris Pharmaceuticals, Inc.