

May 10, 2017



# Pieris Pharmaceuticals Reports Financial Results for the First Quarter Ended March 31, 2017 and Provides Corporate Update

## Company to Host an Investor Conference Call Tomorrow at 10:00 AM EDT

BOSTON, MA -- (Marketwired) -- 05/10/17 -- Pieris Pharmaceuticals, Inc.(NASDAQ: PIRS), a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary [Anticalin](#)® technology platform for cancer, respiratory and other diseases, today reported financial results for the first quarter of 2017 and provided an update on the Company's recent developments, including:

- Secured global and transformative alliances in our two core therapeutic areas of immuno-oncology and respiratory diseases with Servier and AstraZeneca
- Advanced Pieris' clinical and preclinical programs, with Phase 1 trial initiation of Pieris' lead immuno-oncology asset, PRS-343, anticipated in the first half of this year and Phase 1 trial initiation of Pieris' lead respiratory asset, PRS-060, anticipated in the second half of this year
- Secured a regional partnership for Pieris' hepcidin antagonist, PRS-080, in Japan and other Asian territories as Pieris seeks to carefully divest the asset while it focuses on its key therapeutic areas

During the first quarter of 2017, Pieris announced two significant partnerships. In January, the Company announced a global, multi-target, multi-year alliance in immuno-oncology with Servier to jointly pursue up to eight bispecific therapeutic programs, including Pieris' proprietary dual checkpoint inhibitor, PRS-332. Under the terms of the alliance, Pieris received an upfront payment of EUR30.0 million (approximately \$32.3 million), and stands to receive, collectively, up to EUR1.7 billion (approximately \$1.8 billion) in success-based milestone payments and up to double-digit royalties from potential sales. Pieris and Servier will jointly develop PRS-332, with Pieris retaining all commercial rights in the United States and Servier having commercial rights in the rest of the world. Pieris has the option, at a predefined time point, to co-develop and retain commercial rights in the United States for up to three programs beyond PRS-332.

In February, Pieris announced that it had granted ASKA Pharmaceutical Co. an exclusive option to license development and commercial rights in Japan for its most advanced drug

candidate, PRS-080, to treat anemia in dialysis-dependent patients. Under the terms of the agreement, Pieris received an option payment of \$2.75 million, and should ASKA exercise its option to develop and commercialize PRS-080 following positive results from the forthcoming Phase 2a study, Pieris would be eligible for more than \$80 million in combined option exercise fee and milestone payments stemming from successful commercialization of PRS-080 in the first indication in Japan. Pieris may receive further development milestones for additional indications, as well as in other countries within the ASKA territory, and may receive double-digit royalties on net sales of PRS-080 up to the mid- to high-teens.

Following the close of the first quarter, the Company also announced a global strategic co-development and co-commercialization respiratory-focused alliance including PRS-060 with AstraZeneca. Details of this alliance are summarized below, and were also previously disclosed in a May 3, 2017 press release.

During the first quarter, the Company made substantial advances across its key pipeline programs, covering all of its lead therapeutic areas:

#### Immuno-oncology:

Pieris' lead program, PRS-343, is a bispecific fusion protein made up of a monoclonal antibody that targets a clinically-validated protein on certain tumor cell surfaces called HER-2, fused with an Anticalin protein targeting the T cell co-stimulatory receptor CD137, better known as 4-1BB. During the quarter, Pieris advanced PRS-343 through IND-enabling studies, and it remains on track to enter a Phase I multi-ascending dose study involving HER2-positive solid tumors representing unmet medical needs (such as breast, gastrointestinal and bladder cancers) in the first half of 2017. Pieris owns worldwide commercial rights for PRS-343.

In April, at the Annual Meeting of the American Association for Cancer Research (AACR), Pieris presented additional preclinical data for PRS-343 that further validated the understanding of its differentiated mechanism of action and helped to inform a first-in-patient trial expected to start in the first half of 2017. Notably, PRS-343 was well tolerated in IND-enabling toxicology studies. In preclinical models, PRS-343 elicited robust T cell activation when engaging HER2 on trastuzumab-resistant cancer cells.

#### Respiratory:

Pieris' lead respiratory program, PRS-060, is an Anticalin differentiated from standard of care and emerging standard of care on several important levels, including by its inhaled mode of delivery and its mode of action involving inhibition of the inflammatory effects of the key cytokine proteins (IL-4 and IL-13) that activate a clinically-validated receptor on the surface of respiratory cells, called IL-4 receptor alpha. PRS-060 represents a potential first-in-class inhaled treatment for uncontrolled asthma that is based on IL-4 receptor alpha blockade. Pieris believes PRS-060 targets a very large potential commercial opportunity of approximately 20 million patients globally. PRS-060 currently is in IND-enabling studies and is set to enter a first-in-man clinical trial later this year.

Following the conclusion of the first quarter, on May 3, Pieris announced a global strategic alliance with AstraZeneca for PRS-060 and several additional programs for respiratory diseases. Under the terms of this agreement, Pieris will receive \$57.5 million in upfront and near-term milestone payments, and up to approximately \$2.1 billion in total success-based payments across up to five programs, including PRS-060, as well as royalties from future sales. Pieris is responsible for advancing its lead respiratory program, PRS-060, which will be funded by AstraZeneca. Following the first proof-of-concept Phase 2a trial in asthma patients, Pieris may then exercise an option to co-develop and, separately, to co-commercialize this program in the United States, and doing so would afford Pieris the ability to receive increased royalties, up to the high teens, or a gross margin share of future sales, dependent on the level of Pieris' co-development investment. The alliance additionally includes four undisclosed novel programs. Pieris has an option to co-develop up to two of these programs, and would also have the option to co-commercialize these programs in the United States. AstraZeneca will be responsible for development and worldwide commercialization of any programs for which Pieris does not exercise its option to co-develop and co-commercialize, and under this condition, Pieris would be eligible to receive royalties from future sales.

#### Anemia:

Pieris' most advanced program, PRS-080, is a highly potent inhibitor of hepcidin, a key negative regulator of iron metabolism and is being developed to treat functional iron deficient (FID) anemia. In the first quarter of 2017, Pieris completed dosing in a Phase 1b study in chronic kidney disease patients on hemodialysis and will present these data at the European Renal Association & European Dialysis and Transplant Association (ERA-EDTA) Congress in Madrid, Spain, in June 2017. Pieris will next initiate a multi-dose, Phase 2a study in dialysis-dependent patients exhibiting FID anemia. Completion of this trial would trigger a review period for ASKA to exercise its option under the parties' February 2017 agreement.

"During the first quarter of 2017 and the early part of the second quarter, we have built dramatically on the foundational work that was put into place last year. We have secured two global and transformative alliances in our two core therapeutic areas of immuno-oncology and respiratory diseases, and an important regional alliance for our anemia program, PRS-080, as we seek to divest that asset in a careful manner while we focus our organization on high-value therapies within immunology. Our partnerships with global leaders like AstraZeneca and Servier, and regional partners like ASKA, have generated approximately \$80 million in cash flow in 2017, while our combined partnerships could result in more than \$4.5 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. With our current balance sheet, we have the financial resources to invest more robustly into our proprietary pipeline, while extending our financial runway through a series of critical value inflection points," said Stephen Yoder, President and CEO of Pieris. "We also advanced our clinical and preclinical programs, and remain on track to take our wholly-owned lead IO asset, PRS-343, into a Phase 1 trial during the current quarter, while planning to advance our now-partnered lead respiratory asset, PRS-060, into first in human trials in the second half of this year in collaboration with AstraZeneca, in addition to making steady progress across all of our additional partnerships. Based on not only the corporate

milestones achieved to date, but also the additional corporate milestones we intend to achieve later this year, we continue to believe that 2017 can be the most value-creating year in the history of our company."

### ***First Quarter Financial Update:***

***Cash Position*** -- Cash and cash equivalents totalled \$55.2 million as of March 31, 2017, compared to \$29.4 million as of December 31, 2016. This increase in cash was driven primarily by the upfront payment received from Servier and the option payment received from Aska, offset principally by \$8.8 million operating expenditures during the quarter.

***R&D Expense*** -- Research and development expenses were \$5.4 million for the quarter ended March 31, 2017, compared to \$3.7 million for the quarter ended March 31, 2016. The \$1.7 million increase was primarily attributable to a \$0.9 million increase in pre-clinical development, CMC, and clinical costs for PRS-343 as we carry out IND-enabling studies and a \$0.5 million net increase in CMC and other costs associated with PRS-060 as we continue IND-enabling studies.

***G&A Expense*** -- General and administrative expenses for the quarter ended March 31, 2017 were \$4.0 million, compared to \$2.0 million for the quarter ended March 31, 2016. The \$2.0 million increase in G&A expenses was primarily due to \$0.8 million in higher personnel related costs, including stock compensation, \$0.9 million increase for professional fees principally on account of success-based fees, and \$0.3 million increase in for administrative travel, recruiting, and other administrative costs.

***Net Loss*** -- Net loss was \$8.0 million or (\$0.19) per share for the quarter ended March 31, 2017, compared to a net loss \$4.2 million or (\$0.10) per share for the quarter ended March 31, 2016.

### ***Conference Call***

Pieris management will host a conference call beginning at 10:00 AM Eastern Daylight Time on Thursday, May 11, 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 1-412-902-1010 (International) at least 10 minutes prior to the start of the call. An archived replay of the call will be available by dialling 877-660-6853 (US & Canada) or 1-201-612-7415 (International) and providing the Conference ID #: 13652361.

### ***About Pieris***

Pieris is a clinical-stage biotechnology company that discovers and develops Anticalin® protein-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immuno-oncology multi-specifics tailored for the tumor 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](http://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, 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; 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](http://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.

(tables to follow)

PIERIS PHARMACEUTICALS, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS

	<i><b>March 31,</b></i>	<i><b>December 31,</b></i>
	<i><b>2017</b></i>	<i><b>2016</b></i>
	<u>                    </u>	<u>                    </u>
<b>Assets:</b>		
Cash and cash equivalents	\$ 55,241,957	\$ 29,355,528
Accounts receivable	39,013	57,582
Prepaid expenses and other current assets	3,475,013	3,259,503
	<u>58,755,983</u>	<u>32,672,613</u>
Total current assets		
Property and equipment, net	2,993,005	2,264,477
Other noncurrent assets	126,193	125,741
	<u>                    </u>	<u>                    </u>
<b>Total Assets</b>	<u><u>\$ 61,875,181</u></u>	<u><u>\$ 35,062,831</u></u>
 <b>Liabilities and stockholders' equity:</b>		
Accounts payable	\$ 3,317,122	\$ 2,386,183
Accrued expenses	2,958,877	3,719,457
Deferred revenue, current portion	5,168,614	2,274,514
	<u>                    </u>	<u>                    </u>

Total current liabilities	11,444,614	8,380,154
Deferred revenue, net of current portion	32,352,662	1,409,483
Other long-term liabilities	42,086	46,667
<b>Total Liabilities</b>	43,839,361	9,836,304
Total stockholders' equity	18,035,820	25,226,527
<b>Total liabilities and stockholders' equity</b>	<u>\$ 61,875,181</u>	<u>\$ 35,062,831</u>

PIERIS PHARMACEUTICALS, INC  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

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Source: Pieris Pharmaceuticals, Inc.