

Pieris Pharmaceuticals Reports Full-Year 2016 Financial Results and Corporate Update

Company to Host an Investor Conference Call on Thursday, March 23, 2017 at 10:00 AM EDT

BOSTON, MA -- (Marketwired) -- 03/22/17 -- Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS), a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform for cancer and other diseases, today reported financial results for the fourth quarter and fiscal year of 2016 and provided an update on the Company's recent developments.

"2016 was a highly productive year for Pieris marked by: i) broad advancement of our proprietary clinical and preclinical programs, ii) completion of a \$16.5 million private placement financing that strengthened our shareholder base, iii) achievement of several milestones in our collaborative programs, and iv) expansion of our Board of Directors and the appointment of a Chief Business Officer. At several R&D conferences throughout the year, including in the fourth quarter at the annual meeting of the Society of Immunotherapy of Cancer (SITC), we presented preclinical data demonstrating a differentiated mode of action for PRS-343, our lead 4-1BB (CD137)-based HER-2 bispecific immuno-oncology program, which remains on track for Phase I initiation in the first half of this year," said Stephen Yoder, President and CEO. "Our targeted, inhaled asthma program, PRS-060, which engages the IL4a receptor, is differentiated from systemically administered therapies, and is on track to enter a Phase I study in mid-2017. Pieris has also completed dosing of all patients in a Phase Ib single ascending dose study of our most advanced program, PRS-080, in dialysis-dependent chronic kidney disease patients and expects to present this data in the first half of this year."

"With these accomplishments behind us, we started 2017 on a very strong note, as we have already consummated a multi-target, multi-year, transformative partnership in the immuno-oncology space with Servier, the second largest pharmaceutical company in France. This alliance includes our dual checkpoint inhibitor, PRS-332, as well as four additional bispecific programs and may be expanded to eight total programs. Notably, Pieris has the option to codevelop and retain full US rights for four of these programs, including PRS-332, and is eligible to receive up to approximately \$1.8 billion in total potential milestones, and up to low double-digit royalties on potential future product sales, in addition to having received an upfront payment of approximately \$31.0 million. We also recently announced a regional partnership in Japan with Aska Pharmaceutical Co., Ltd. for PRS-080, which will allow us to

invest in manufacturing efficiencies and drug supply for additional clinical studies beyond our planned Phase IIa study, which we believe could help set the stage for additional potential partnerships outside of Japan, following the completion of that study. Finally, we continue to advance our preclinical portfolio of novel multispecific therapeutic proteins, as well as our existing partnerships, while continuing to explore additional collaborations. We ended the fourth quarter in a solid financial position and, considering the upfront payments we have received in the first quarter of 2017, we believe we can manage our financial runway into 2019, enabling us to reach several key value inflection points along the way."

Fourth Quarter and 2016 Highlights:

- Advanced PRS-080 through an ongoing Phase Ib single ascending dose study in anemia of chronic disease, having completed patient dosing in early 2017, which will assess the effect of PRS-080 on iron mobilization and transferring saturation in dialysis-dependent anemia patients.
- Advanced PRS-343 through IND-enabling studies and towards a first-in-patient study for HER-2 positive cancers.
- Advanced PRS-060, a novel inhaled therapeutic for moderate to severe asthma, through IND-enabling studies.
- Advanced our novel multi-checkpoint blockade bispecific, PRS-332, comprised of an anti-PD-1 antibody genetically linked to an existing Anticalin against an undisclosed checkpoint, through preclinical studies.
- Strengthened our Board of Directors with the addition of Julian Adams, Ph.D. and Christopher Kiritsy.
 - o Dr. Adams is the former President of Research & Development at Infinity Pharmaceuticals. During his career, Dr. Adams has had global responsibility for multiple drug discovery programs, including the discovery and development of Velcade® (bortezomib), a proteasome inhibitor for cancer therapy, and Viramune® (nevirapine) for HIV. Dr. Adams has received many awards, including the 2012 Warren Alpert Foundation Prize for his role in the discovery and development of bortezomib, the 2012 C. Chester Stock Award Lectureship from Memorial Sloan-Kettering Cancer Center, and the 2001 Ribbon of Hope Award for Velcade® from the International Myeloma Foundation.
 - Mr. Kiritsy is the Chief Executive Officer and co-founder of Arisaph Pharmaceuticals. Prior to Arisaph, Mr. Kiritsy served as Executive Vice President, Corporate Development and Chief Financial Officer of Kos Pharmaceuticals, Inc., where he played a key operating role in building the company from start-up to a highly profitable, publicly traded, commercial company.
- Appointed Claude Knopf as Senior Vice President and Chief Business Officer. Prior to joining Pieris, Mr. Knopf served as Global Head Business Development & Licensing/Mergers and Acquisitions at Baxalta. Prior to joining Baxalta, a spin-off of Baxter where he held a similar position for the Baxter Bioscience Division up to the creation of Baxalta. Prior to joining Baxter, Mr. Knopf held several business development, alliance management, and licensing and marketing roles at Novartis, most recently as the Head of Business Development and Licensing, Strategic Planning, Vaccines European Region.

Fiscal Year Financial Update:

<u>Cash Position</u> - Cash and cash equivalents totalled \$29.4 million as of December 31, 2016, compared to \$29.3 million as of December 31, 2015. The increase in cash was driven primarily by the \$16.5 million gross private placement financing completed in June 2016 offset by cash used in our operating activities.

R&D Expense - Research and development expenses were \$19.7 million for the year ended December 31, 2016, compared to \$8.2 million for the year ended December 31, 2015. The \$11.5 million increase was primarily due to a \$5.6 million increase in pre-clinical development and CMC costs for PRS-343 as we carry out IND enabling studies and increased development costs for our other PRS-300 series programs, and a \$1.2 million increase in CMC costs associated with PRS-060 as we carry out IND enabling studies, offset by a \$0.2 million decrease for our PRS-080 program due to the completion of our Phase Ia clinical trial in 2015. Other R&D expenses also increased by \$4.9 million primarily due to higher personnel-related expenses including stock-based compensation expense and increased costs for license fees, as well as higher legal and consulting costs. Additionally, costs for general lab supplies increased due to an upturn in program activities.

<u>G&A Expense</u> - General and administrative expenses for the year ended December 31, 2016 were \$8.9 million, compared to \$8.4 million for the year ended December 31, 2015. The \$0.5 million increase in G&A expenses is primarily due to an increase in personnel-related costs, including stock-based compensation expense, higher legal and recruiting costs, and costs associated with being a public company such as financial printing costs and transaction fees.

<u>Net Loss</u> - Net loss was \$22.8 million or (\$0.55) per share for the year ended December 31, 2016, compared to a net loss \$14.1 million or (\$0.41) per share for the year ended December 31, 2015.

Upcoming Milestones:

The Company expects to reach the following milestones during 2017:

- PRS-080: Present Phase Ib data and initiate a multi-dose, Phase IIa study in dialysisdependent anemia patients during the second quarter, which we estimate will be completed by the end of 2017.
- PRS-343: Initiate a Phase I multi-ascending dose study involving a range of HER2positive solid cancers representing unmet medical needs (such as breast, gastrointestinal and bladder cancers) in the first half of 2017.
- PRS-332: Progress preclinical evaluation in collaboration with Servier, with INDenabling activities planned for later in 2017.
- PRS-060: Initiate a Phase I study in mid-2017.

Upcoming Scientific Presentations:

 PRS-343: IND-enabling data informing the design of a first-in-patient clinical trial for PRS-343 will be presented in a poster session at next month's Annual Meeting of the American Association for Cancer Research (AACR) to be held in Washington D.C. The poster will be presented on Tuesday, April 4, 2017 in a session from 8am to 12pm EDT.

Conference Call:

Pieris management will host a conference call beginning at 10:00 AM Eastern Daylight Time on Thursday, March 23, 2017, to discuss the full year financial results and provide a corporate update. You can join the call by dialing +1-877-407-8920 (US & Canada) or +1-412-902-1010 (International). An archived replay of the call will be available by dialling +1-877-660-6853 (US & Canada) or +1-201-612-7415 (International) and providing the Conference ID #: 13657695.

About Pieris Pharmaceuticals:

Pieris is a clinical stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immuno-oncology multi-specifics tailored for the tumor micro-environment, an inhaled Anticalin to treat uncontrolled asthma and a half-life-optimized Anticalin to treat anemia. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin® is a registered trademark of Pieris. Pieris has partnerships with Servier, ASKA, Roche, Sanofi, Daiichi Sankyo and Zydus. 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, the Company's ability to manage its financial runway into 2019 and to reach certain inflection points; references to novel technologies and methods; existing and potential additional collaborations; our business and product development plans; and the timing, progress and results of our development activities, preclinical studies and clinical trials. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, 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; the progress of our existing collaborations and our ability to develop additional collaborations; our ability to raise the additional funding we will need to continue to pursue our business and product development plans. These forward-looking statements are made as of the date of this press release, and we assume no obligation to update the forwardlooking 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, 2015 and the Company's Quarterly Reports on Form 10-Q.

(tables to follow)

PIERIS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2016		December 31, 2015	
Assets:				
Cash and cash equivalents Accounts receivable	\$	29,355,528 57,582	\$	29,349,124
Prepaid expenses and other current assets		3,259,503		2,311,385
Total current assets		32,672,613		31,660,509
Property and equipment, net		2,264,477		2,162,771
Other noncurrent assets		125,741		126,781
Total Assets	\$	35,062,831	\$	33,950,061
Liabilities and stockholders' equity:				
Accounts payable	\$	2,386,183		1,058,536
Accrued expenses		3,719,457		1,739,380
Deferred revenue, current portion		2,274,514		<u>-</u>
Total current liabilities		8,380,154		2,797,916
Deferred revenue, net of current portion		1,409,483		-
Other long-term liabilities		46,667		23,852
Total Liabilities		9,836,304		2,821,768
Total stockholders' equity		25,226,527		31,128,293
Total liabilities and stockholders' equity	\$	35,062,831	\$	33,950,061

PIERIS PHARMACEUTICALS, INC CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended 2016		December 31, 2015	
Revenues	\$	5,830,674	\$ 2,931,931	
Operating expenses Research and development				
General and administrative		(19,698,803) (8,890,886)	(8,244,751) (8,368,215)	

Total operating expenses	(28,589,689)	(16,612,966)
Loss from operations	(22,759,015)	(13,681,035)
Interest income (expense), net Other income (expense), net	2,320 119,501	(184,645) 10,905
Loss before income taxes Provision for income tax	 (22,637,194) 161,970	(13,854,775) 203,866
Net loss	\$ (22,799,164)	(14,058,641)
Basic and diluted net loss per share	\$ (0.55) \$	(0.41)
Basic and diluted weighted average shares outstanding	41.713.223	34.392.636

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