

# Pieris Pharmaceuticals Reports Third Quarter 2022 Financial Results and Provides Corporate Update

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON WEDNESDAY, NOVEMBER 2, 2022 AT 8:00 AM EDT

- Elarekibep (PRS-060/AZD1402) phase 2a study for asthma enrollment continues
- First subject dosed in PRS-220 phase 1 study for idiopathic pulmonary fibrosis (IPF)
- PRS-344/S095012 phase 1 study for solid tumors in collaboration with Servier continues
- IND accepted for SGN-BB228 (also known as PRS-346) phase 1 immunooncology study; preclinical data to be presented at SITC 2022
- PRS-342/BOS-342 phase 1 for solid tumors expected to begin in the next six months
- PRS-400 preclinical data for muco-obstructive diseases presented at ERS

BOSTON, MA / ACCESSWIRE / November 2, 2022 / Pieris Pharmaceuticals, Inc. (NASDAQ:PIRS), a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin<sup>®</sup> technology platform for respiratory diseases, cancer, and other indications, reported financial results for the third quarter of 2022 ended September 30, 2022, and provided an update on the Company's recent and anticipated future developments.

"Today's update highlights the value of our partnerships, which are validating our science, advancing and replenishing our clinical-stage pipeline, and satisfying a significant amount of our funding needs. AstraZeneca continues to advance our lead inhaled respiratory asset, elarekibep, while we continue to advance our lead IO bispecific program, PRS-344/S095012, in co-development with Servier. Furthermore, we are excited that Seagen and Boston Pharmaceuticals will soon initiate clinical development for their respective IO bispecifics programs, SGN-BB228 and PRS-342/BOS-342, which use Pieris' platform technology. This clinical progress follows the recent phase 1 initiation of our fully proprietary inhaled respiratory program, PRS-220," said Stephen S. Yoder, President and CEO of Pieris. "We will continue to make disciplined pipeline investments that demonstrate our commitment to achieve inflection points in the next year within our partnered and proprietary programs."

• Elarekibep and AstraZeneca Collaboration: AstraZeneca has completed enrollment

of part 1b (safety of 10 mg cohort) and continues to enroll part 2 (efficacy of 3 mg cohort) of the multi-center, placebo-controlled phase 2a study of dry powder inhaler-formulated elarekibep (PRS-060/AZD1402), an IL-4 receptor alpha inhibitor Pieris is developing with AstraZeneca for the treatment of moderate-to-severe asthma. AstraZeneca has completed all submissions of the previously announced protocol amendments to improve enrollment. Topline results, which will include FEV1 improvement of the 3 mg cohort versus placebo, are expected to be reported by the third quarter of 2023. Upon delivery of these results, Pieris may choose to exercise its co-development option. Separately, Pieris will have a future option to co-commercialize elarekibep in the United States. Beyond elarekibep, Pieris continues to work on two discovery-stage programs with AstraZeneca, for which the research term was recently extended. Pieris retains co-development and U.S. co-commercialization options for these two programs.

- PRS-344/S095012 and Servier Collaboration: Pieris and Servier continue to enroll
  the escalation portion of the phase 1/2 study of PRS-344/S095012, a 4-1BB/PD-L1
  bispecific Mabcalin<sup>TM</sup> (antibody-Anticalin fusion) compound for the treatment of solid
  tumors, for which Pieris holds full U.S. rights and will receive royalties on ex-U.S. sales
  by Servier. The companies expect to present data from the study at a medical meeting
  in 2023. Additionally, Servier is continuing development of PRS-352/S095025, an
  OX40/PD-L1 bispecific Mabcalin compound.
- PRS-220: Pieris has dosed the first subject in the phase 1 study in healthy volunteers
  of PRS-220, a proprietary inhaled Anticalin protein targeting connective tissue growth
  factor (CTGF) for the treatment of IPF and other forms of fibrotic lung disease. The
  Company expects to report the outcome from the study in 2023. PRS-220 continues to
  benefit from a meaningful grant from the Bavarian government, which supports earlystage clinical development of this program.
- Seagen Collaboration: The investigational new drug (IND) application for the phase 1 study of SGN-BB228 (also known as PRS-346), a first-in-class 4-1BB/CD228 bispecific Mabcalin compound, has been accepted. Seagen plans to initiate a phase 1 study for SGN-BB228 in the coming months, for which Pieris will receive a milestone payment. Seagen will also present preclinical data for the program at a poster session during the Society for Immunotherapy of Cancer 37<sup>th</sup> Annual Meeting. Seagen continues to develop a second undisclosed bispecific program under the companies' immuno-oncology collaboration. Pieris has a multi-asset collaboration with Seagen and has an opt-in option to a U.S. co-promotion for one program in the collaboration.
- PRS-342/BOS-342: Boston Pharmaceuticals continues to advance PRS-342/BOS-342, a 4-1BB/GPC3 bispecific Mabcalin compound, towards the clinic, with phase 1 expected to begin in the next six months.
- PRS-400: Pieris unveiled and presented preclinical data for PRS-400, an inhaled Jagged-1 Anticalin protein the Company is developing for the treatment of mucoobstructive lung diseases, at the European Respiratory Society (ERS) International Congress 2022.

# Second Quarter Financial Update:

<u>Cash Position</u> - Cash, cash equivalents, and investments totaled \$69.8 million for the quarter ended September 30, 2022, compared to a cash and cash equivalents balance of \$117.8 million for the year ended December 31, 2021. The decrease is due to funding operations in 2022. Including the proceeds from anticipated near-term milestones, the

Company believes operations are sufficiently funded into the second quarter of 2024.

**R&D Expense** - R&D expenses were \$13.6 million for the quarter ended September 30, 2022, compared to \$18.9 million for the quarter ended September 30, 2021. The decrease is due to lower program costs, as work related to the Company's sponsored phase 1 trial of elarekibep was largely complete in 2021, as well as due to lower manufacturing costs across all later-stage respiratory and immuno-oncology programs, and lower consulting costs. These lower costs were partially offset by higher clinical costs for PRS-344/S095012, higher pre-clinical costs for earlier stage programs, and an increase in personnel costs.

**G&A Expense** - G&A expenses were \$3.9 million for the quarter ended September 30, 2022, compared to \$4.1 million for the quarter ended September 30, 2021. The period-over-period decrease was driven primarily by lower personnel and legal costs, partially offset by higher professional services and travel costs.

<u>Other Income</u> - For the quarter ended September 30, 2022, \$1.5 million of grant income was recorded with respect to PRS-220, compared to \$1.8 million for the quarter ended September 30, 2021. The decrease is due to lower overall costs incurred this quarter on PRS-220.

**Net Loss** - Net loss was \$9.7 million or \$(0.13) per share for the quarter ended September 30, 2022, compared to a net loss of \$16.5 million or \$(0.24) per share for the quarter ended September 30, 2021.

### Conference Call:

Pieris management will host a conference call beginning at 8:00 AM EDT on Wednesday, November 2, 2022, to discuss the third quarter financial results and provide a corporate update. Individuals can join the call by dialing (888) 645-4404 (Toll Free US & Canada) or (862) 298-0702 (International). Alternatively, a listen-only audio webcast of the call can be accessed here.

For those unable to participate in the conference call or listen to the webcast, a replay will be available on the Investors section of the Company's website, <a href="https://www.pieris.com">www.pieris.com</a>.

#### About Pieris Pharmaceuticals:

Pieris is a clinical-stage biotechnology company that combines leading protein engineering capabilities and deep understanding into molecular drivers of disease to develop medicines that drive local biology to produce superior clinical outcomes for patients. Our pipeline includes inhalable Anticalin proteins to treat respiratory diseases and locally-activated bispecifics for immuno-oncology. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by respiratory and immuno-oncology focused partnerships with leading pharmaceutical companies. For more information, visit <a href="https://www.pieris.com">www.pieris.com</a>.

## Forward-looking Statements:

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements in this press release that are not purely historical are

forward-looking statements. Such forward-looking statements include, among other things, our expected cash runway; the potential for Pieris' development programs such as elarekibep, PRS-344/S095012, PRS-220, PRS-400, PRS-352/S095025, PRS-346/SGN-BB228 and PRS-342/BOS-342 to address our core focus areas such as respiratory diseases and immuno-oncology; the advancement of our proprietary and co-development programs into and through the clinic and the expected timing for reporting data; the receipt of royalty and/or milestone payments provided for in our collaboration agreements; making IND filings or achieving other milestones related to our programs, including elarekibep, PRS-220, PRS-400, PRS-344/S095012, PRS-352/S095025, PRS-346/SGN-BB228 and PRS-342/BOS-342; the therapeutic potential of our Anticalin platform; our continued progress in the areas of costim bispecifics and inhaled therapeutics; and the advancement and funding of our developmental programs generally. Actual results could differ from those projected in any forward-looking statement due to numerous factors. Such factors include, among others, the amounts of anticipated funding actually received for our continued development programs and our actual reductions in spending as compared to anticipated cost reductions; 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; competition in the industry in which we operate; delays or disruptions due to COVID-19 or geopolitical issues, including the conflict in Ukraine; 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 Securities and Exchange Commission available at www.sec.gov, including, without limitation, the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and the Company's Quarterly Reports on Form 10-Q.

## **Investor Relations Contact:**

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PIERIS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited, in thousands)

September 30,	December 31,
2022	2021

Assets:

	\$ 48,423	\$ 117,764
Cash and cash equivalents		
Short term investments	21,400	-
Accounts receivable	829	3,313
Prepaid expenses and other current assets	7,908	6,548
Total current assets	78,560	127,625
Property and equipment, net	15,897	19,122
Operating lease right-of-use assets 3,3		3,909
Other non-current assets	1,307	2,904
Total Assets	\$ 99,163	\$ 153,560
Liabilities and stockholders' equity:		
Accounts payable	\$ 3,641	\$ 8,609
Accrued expenses	11,382	16,836
Deferred revenue, current portion	18,498	25,116
Total current liabilities	33,521	50,561
Deferred revenue, net of current portion	18,484	38,403
Operating lease liabilities	11,391	13,841
Total Liabilities	63,396	102,805

Total stockholders' equity	35,767	50,755
Total liabilities and stockholders' equity	\$ 99,163	\$ 153,560

PIERIS PHARMACEUTICALS, INC CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited, in thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Revenues	\$ 5,370	\$ 4,057	\$ 20,056	\$ 22,975
Operating expenses				
Research and development	13,589	18,937	39,602	51,299
General and administrative	3,949	4,132	12,409	12,508
Total operating expenses	17,538	23,069	52,011	63,807
Loss from operations	(12,168)	(19,012)	(31,955)	(40,832)
Interest income	241	4	370	10
Grant income	1,468	1,794	4,782	2,590
Other income (expense), net	723	678	1,628	2,026
Net loss	\$ (9,736)	\$ (16,536)	\$ (25,175)	\$ (36,206)
Basic and diluted net loss per share	\$ (0.13)	\$ (0.24)	\$ (0.34)	\$ (0.58)

Basic and diluted weighted average shares outstanding

74,397 67,730 74,080 62,019

**SOURCE:** Pieris Pharmaceuticals, Inc.

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