August 4, 2022

Pieris Pharmaceuticals Reports Second Quarter 2022 Financial Results and Provides Corporate Update

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON THURSDAY, AUGUST 4, 2022 AT 8:00 AM EDT

- ***Adjustments to PRS-060/AZD1402 phase 2 study design boost enrollment rate and facilitate a topline readout by 3Q23***
- ***Cinrebafusp alfa (PRS-343) demonstrating clinical benefit in HER2-expressing gastric cancer patients, but Company will cease enrollment to focus its resources***
- ***First-in-human regulatory submission for PRS-220 achieved, with first subject dosing planned following regulatory clearance***
- ***Escalation of PRS-344/S095012 in collaboration with Servier continues***
- ***AstraZeneca extends research collaboration, focusing on two discovery-stage programs with Pieris retaining co-development and U.S. co-commercialization options on both programs***
- ***Strategic pipeline prioritization results in cash reach to the second quarter of 2024***

BOSTON, MA / ACCESSWIRE / August 4, 2022 / ***Pieris Pharmaceuticals, Inc. (NASDAQ:PIRS)***, a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform for respiratory diseases, cancer, and other indications, reported financial results for the second quarter of 2022 ended June 30, 2022, and provided an update on the Company's recent and anticipated future developments.

"AstraZeneca's deep support of PRS-060/AZD1402 and the Anticalin platform continues and has resulted in thoughtful adjustments to the PRS-060/AZD1402 phase 2a study design, allowing us to enroll patients amidst the challenges presented by COVID-19 precautions, as well as an extension of our research collaboration for two earlier-stage programs," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "Since the PRS-060/AZD1402 phase 2 study will take more time to enroll than originally planned, we have made the difficult but necessary decision to discontinue cinrebafusp alfa (PRS-343), despite showing clear single-agent activity in phase 1 and meaningful clinical benefit in the ongoing phase 2 study in HER2-expressing gastric cancer patients. We will continue the cost-effective development of PRS-344/S095012, our 4-1BB/PD-L1 bispecific co-developed with Servier, and PRS-220, our fully proprietary inhaled CTGF antagonist that has the generous

grant support from the Bavarian government, through key clinical readouts over the next twelve months. With a more focused pipeline and co-funding mechanisms in place for our most advanced assets, we are better positioned to deliver on our overall pipeline objectives in 2023, retain a leadership position in both inhaled respiratory medicines and 4-1BB biology, and now project that our cash runway extends into the second quarter of 2024."

- **PRS-060/AZD1402 and AstraZeneca Collaboration:** AstraZeneca continues to enroll part 2a (efficacy of 1 mg and 3 mg cohorts) and part 1b (safety of 10 mg cohort) of the multi-center, placebo-controlled phase 2a study of dry powder inhaler-formulated PRS-060/AZD1402, an IL-4 receptor alpha inhibitor Pieris is developing with AstraZeneca for the treatment of moderate-to-severe asthma. AstraZeneca conducted a reforecast of the study, which has taken into account the global challenges of recruiting for respiratory clinical trials caused by the continued impact of the COVID-19 pandemic, is broadening enrollment criteria to facilitate recruitment of the study, and plans to focus on the 3 mg cohort for the efficacy readout. Topline results are now 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 PRS-060/AZD1402 in the United States. Beyond PRS-060/AZD1402, 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.
- **Cinrebafusp Alfa (PRS-343):** Cinrebafusp alfa, a 4-1BB/HER2 Anticalin-based bispecific, has demonstrated clinical benefit in phase 1 studies, including single-agent activity in a monotherapy setting, and in the phase 2 study in HER2-expressing gastric cancer, giving the Company confidence in its broader 4-1BB franchise. However, Pieris will cease further enrollment in the ongoing two-arm, multicenter, open-label phase 2 study as part of a strategic pipeline prioritization to focus its resources.
- **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 Anticalin-based bispecific 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 initiate expansion cohorts in jointly-vetted indications next year. Additionally, Servier is continuing development of PRS-352/S095025, an OX40/PD-L1 bispecific.
- **PRS-220:** Pieris has submitted the first regulatory filing for PRS-220, a proprietary inhaled Anticalin protein targeting connective tissue growth factor for the treatment of idiopathic pulmonary fibrosis. The Company expects to dose the first healthy volunteer in a phase 1 study later this year and to report the outcome from the study next year.
- **PRS-342/BOS-342:** Boston Pharmaceuticals continues to advance PRS-342/BOS-342, a 4-1BB/GPC3 bispecific, towards the clinic, with phase 1 expected to begin in the first half of 2023.
- **Seagen Collaboration:** Seagen continues development of two undisclosed bispecific programs as part of its immuno-oncology collaboration with the Company. Pieris has a U.S. co-promotion option for one program in the collaboration.

Second Quarter Financial Update:

Cash Position - Cash, cash equivalents, and investments totaled $80.9 million for the quarter ended June 30, 2022, compared to a cash and cash equivalents balance of $117.8 million for the quarter ended December 31, 2021. The decrease is due to funding operations

in the first half of 2022. With the wind down of the cinrebafusp alfa phase 2 trials, along with the expectation of modest near-term development milestones, the Company believes operations are sufficiently funded into the second quarter of 2024.

R&D Expense - R&D expenses were $11.9 million for the quarter ended June 30, 2022, compared to $15.8 million for the quarter ended June 30, 2021. The decrease is due to lower program costs, as work related to the Company's sponsored phase 1 trial of PRS-060/AZD1402 was largely complete in 2021, as well as due to lower manufacturing costs across all later-stage respiratory and immuno-oncology programs, lower collaboration license fees, and lower consulting costs. These lower costs were partially offset by higher clinical costs for PRS-344/S095012, higher manufacturing and pre-clinical costs for earlier stage programs, and an increase in personnel costs.

G&A Expense - G&A expenses were $4.1 million for the quarter ended June 30, 2022, compared to $4.2 million for the quarter ended June 30, 2021. The period-over-period decrease was driven primarily by lower professional service costs and lower facilities costs, partially offset by higher travel expenses.

Other Income - For the quarter ended June 30, 2022, $1.2 million of grant income was recorded with respect to PRS-220 compared to $0.8 million for the quarter ended June 30, 2021. The increase is due to higher levels of activity as the Company plans to initiate a phase 1 study for PRS-220 this year.

Net Loss - Net loss was $10.3 million or $(0.14) per share for the quarter ended June 30, 2022, compared to a net loss of $15.5 million or $(0.25) per share for the quarter ended June 30, 2021.

Conference Call*:*

Pieris management will host a conference call beginning at 8:00 AM EDT on Thursday, August 4, 2022, to discuss the second quarter financial results and provide a corporate update. Individuals can join the call by dialing (800) 285-6670 (Toll Free US & Canada) or (713) 481-1320 (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, www.pieris.com.

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 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, 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 PRS-060/AZD1402, PRS-344/S095012 and PRS-220 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 PRS-060/AZD1402, PRS-220, PRS-344/S095012, PRS-352/S095025 and PRS-342/BOS-342; the therapeutic potential of our Anticalin platform; our continued progress in the areas of co-stim 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:

Pieris Pharmaceuticals, Inc.
Maria Kelman
Executive Director, Investor Relations
+1 857 362 9635
kelman@pieris.com

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

	June 30, 2022	December 31, 2021
Assets:		

Cash and cash equivalents	$ 54,257	$ 117,764
Short term investments	26,679	-
Accounts receivable	1,264	3,313
Prepaid expenses and other current assets	8,704	6,548
Total current assets	90,904	127,625
Property and equipment, net	17,430	19,122
Operating lease right-of-use assets	3,617	3,909
Other non-current assets	2,358	2,904
Total Assets	$ 114,309	$ 153,560
Liabilities and stockholders??? equity:		
Accounts payable	$ 1,898	$ 8,609
Accrued expenses	10,785	16,836
Deferred revenue, current portion	22,863	25,116
Total current liabilities	35,546	50,561
Deferred revenue, net of current portion	22,063	38,403
Operating lease liabilities	12,335	13,841
Total Liabilities	69,944	102,805
Total stockholders' equity	44,365	50,755
Total liabilities and stockholders' equity	$ 114,309	$ 153,560

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

	Three months ended June 30,		Six months ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenues	$ 3,698	$ 3,285	$ 14,686	$ 18,918
Operating expenses				
Research and development	11,947	15,800	26,013	32,362
General and administrative	4,081	4,246	8,460	8,376
Total operating expenses	16,028	20,046	34,473	40,738
Loss from operations	(12,330)	(16,761)	(19,787)	(21,820)
Interest income	132	3	129	6
Grant income	1,184	796	3,314	796
Other income (expense), net	676	464	905	1,348
Net loss	$ (10,338)	$ (15,498)	$ (15,439)	$ (19,670)
Basic and diluted net loss per share	$ (0.14)	$ (0.25)	$ (0.21)	$ (0.33)
Basic and diluted weighted average shares outstanding	74,125	61,905	73,919	59,116

SOURCE: Pieris Pharmaceuticals, Inc.

View source version on accesswire.com:
https://www.accesswire.com/710828/Pieris-Pharmaceuticals-Reports-Second-Quarter-2022-Financial-Results-and-Provides-Corporate-Update