March 1, 2022

Pieris Pharmaceuticals Reports Full-Year 2021 Financial Results and Provides Corporate Update

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON TUESDAY, MARCH 1, 2022 AT 8:00 AM EST

- ***Initiated efficacy part of phase 2a study of PRS-060/AZD1402; expected topline readout this year***
- ***Dosed first patient in phase 2 gastric study of cinrebafusp alfa; HER2-low arm data expected this year and HER2-high arm data expected in 2023***
- ***Dosed first patient in phase 1/2 solid tumor study of PRS-344/S095012***
- ***PRS-220 phase 1 initiation on track for this year***
- ***Year-end cash and cash equivalents totaled $117.8 million***

BOSTON, MA / ACCESSWIRE / March 1, 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, today reported financial results for the fiscal year ended December 31, 2021 and provided an update on the Company's recent and anticipated future developments.

"Last year was one of steady execution as we laid the groundwork for 2022, which we believe promises to be the most important catalyst year in the Company's history, including key efficacy data for cinrebafusp alfa and PRS-060/AZD1402. We announced a collaboration with R&D leader Genentech, reported data from several clinical and preclinical programs, and initiated multiple clinical trials. Later this year, we expect to report topline data from the phase 2a trial of PRS-060/AZD1402, which has recently cleared the safety gate for the 1 mg and 3 mg dose cohorts. Beyond PRS-060/AZD1402, we currently have two bispecific immuno-oncology programs in clinical development and plan on initiating clinical development for our proprietary inhaled-delivery idiopathic pulmonary fibrosis (IPF) drug program, PRS-220, later this year, with generous grant support from the Bavarian government," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "Through these initiatives, we have advanced our pipeline assets while strengthening our balance sheet through partnerships, grant funding, and focused utilization of our ATM facility, all with the focus of driving toward our key inflection points."

- **PRS-060/AZD1402 and AstraZeneca Collaboration:** Enrollment of part 2a (efficacy of 1 mg and 3 mg cohorts) and part 1b (safety of 10 mg cohort) has begun following successful completion of the sponsor safety review of part 1a (safety of 1 mg and 3 mg

cohorts) of the multi-center, placebo-controlled phase 2a study of dry powder inhaler-formulated PRS-060/AZD1402. PRS-060/AZD1402 is an IL-4 receptor alpha inhibitor under development in collaboration with AstraZeneca for the treatment of moderate-to-severe asthma. Pieris and AstraZeneca expect to announce topline data from the phase 2a study this year, although the companies are actively evaluating the feasibility of study timelines in the current geopolitical environment and will update guidance in the orderly course of business, if needed.Upon completion of the study, which is being sponsored and funded by AstraZeneca, Pieris may choose to exercise its co-development option, which would be on a 25% cost-share basis with a cost cap or a 50% cost-share basis without a cost cap. Separately, Pieris will have a future option to co-commercialize PRS-060/AZD1402 in the United States.

- **Cinrebafusp Alfa (PRS-343) :** In January 2022, the first patient was dosed in the phase 2 study of cinrebafusp alfa, a 4-1BB/HER2 Anticalin-based bispecific for the treatment of HER2-expressing gastric cancer. The two-arm, multicenter, open-label phase 2 study is evaluating the efficacy, safety, and tolerability of cinrebafusp alfa in combination with standard of care agents ramucirumab and paclitaxel in patients with HER2-high gastric cancer and in combination with tucatinib in patients with HER2-low gastric cancer. Pieris plans to report data from the HER2-low arm this year. Separately, the Company plans to disclose data from the HER2-high arm in 2023.
- **PRS-344/S095012 and Servier Collaboration:** The first patient was dosed in November 2021 in the phase 1/2 study of PRS-344/S095012, a 4-1BB/PD-L1 Anticalin-based bispecific for the treatment of solid tumors, triggering an undisclosed milestone payment to Pieris. Pieris holds exclusive commercialization rights for PRS-344/S095012 in the United States and will receive royalties on any ex-U.S. sales for this program. Additionally, Servier is continuing development of PRS-352, an undisclosed Anticalin-based bispecific beyond 4-1BB.
- **PRS-220:** Pieris remains on track to begin a phase 1 trial this year for PRS-220, a proprietary inhaled Anticalin protein targeting connective tissue growth factor for the treatment of IPF.

Year End Financial Update:

Cash Position - Cash and cash equivalents totaled $117.8 million for the year ended December 31, 2021, compared to a cash and cash equivalents balance of $70.4 million for the year ended December 31, 2020. The increase since December 2020 is due to cash received from new and existing collaboration agreements, including milestone achievements. In addition, during 2021, the ATM program was utilized to raise a total of $38.5M in net proceeds at an average price of $4.85 per share. These increases were partially offset by cash used to fund operations in 2021.

R&D Expense - R&D expenses were $66.7 million for the year ended December 31, 2021, compared to $46.5 million for the year ended December 31, 2020. The increase reflects higher spending on preclinical and manufacturing activities for PRS-220, an increase in manufacturing costs across multiple immuno-oncology programs, higher clinical costs on cinrebafusp alfa and higher employee related costs. These increases were partially offset by lower manufacturing costs on PRS-060, which were fully reimbursed.

G&A Expense - G&A expenses were $16.5 million for the year ended December 31, 2021, compared to $16.7 million for the year ended December 31, 2020. Total G&A spending was

consistent year-over-year as higher fixed and variable compensation and higher insurance costs in 2021 were offset by lower legal, accounting, and project management costs, along with lower one-time office and building equipment costs related to the move to the new R&D facility in Hallbergmoos, Germany in the prior year.

Other Income - For the year ended December 31, 2021, $3.7 million of other income was recorded for PRS-220 program costs that qualified for reimbursement under the Bavarian grant that was announced in June 2021. The Bavarian government reimburses these qualifying program costs as incurred over the PRS-220 development period.

Net Loss - Net loss was $45.7 million or $(0.71) per share for the year ended December 31, 2021, compared to a net loss of $37.2 million or $(0.68) per share for the year ended December 31, 2020.

Conference Call *:*

Pieris management will host a conference call beginning at 8:00 AM EST on Tuesday, March 1, 2022, to discuss the full-year financial results and provide a corporate update. Individuals can join the call by dialing +1-877-407-8920 (US & Canada) or +1-412-902-1010 (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, the potential for Pieris' development programs such as PRS-060/AZD1402, cinrebafusp alfa, 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; making IND filings or achieving other milestones related to our programs, including PRS-060/AZD1402, cinrebafusp alfa, PRS-344/S095012 and PRS-220; the therapeutic potential of our Anticalin platform; our continued progress in the areas of co-stim bispecifics and inhaled therapeutics; and the advancement 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, 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 geo-political 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.

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

	December 31, 2021	December 31, 2020
Assets:		
Cash and cash equivalents	$ 117,764	$ 70,436
Short term investments	-	-
Accounts receivable	3,313	1,706
Prepaid expenses and other current assets	6,548	3,579
Total current assets	127,625	75,721
Property and equipment, net	19,122	22,046
Operating lease right-of-use assets	3,909	3,934
Other non-current assets	2,904	3,309
Total Assets	$ 153,560	$ 105,010
Liabilities and stockholders' equity:		
Accounts payable	$ 8,609	$ 1,787
Accrued expenses	16,836	7,731
Deferred revenue, current portion	25,116	12,627

Total current liabilities	50,561	22,145
Deferred revenue, net of current portion	38,403	35,900
Operating lease liabilities	13,841	15,932
Other long-term liabilities	-	6
Total Liabilities	102,805	73,983
Total stockholders' equity	50,755	31,027
Total liabilities and stockholders' equity	$ 153,560	$ 105,010

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

	Twelve Months Ended December 31,	
	2021	**2020**
Revenues	$ 31,418	$ 29,323
Operating expenses		
Research and development	66,656	46,531
General and administrative	16,593	16,713
Total operating expenses	83,249	63,244
Loss from operations	(51,831)	(33,921)
Interest income	4	511
Grant income	3,685	-
Other income (expense), net	2,404	(3,656)
Loss before income taxes	(45,738)	(37,066)
Provision for income tax	-	164
Net loss	$ (45,738)	$ (37,230)
Basic and diluted net loss per share	$ (0.71)	$ (0.68)
Basic and diluted weighted average shares outstanding	64,547	54,481

SOURCE: Pieris Pharmaceuticals, Inc.

View source version on accesswire.com:
https://www.accesswire.com/690832/Pieris-Pharmaceuticals-Reports-Full-Year-2021-Financial-Results-and-Provides-Corporate-Update