March 30, 2021

Pieris Pharmaceuticals Reports Full-Year 2020 Financial Results and Provides Corporate Update

Company To Host an Investor Conference Call on Tuesday, March 30, 2021 at 8:00 AM EDT

- ***Pieris achieves $13 million milestone from AstraZeneca for initiation of PRS-060/AZD1402 phase 2a study and AstraZeneca to purchase $10 million equity stake in Pieris common stock as part of an amended collaboration agreement***
- ***$13 million equity investment by Seagen in Pieris, in addition to a clinical trial and supply agreement to evaluate cinrebafusp alfa (PRS-343) in combination with TUKYSA® (tucatinib) in HER2-low gastric cancer as part of an amended collaboration agreement***
- ***Additional clinical benefit and safety data from the highest dose cohort and updated biomarker data across all active dose cohorts from cinrebafusp alfa phase 1 monotherapy study to be presented at American Association for Cancer Research Annual Meeting 2021***
- ***Synergistic preclinical PRS-344 data to be presented at American Association for Cancer Research Annual Meeting 2021, including in vitro data evaluating potential effects of combining 4-1BB with PD-L1 and the effects of PRS-344 on CD8+ T cells, as well as dose-dependent anti-tumor response in in vivo preclinical models***

BOSTON, MA / ACCESSWIRE / March 30, 2021 /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, 2020 and provided an update on the Company's recent and anticipated future developments.

"We are pleased to announce the achievement of our second clinical milestone for PRS-060/AZD1402, triggered by the initiation of phase 2a by our partner, AstraZeneca, who further demonstrated their commitment to our respiratory-focused alliance with an equity investment," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "Within our immuno-oncology franchise, we look forward to presenting additional data for two of our 4-1BB-based bispecific programs at AACR, cinrebafusp alfa (PRS-343) and PRS-344, reinforcing our commitment to and leadership in the 4-1BB space. Following the generation of synergistic *in vitro* data for the combination of cinrebafusp alfa with TUKYSA® (tucatinib), we plan to pursue this combination in lower HER2-expressing gastric cancer patients with

Seagen. Seagen has also recently made an equity investment in Pieris, further strengthening the alliance we signed in 2018. Partnerships are an important part of our corporate strategy, and our recent announcements reinforce the value our current alliances continue to bring."

- **PRS-060 & AstraZeneca Collaboration:** Pieris will receive a $13 million milestone payment from AstraZeneca for the initiation of patient enrollment in the phase 2a study of PRS-060/AZD1402, an inhaled IL-4 receptor alpha inhibitor the companies are developing for the treatment of moderate-to-severe asthma. The global phase 2a study of PRS-060/AZD1402 is a two-part, multi-center, placebo-controlled clinical study that will evaluate the drug candidate at up to three dose levels using a dry powder formulation administered twice daily on top of standard of care. Additionally, the companies amended their existing agreement to restructure certain commercial economics for PRS-060/AZD1402 by adjusting various milestones and royalty provisions, while fundamentally maintaining the overall value split between AstraZeneca and Pieris. In connection with the amendment, AstraZeneca will make a $10 million equity investment in Pieris through the purchase of 3,584,230 newly-issued shares of Pieris common stock at a price of $2.79 per share.
- **Cinrebafusp Alfa (PRS-343):** Pieris will present an updated dataset for cinrebafusp alfa (PRS-343), a 4-1BB/HER2 bispecific for the treatment of HER2-expressing solid tumors, in an oral presentation at the American Association for Cancer Research Annual Meeting 2021 (AACR) on April 10, 2021. The presentation will include additional clinical benefit and safety data from cohort 13b (18 mg/kg, administered Q2W), as well as biomarker data across all active dose cohorts. The Company is preparing for the phase 2 study of cinrebafusp alfa, expected to begin in the summer of 2021. The phase 2 study will evaluate cinrebafusp alfa in combination with ramucirumab and paclitaxel in high HER2-expressing gastric cancer and in combination with tucatinib in low HER2-expressing gastric cancer. Collaboration partners Lilly and Seagen will supply ramucirumab and tucatinib, respectively, for these study arms.
- **Seagen Collaboration Expansion:** Seagen made a $13 million equity investment in Pieris as part of an ongoing collaboration between the companies. Additionally, the companies have entered into a clinical trial and supply agreement to evaluate the safety and efficacy of combining Pieris' cinrebafusp alfa with Seagen's TUKYSA® (tucatinib), a small-molecule tyrosine kinase HER2 inhibitor, for the treatment of gastric cancer patients expressing lower HER2 levels (IHC2+/ISH- & IHC1+) as part of the upcoming phase 2 study to be conducted by Pieris. The companies have also amended their existing immuno-oncology collaboration whereby Pieris' option to co-develop and co-commercialize the second of three programs in the collaboration has been converted to a co-promotion option in the United States.
- **PRS-344 & Servier Collaboration:** Pieris and Servier will present preclinical data for PRS-344/S095012, a 4-1BB/PD-L1 bispecific, as part of a poster session at the AACR Annual Meeting 2021. The presentation will showcase synergistic data, including *in vitro* data evaluating potential effects of combining 4-1BB with PD-L1 and the effects of PRS-344 on CD8+ T cells, as well as dose-dependent anti-tumor response in *in vivo* preclinical models. PRS-344 is expected to enter phase 1 studies this year. Pieris holds exclusive commercialization rights for PRS-344 in the United States and will receive royalties on ex-U.S. sales by Servier for this program. Additionally, Pieris completed non-GLP preclinical work for PRS-352, a preclinical-stage program

addressing undisclosed targets for immuno-oncology, last quarter; Servier is fully responsible for further development of that program.
- **Preclinical Respiratory Pipeline:** Pieris and AstraZeneca continue to advance each of the four programs in the collaboration beyond PRS-060/AZD1402. Pieris also continues to advance several proprietary discovery-stage respiratory programs and expects to share data and rationale for advancement of one of its proprietary programs this year.

AACR Details:

Cinrebafusp Alfa Oral Presentation:

Title: *Clinical and biomarker activity of PRS-343, a bispecific fusion protein targeting 4-1BB and HER2, from a Phase 1 study in patients with advanced solid tumors*
Abstract: CT017
Session: CTMS01 - Early Clinical Trials with New Anticancer Agents
Date/Time: The presentation will take place at 2:05 PM EDT on Saturday, April 10, 2021 on Channel 08.

PRS-344 Poster:

Title: *Simultaneous costimulatory T-cell engagement and checkpoint inhibition by PRS-344/S095012, a PD-L1 / 4-1BB bispecific compound for tumor localized activation of the immune system*
Abstract: LB135
Session: PO.ET01.08 - Targeting the Tumor Microenvironment in Drug Development
Date/Time: This poster will be available beginning at 8:30AM EDT on Saturday, April 10, 2021.

Fiscal Year Financial Update:

Cash Position - Cash and cash equivalents totaled $70.4 million for the year ended December 31, 2020, compared to a cash, cash equivalents, and investments balance of $104.2 million for the year ended December 31, 2019. The decrease was primarily due to funding operating and capital expenses in 2020, partially offset by ATM proceeds and milestone achievements during the year. The December 31, 2020 ending cash position excludes the $13 million received from Seagen in March 2021 and the $23 million to be received from AstraZeneca in connection with the phase 2a study initiation and equity investment.

R&D Expense - R&D expenses were $46.5 million for the year ended December 31, 2020, compared to $55.0 million for the year ended December 31, 2019. The decrease in R&D expenses was primarily due to lower clinical and manufacturing costs on our immuno-oncology programs, in part due to the partial clinical hold on cinrebafusp alfa, lower manufacturing spending on PRS-060 (which is fully reimbursed by AstraZeneca), and lower travel-related expenditures due to COVID-19 restrictions. The overall decrease was partially offset by an increase in allocated IT and facility costs due to the move to a new R&D facility in Hallbergmoos, Germany in early 2020.

G&A Expense - G&A expenses were $16.7 million for the year ended December 31, 2020,

compared to $18.4 million for the year ended December 31, 2019. The decrease in G&A expenses was primarily due to lower personnel costs, lower audit and professional fees related to Sarbanes-Oxley readiness, and lower travel-related expenditures due to COVID-19 restrictions. These decreases were partially offset by higher allocated IT and facility costs due to the move to the new R&D facility.

Net Loss - Net loss attributable to common stockholders was $37.2 million or $(0.68) per share for the year ended December 31, 2020, compared to a net loss of $28.3 million or $(0.56) per share for the year ended December 31, 2019.

***Conference Call**:*

Pieris management will host a conference call beginning at 8:00 AM EDT on Tuesday, March 30, 2021, 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). An archived replay of the call will be available by dialing +1-877-660-6853 (US & Canada) or +1-201-612-7415 (International) and providing the Conference ID #: 13661472.

***About Pieris Pharmaceuticals**:*

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 inhalable Anticalin proteins to treat respiratory diseases and immuno-oncology multi-specifics tailored for the tumor microenvironment. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies, including AstraZeneca, Seagen, and Servier. Anticalin® is a registered trademark of Pieris. 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, whether the combination of cinrebafusp alfa and TUKYSA could address a high medical need in HER2 low-expressing gastric cancer patients who do not respond to traditional HER2-targeted therapies; whether the effects of the combination of cinrebafusp alfa and TUKYSA seen in preclinical studies will be observed in clinical trials; whether data from patients enrolled to date will be sufficient to inform the recommended phase 2 dose for the Company's planned proof of concept study of cinrebafusp alfa in gastric cancer; the expected timing and potential outcomes of the reporting by the Company of key clinical data from its programs, references to novel technologies and methods and our business and product development plans, including 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, and PRS-352 and the expected timing of the initiation of the next stage of cinrebafusp alfa's development in gastric cancer. 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, including our ability to recruit and enroll patients in our studies; our ability to address the requests of the FDA; competition in the industry in which we operate; delays or disruptions due to COVID-19; 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, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 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, 2020	December 31, 2019
Assets:		
Cash and cash equivalents	$ 70,436	$ 62,260
Short term investments	-	41,894
Accounts receivable	1,706	6,787
Prepaid expenses and other current assets	3,579	4,072
Total current assets	75,721	115,013
Property and equipment, net	22,046	19,502
Operating lease right-of-use assets	3,934	3,436
Other non-current assets	3,309	3,146
Total Assets	$ 105,010	$ 141,097
Liabilities and stockholders' equity:		
Accounts payable	$ 1,787	$ 5,803
Accrued expenses	7,731	9,944
Deferred revenue, current portion	12,627	11,256
Total current liabilities	22,145	27,003
Deferred revenue, net of current portion	35,900	47,258

Operating lease liabilities	15,932	15,484
Other long-term liabilities	6	-
Total Liabilities	73,983	89,745
Total stockholders' equity	31,027	51,352
Total liabilities and stockholders' equity	$ 105,010	$ 141,097

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

	Twelve Months Ended December 31,	
	2020	**2019**
Revenues	$ 29,323	$ 46,279
Operating expenses		
Research and development	46,531	54,996
General and administrative	16,713	18,440
Total operating expenses	63,244	73,436
Loss from operations	(33,921)	(27,157)
Interest income	511	1,714
Other income (expense), net	(3,656)	(26)
Loss before income taxes	(37,066)	(25,469)
Provision for income tax	164	-
Net loss	$ (37,230)	$ (25,469)
Basic and diluted net loss per share	$ (0.68)	$ (0.56)
Basic and diluted weighted average shares outstanding	54,481	50,625

SOURCE: Pieris Pharmaceuticals, Inc.

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https://www.accesswire.com/638041/Pieris-Pharmaceuticals-Reports-Full-Year-2020-Financial-Results-and-Provides-Corporate-Update