August 4, 2021

Pieris Pharmaceuticals Reports Second Quarter 2021 Financial Results and Provides Corporate Update

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON WEDNESDAY, AUGUST 4, 2021 AT 8:00 AM EDT

- ***Announced inhaled program PRS-220 for the treatment of IPF and was selected to receive a Bavarian government grant of approximately $17 million to evaluate the program for post-COVID pulmonary fibrosis***
- ***Signed respiratory and ophthalmology agreement with Genentech with a $20 million upfront payment and more than $1.4 billion in potential additional milestone payments***
- ***Tim Demuth, M.D., Ph.D., appointed Chief Medical Officer and Shane Olwill, Ph.D., promoted to Chief Development Officer***
- ***Reiterated guidance for near-term and ongoing clinical studies***
- ***June 30th ending cash balance in excess of $119M***

BOSTON, MA / ACCESSWIRE / August 4, 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 second quarter of 2021 ended June 30, 2021 and provided an update on the Company's recent and anticipated future developments.

"We had a very productive second quarter, having advanced and expanded our pipeline while ending with a cash balance exceeding $119 million, largely bolstered by additional non-dilutive funding. As we further validate the Anticalin platform for local applications, we are pleased to have closed a strategic partnership with Genentech in the areas of respiratory and ophthalmology, providing another opportunity to grow our respiratory franchise while exploring a novel application for Anticalin proteins via ocular delivery. We are also excited to have unveiled our proprietary inhaled respiratory program PRS-220 for IPF alongside a grant from the Bavarian government to evaluate the program for post-COVID pulmonary fibrosis. PRS-220 is expected to enter the clinic next year. Additionally, we have made significant progress in advancing our immuno-oncology pipeline. In the coming weeks, we expect to dose the first patient in the phase 2 trial of cinrebafusp alfa in HER2-expressing cancers, for which FDA recently granted orphan drug designation, and we expect to start the phase 1 trial of PRS-344/S095012 with our partner, Servier, later this year," said Stephen S. Yoder, President and Chief Executive Officer of Pieris.

- **PRS-060/AZD1402 and AstraZeneca Collaboration:** Enrollment continues in the first (safety) part of the global phase 2a study of PRS-060/AZD1402, an inhaled 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 data from the phase 2a study next year.Upon completion of the study, which is being sponsored and funded by AstraZeneca, Pieris will have the options to co-develop and, separately, co-commercialize PRS-060/AZD1402 in the United States. Pieris and AstraZeneca continue to advance each of the four programs in the collaboration beyond PRS-060/AZD1402.
- **Cinrebafusp Alfa (PRS-343):** Pieris plans to dose the first patient in a two-arm phase 2 study for cinrebafusp alfa, a 4-1BB/HER2 bispecific for the treatment of HER2-expressing solid tumors, in gastric cancer in the coming weeks. One arm of the study will evaluate cinrebafusp alfa in combination with ramucirumab and paclitaxel in HER2-high gastric cancer, and the other arm of the study will evaluate cinrebafusp alfa in combination with tucatinib in HER2-low gastric cancer. As previously indicated, Go/No-Go criteria for advancement of this program will evaluate a composite of measures, including a minimum target of 50% ORR in the HER2-high arm and a minimum target of 40% ORR in the HER2-low arm, duration of response, and safety. The Company expects to report results from both study arms next year. Recently, FDA granted orphan drug designation to cinrebafusp alfa for the treatment of HER2-high and HER2-low expressing gastric cancers.
- **PRS-344/S095012 and Servier Collaboration:** The phase 1 study of PRS-344/S095012, a 4-1BB/PD-L1 bispecific, is expected to begin later this year. Pieris holds exclusive commercialization rights for PRS-344/S095012 in the United States and will receive royalties on ex-U.S. sales for this program. Additionally, Servier has obtained *in vivo* proof of concept for PRS-352, an Anticalin-based bispecific beyond 4-1BB, triggering an undisclosed milestone payment to Pieris. Servier is responsible for further development of the program.
- **PRS-220:** Pieris is developing PRS-220, a proprietary inhaled Anticalin protein targeting connective tissue growth factor (CTGF) for the treatment of idiopathic pulmonary fibrosis (IPF). The Company was selected to receive a 14.2 million euro (approximately 17 million USD) grant from the Bavarian government for the research and development of PRS-220 for post-acute sequelae of SARS-CoV-2 infection (PASC) pulmonary fibrosis (PASC-PF), also known as post-COVID pulmonary fibrosis. The Company plans to present initial preclinical data from the program at the European Respiratory Society International Congress 2021 (ERS) in September, and clinical development is expected to begin next year.
- **Genentech Collaboration:** Pieris entered into a multi-program research collaboration and license agreement with Genentech to discover, develop, and commercialize locally delivered respiratory and ophthalmology therapies that leverage Pieris' proprietary Anticalin technology. Under the terms of the agreement, Pieris received a $20 million upfront payment, and may be eligible to receive more than $1.4 billion in additional milestone payments across multiple programs, including up to $11 million in preclinical milestones for each program, as well as tiered royalties up to low double-digits for any commercialized programs. The collaboration comprises two committed programs, and Genentech has an option to initiate up to two additional programs for a further payment of $10 million per program.
- **Executive R&D Leadership:** Pieris announced the appointment of Tim Demuth, M.D., Ph.D. as SVP and Chief Medical Officer. Dr. Demuth will oversee all clinical, medical,

safety, and regulatory aspects at the Company. Pieris additionally announced the promotion of Shane Olwill, Ph.D., to SVP and Chief Development Officer. In his new role, Dr. Olwill will lead all translational activities to inform the replenishing and positioning of Pieris' portfolio across all stages of development in addition to overseeing project leadership on projects following declaration of a development candidate.

First Quarter Financial Update:

Cash Position - Cash and cash equivalents totaled $119.1 million for the quarter ended June 30, 2021, compared to a cash and cash equivalents balance of $70.4 million for the year ended December 31, 2020. The cash increase in the first half of 2021 was more than $78.0 million, primarily due to new and existing collaboration agreements, along with targeted use of the Company's ATM program. This increase was partially offset by cash used to fund operations for the first six months of 2021. The June 30th cash position does not include the impact of the Bavarian government grant, as those proceeds will be reimbursed for qualifying program costs incurred over the PRS-220 development period.

R&D Expense - R&D expenses were $15.8 million for the quarter ended June 30, 2021, compared to $11.3 million for the quarter ended June 30, 2020. The increase reflects higher spending on preclinical activities for PRS-220, an increase in manufacturing costs across multiple immuno-oncology programs, and higher royalty costs associated with entering new collaboration agreements.

G&A Expense - G&A expenses were $4.2 million for the quarter ended June 30, 2021, compared to $4.6 million for the quarter ended June 30, 2020. The decrease reflects lower legal and project management costs in 2021, along with higher one-time office and building equipment costs incurred related to the move to the new R&D facility in Hallbergmoos, Germany in the prior year.

Net Loss - Net loss was $15.5 million or $(0.25) per share for the quarter ended June 30, 2021, compared to a net loss of $5.0 million or $(0.09) per share for the quarter ended June 30, 2020.

Conference Call:
Pieris management will host a conference call beginning at 8:00 AM EDT on Wednesday, August 4, 2021, to discuss the second quarter of 2021 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 and cinrebafusp alfa 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 and cinrebafusp alfa, 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 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 U.S. Food and Drug Administration; 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 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, 2020 and the Company's Quarterly Reports on Form 10-Q.

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

	June 30, 2021	December 31, 2020

Assets:		
Cash and cash equivalents	$ 119,097	$ 70,436
Accounts receivable	2,803	1,706
Prepaid expenses and other current assets	5,773	3,579
Total current assets	127,673	75,721
Property and equipment, net	20,373	22,046
Operating lease right-of-use assets	3,861	3,934
Other non-current assets	3,123	3,309
Total Assets	$ 155,030	$ 105,010
Liabilities and stockholders' equity:		
Accounts payable	$ 2,310	$ 1,787
Accrued expenses	16,082	7,731
Deferred revenue, current portion	25,536	12,627
Total current liabilities	43,928	22,145
Deferred revenue, net of current portion	49,421	35,900
Operating lease liabilities	14,960	15,932
Other long-term liabilities	-	6
Total Liabilities	108,309	73,983
Total stockholders' equity	46,721	31,027
Total liabilities and stockholders' equity	$ 155,030	$ 105,010

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,	
	2021	**2020**	**2021**	**2020**
Revenues	$ 3,285	$ 11,246	$ 18,918	$ 24,507
Operating expenses				
Research and development	15,800	11,333	32,362	24,091
General and administrative	4,246	4,568	8,376	8,927
Total operating expenses	20,046	15,901	40,738	33,018
Loss from operations	(16,761)	(4,655)	(21,820)	(8,511
Interest income	3	129	6	448
Grant income	796	-	796	-
Other income (expense), net	464	(424)	1,348	(484
Loss before income taxes	(15,498)	(4,950)	(19,670)	(8,547

Provision for income tax	-	-	-	-
Net loss	$ (15,498)	$ (4,950)	$ (19,670)	$ (8,547
Basic and diluted net loss per share	$ (0.25)	$ (0.09)	$ (0.33)	$ (0.16
Basic and diluted weighted average shares outstanding	61,905	52,371	59,116	53,792

SOURCE: Pieris Pharmaceuticals, Inc.

View source version on accesswire.com:
https://www.accesswire.com/658314/Pieris-Pharmaceuticals-Reports-Second-Quarter-2021-Financial-Results-and-Provides-Corporate-Update