March 29, 2023

Pieris Pharmaceuticals Reports Full-Year 2022 Financial Results and Business Updates

COMPANY TO HOST AN INVESTOR CONFERENCE CALL TODAY, WEDNESDAY, MARCH 29, 2023, AT 8:00 AM EDT

- ***Continued advancement of pipeline, including two clinical-stage inhaled respiratory programs and additional therapeutic programs for serious diseases***
- ***Elarekibep (PRS-060/AZD1402) Phase 2a study for asthma continues to be enrolled by AstraZeneca; clinical data anticipated by mid-2024***
- ***PRS-220, inhaled Anticalin protein for idiopathic pulmonary fibrosis (IPF), continues in Phase 1 study; topline results expected in the second half of this year***
- ***PRS-400, targeting muco-obstructive respiratory disease, advances toward development candidate nomination; additional preclinical data expected this year***

BOSTON, MA / ACCESSWIRE / March 29, 2023 / 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 fiscal year ended December 31, 2022, and provided a business update.

"Pieris continues to advance potentially transformative clinical and preclinical programs, while remaining committed to cost-effective operations. Our top priority is to obtain data from the elarekibep Phase 2a study in asthma. We are pleased that our partner and study sponsor, AstraZeneca, is significantly increasing operational resources to complete the trial. As an inhaled therapeutic, elarekibep offers the promise of a superior product profile compared to currently available injectable drugs and further validation of our broader respiratory franchise," said Stephen S. Yoder, President and CEO of Pieris. "Respiratory diseases such as asthma, IPF and chronic obstructive pulmonary disease are underserved by the biopharma industry despite high mortality rates, impaired quality of life, and a significant burden on the healthcare system. We believe Pieris is well positioned to develop differentiated inhaled biologics medicines that could fundamentally alter how respiratory diseases are managed.

"Alongside our lead program, elarekibep, Pieris is advancing additional clinical and preclinical programs that could result in meaningful new medicines. We are evaluating

opportunities to support the long-term development of these promising therapeutic candidates."

Respiratory Pipeline:

- **Elarekibep and AstraZeneca Collaboration:** Enrollment is ongoing in the multi-center, placebo-controlled Phase 2a study of dry powder inhaler-formulated elarekibep, an IL-4 receptor alpha (IL-4Rα) inhibitor being developed for the treatment of moderate-to-severe asthma. Topline results measuring placebo-adjusted FEV1 improvement at four weeks are now expected to be reported by the middle of 2024 based on AstraZeneca's most recent projections. AstraZeneca has communicated to the Company that completion of the Phase 2a study remains an important priority and that additional resources have been provided to achieve study completion, including a commitment to adding several new countries and a significant number of additional clinical sites, bringing the total number to more than 100 sites.

  Elarekibep is validated by dupilumab, an FDA-approved inhibitor of IL-4Rα, that has demonstrated reduced levels of fractional exhaled nitric oxide (FeNO) and clinical efficacy in uncontrolled, moderate-to-severe asthma. Furthermore, recently reported dupilumab Phase 3 study results have shown efficacy in chronic obstructive pulmonary disease (COPD). Previously reported elarekibep Phase 1 results demonstrated reduced FeNO levels in mild asthma patients, and a favorable safety profile.

  Pieris retains co-development and U.S. co-commercialization rights for elarekibep, exercisable following completion of the ongoing Phase 2a study. Beyond elarekibep, Pieris continues to develop two preclinical programs with AstraZeneca for which it also retains co-development and U.S. co-commercialization options.
- **PRS-220:** Pieris continues the development of an inhaled Anticalin protein targeting connective tissue growth factor (CTGF) for the treatment of IPF and other fibrotic lung diseases. In preclinical models, PRS-220 demonstrated superior on-target potency compared to pamrevlumab, an intravenously infused CTGF antagonist in late-stage clinical development. The Company believes that the inhaled route of administration allows for superior lung exposure. These attributes, combined with the convenience of at-home administration via inhalation, result in PRS-220 having best-in-class potential.

  The Company is currently dosing healthy volunteers in a Phase 1 study of PRS-220 and expects to report results in the second half of this year. Pieris continues to benefit from a meaningful grant from the Bavarian government, which supports early-stage development of this program.
- **PRS-400:** Pieris continues to advance PRS-400, an inhaled anti-Jagged-1 Anticalin therapeutic program with potential in a wide range of respiratory diseases driven by mucus hypersecretion. PRS-400 is designed to exert clinical activity by disrupting mucus-mediated pathology in the airways, while avoiding inhibition of healthy mucus production outside of the lungs. Previously presented preclinical data demonstrate that PRS-400 potently inhibits Jagged-1-induced Notch 2 signaling in relevant tissue in the lung. In patients with muco-obstructive respiratory diseases, such as those living with inadequately controlled COPD with chronic bronchitis, PRS-400 has potential to improve clinical outcomes and improve quality of life. PRS-400 is advancing toward development candidate nomination later this year.

Immuno-Oncology Pipeline:

Pieris's immuno-oncology pipeline continues to progress in a cost-efficient manner with the benefit of its partners. The Company believes that multiple opportunities exist to generate value from this portfolio based on promising preclinical and clinical data.

- **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™ (antibody-Anticalin protein) compound for the treatment of solid tumors, for which Pieris holds full U.S. rights and will receive development milestones and royalties on ex-U.S. sales by Servier. Additionally, Servier discontinued development of PRS-352/S095025, an PD-L1/OX40 bispecific Mabcalin compound, for strategic reasons.
- **Seagen Collaboration:** In January 2023, Seagen initiated a Phase 1 study for SGN-BB228 (also known as PRS-346), triggering a $5 million milestone payment to Pieris. SGN-BB228 is a first-in-class CD228/4-1BB bispecific antibody-Anticalin compound designed to provide a potent costimulatory bridge between tumor-specific T cells and CD228-expressing tumor cells. Pieris and Seagen continue to collaborate on two other undisclosed bispecific programs.
- **PRS-342/BOS-342:** Boston Pharmaceuticals continues to advance PRS-342/BOS-342, a 4-1BB/GPC3 bispecific Mabcalin compound, toward the clinic, with Phase 1 expected to begin in the coming months.

Fiscal Year End Financial Update:

Cash Position - Cash, cash equivalents, and investments totaled $59.2 million for the year ended December 31, 2022, compared to a cash and cash equivalents balance of $117.8 million for the year ended December 31, 2021. The decrease was due to funding operations in 2022. The Company believes operations are sufficiently funded for more than the next 12 months.

R&D Expense - R&D expenses were $53.0 million for the year ended December 31, 2022, compared to $66.7 million for the year ended December 31, 2021. The decrease was due to lower overall program costs for both elarekibep and cinrebafusp alfa, lower manufacturing costs across other later-stage respiratory and immuno-oncology programs, lower license fees and lower consulting costs. These lower costs were partially offset by higher clinical costs for PRS-220 and PRS-344/S095012, higher pre-clinical costs for PRS-400, and an increase in personnel and travel costs.

G&A Expense - G&A expenses were $16.4 million for the year ended December 31, 2022, compared to $16.6 million for the year ended December 31, 2021. The period-over-period decrease was driven primarily by lower personnel, facilities and audit and tax costs, partially offset by higher business development, travel and amortization of deferred costs related to revenue recognition.

Other Income - For the year ended December 31, 2022, $8.2 million of grant income was recorded with respect to PRS-220, compared to $3.7 million for the year ended December 31, 2021. The increase was due to higher overall costs incurred on PRS-220 as the program progressed into a Phase 1 clinical study.

Net Loss - Net loss was $33.3 million or $(0.45) per share for the year ended December 31, 2022, compared to a net loss of $45.7 million or $(0.71) per share for the year ended December 31, 2021.

Conference Call*:*

Pieris management will host a conference call beginning at 8:00 AM EDT on Wednesday, March 29, 2023, to discuss the full-year financial results and provide a corporate update. Individuals can join the call by dialing 877-407-8920 (Toll Free US & Canada) or +1 412-902-1010 (International) at least five minutes prior to the start of the call. 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 inhaled medicines that drive local biology to produce superior clinical outcomes for patients. Our pipeline is focused on 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 strong 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; our product candidates clinical and therapeutic potential in their intended indications; 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, SGN-BB228 and PRS-342/BOS-342; the therapeutic potential of our Anticalin platform; the potential addressable market for our product candidates; our continued progress in the area 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, including in collaboration with other parties, 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 (SEC) available at www.sec.gov, including, without limitation, the Company's most recent Annual Report on Form 10-K, the Company's Quarterly Reports on Form 10-Q, and subsequent filings with the SEC.

Investor Relations Contact:

Pieris Pharmaceuticals, Inc.
Investors@pieris.com

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

	December 31, 2022	December 31, 2021
Assets:		
Cash and cash equivalents	$ 38,635	$ 117,764
Short term investments	20,534	-
Accounts receivable	5,810	3,313
Prepaid expenses and other current assets	8,445	6,548
Total current assets	73,424	127,625
Property and equipment, net	16,992	19,122
Operating lease right-of-use assets	3,705	3,909
Other non-current assets	1,369	2,904
Total Assets	$ 95,490	$ 153,560
Liabilities and stockholders' equity:		
Accounts payable	$ 4,154	$ 8,609
Accrued expenses	11,605	16,836
Deferred revenue, current portion	20,824	25,116
Total current liabilities	36,583	50,561
Deferred revenue, net of current portion	18,734	38,403
Operating lease liabilities	12,244	13,841
Total Liabilities	67,561	102,805
Total stockholders' equity	27,929	50,755
Total liabilities and stockholders' equity	$ 95,490	$ 153,560

PIERIS PHARMACEUTICALS, INC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year ended December 31,	
	2022	**2021**
Revenues	$ 25,902	$ 31,418
Operating expenses		
Research and development	52,982	66,656
General and administrative	16,394	16,593
Total operating expenses	69,376	83,249
Loss from operations	(43,474)	(51,831)
Interest income	721	4
Grant income	8,173	3,685
Other income (expense), net	1,303	2,404
Net loss	$ (33,277)	$ (45,738)
Basic and diluted net loss per share	$ (0.45)	$ (0.71)
Basic and diluted weighted average shares outstanding	74,172	64,547

SOURCE: Pieris Pharmaceuticals, Inc.

View source version on accesswire.com:
https://www.accesswire.com/746363/Pieris-Pharmaceuticals-Reports-Full-Year-2022-Financial-Results-and-Business-Updates