May 10, 2023

Pieris Pharmaceuticals Reports First Quarter 2023 Financial Results and Business Updates

COMPANY TO HOST AN INVESTOR CONFERENCE CALL TODAY, WEDNESDAY, MAY 10, 2023, AT 8:00 AM EDT

- ***Enrollment for elarekibep (PRS-060/AZD1402) Phase 2a study for asthma continues to progress with topline clinical data anticipated by mid-2024; successful safety review completed for 10 mg dose cohort***
- ***PRS-220, inhaled Anticalin protein for idiopathic pulmonary fibrosis (IPF), continues in Phase 1 study with topline results expected H2 2023***
- ***PRS-400, inhaled Anticalin protein for muco-obstructive respiratory disease, advances toward anticipated development candidate nomination H2 2023***
- ***New preclinical data to be presented at the American Thoracic Society (ATS) 2023 International Conference in May 2023 for both PRS-220 and PRS-400***

BOSTON, MA / ACCESSWIRE / May 10, 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 quarter ended March 31, 2023, and provided a business update.

"We continue to be excited by the potential of our inhaled biologics pipeline to reshape the treatment paradigm for patients living with uncontrolled asthma and other chronic respiratory diseases. Our top priority remains the study completion and clinical data read out from the elarekibep Phase 2a study in asthma, which is benefitting from increased operational resources from our partner, AstraZeneca," said Stephen S. Yoder, President and CEO of Pieris. "Pieris continues to make measured investments in PRS-220 and PRS-400 while also expecting additional progress across partnered programs through our capital-efficient collaborations with Boston Pharmaceuticals, Genentech, Seagen and Servier."

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, the study's primary efficacy endpoint, are expected by the middle of 2024. AstraZeneca previously 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. This includes a commitment to adding several new countries and a significant number of additional clinical sites, bringing the anticipated total number to more than 100 sites. As part of this commitment, AstraZeneca is on track to add three new geographies and related sites in the current quarter. Together with the previously announced protocol amendments, which are positively impacting study screening, we anticipate this will enable the achievement of the enrollment targets and timelines. In addition, the safety review of the 10 mg dose cohort in mild controlled asthmatics was successfully completed, which provides additional data supporting the elarekibep safety profile and enables doses greater than 3 mg to be evaluated in the future, if needed.

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

Pieris retains co-development and U.S. co-commercialization rights for elarekibep, which are exercisable following completion of the ongoing Phase 2a study.

- **PRS-220:** Pieris continues clinical development of PRS-220, a potential best-in-class inhaled Anticalin protein targeting connective tissue growth factor (CTGF) for the treatment of IPF, a disease with a large unmet medical need, and other fibrotic lung diseases. Preclinically, PRS-220 demonstrated superior on-target potency compared to pamrevlumab, an intravenously infused CTGF antagonist in late-stage clinical development. The Company believes inhaled administration will deliver high lung exposure, optimal pulmonary target engagement and superior clinical outcomes, while offering convenience of at-home administration.

  The Company is dosing healthy volunteers in a Phase 1 study with PRS-220 and expects to report results in the second half of this year. On May 21, 2023, preclinical data will be presented at the ATS 2023 International Conference, including data demonstrating that inhaled PRS-220 significantly reduced collagen deposition in a silica-induced lung fibrosis mouse model. Pieris continues to benefit from a meaningful grant from the Bavarian government, which supports early-stage development of this program.
- **PRS-400:** Pieris continues its preclinical advancement of PRS-400, an inhaled anti-Jagged-1 Anticalin therapeutic program with transformative potential in a wide range of respiratory diseases driven by mucus hypersecretion. PRS-400 was designed to allow patients to exit the vicious cycle of mucus hypersecretion, infection and airway obstruction, while avoiding inhibition of healthy, normal mucus production outside of the lungs. On May 22, 2023, preclinical data will be presented at the ATS 2023 International Conference demonstrating that PRS-400 reduced inflammation-driven goblet cell metaplasia and mucus hypersecretion in a therapeutic disease model. PRS-400 is advancing toward development candidate nomination in the second half of this year.

Immuno-Oncology Pipeline:

Pieris' 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 data generated to date.

- In April, clinical results from the Company's clinical study of cinrebafusp alfa (PRS-343) in 2L+ HER2-positive gastric cancer were presented at the American Association for Cancer Research annual meeting, including an unconfirmed 100% objective response rate and promising emerging durability profile in the five patients enrolled into the study prior to study discontinuation of enrollment for strategic reasons. Pieris is considering a range of transactions to facilitate program continuation, from an immuno-oncology focused spinout to a traditional partnering transaction.
- Boston Pharmaceuticals continues to advance BOS-342 (also known as PRS-342), a 4-1BB/GPC3 bispecific Mabcalin™ (antibody-Anticalin protein) compound, toward the clinic, with Phase 1 expected to begin in the coming months.
- Pieris and Servier continue to progress the escalation portion of the Phase 1/2 study of PRS-344/S095012, a 4-1BB/PD-L1 bispecific Mabcalin compound for the treatment of solid tumors, for which Pieris holds full U.S. rights.
- As previously announced, 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.

Fiscal Year End Financial Update:

Cash Position - Cash, cash equivalents, and investments totaled $48.4 million for the quarter ended March 31, 2023, compared to a cash and cash equivalents balance of $59.2 million for the year ended December 31, 2022. The decrease was due to funding operations in the first quarter of 2023. The Company believes operations are sufficiently funded for more than the next 12 months.

R&D Expense - R&D expenses were $13.4 million for the quarter ended March 31, 2023, compared to $14.1 million for the quarter ended March 31, 2022. The decrease was due primarily to lower clinical costs for cinrebafusp alfa and lower personnel costs, license fees and software costs. These lower costs were partially offset by higher overall program costs for PRS-220 and higher preclinical costs for discovery-stage programs, both partnered and proprietary.

G&A Expense - G&A expenses were $4.0 million for the quarter ended March 31, 2023, compared to $4.4 million for the quarter ended March 31, 2022. The period-over-period decrease was driven primarily by lower professional services, consulting and insurance costs.

Other Income - For the quarter ended March 31, 2023, $2.0 million of grant income was recorded with respect to PRS-220, compared to $2.1 million for the quarter ended March 31, 2022, indicating that costs incurred on PRS-220 were comparable for both periods. Interest income was $0.4 million for the quarter ended March 31, 2023, given the impact of rising interest rates compared to a de minimis amount of interest income in the quarter ended March 31, 2022

Net Loss - Net loss was $13.2 million or $(0.45) per share for the quarter ended March 31, 2023, compared to a net loss of $5.1 million or $(0.07) per share for the quarter ended March 31, 2022.

Conference Call:

Pieris management will host a conference call beginning at 8:00 AM EDT on Wednesday, May 10, 2023, to discuss the first quarter 2023 financial results and provide a corporate update. Individuals can join the call by dialing 866-682-6100 (Toll Free US & Canada) or +1 862-298-0702 (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.**

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, including the achievement of enrollment targets and timelines, and the expected timing for reporting data, including through participation in conferences; 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 BOS-342; the therapeutic potential and safety profile 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, including through partnership transactions, that 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; the fact that data and results from preclinical and clinical studies may not necessarily be indicative of future results; 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.

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

	March 31, 2023	December 31, 2022
Assets:		
Cash and cash equivalents	$ 39,742	$ 38,635
Short term investments	8,637	20,534
Accounts receivable	1,055	5,810
Prepaid expenses and other current assets	11,071	8,445
Total current assets	60,505	73,424
Property and equipment, net	16,706	16,992
Operating lease right-of-use assets	3,796	3,705
Other non-current assets	1,251	1,369
Total Assets	$ 82,258	$ 95,490
Liabilities and stockholders' equity:		
Accounts payable	$ 5,833	$ 4,154
Accrued expenses	10,354	11,605
Deferred revenue, current portion	26,688	20,284
Total current liabilities	42,875	36,583
Deferred revenue, net of current portion	11,727	18,734
Operating lease liabilities	12,198	12,244

Total Liabilities	66,800	67,561
Total stockholders' equity	15,458	27,929
Total liabilities and stockholders' equity	$ 82,258	$ 95,490

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

	Three months ended March 31,	
	2023	**2022**
Revenues	$ 1,936	$ 10,988
Operating expenses		
Research and development	13,424	14,066
General and administrative	4,023	4,379
Total operating expenses	17,447	18,445
Loss from operations	(15,511)	(7,457)
Interest income	357	(3)
Grant income	2,028	2,130
Other income (expense), net	(57)	229
Net loss	$ (13,183)	$ (4,977)
Basic and diluted net loss per share	$ (0.18)	$ (0.07)
Basic and diluted weighted average shares outstanding	74,519	73,711

SOURCE: Pieris Pharmaceuticals, Inc.

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https://www.accesswire.com/753840/Pieris-Pharmaceuticals-Reports-First-Quarter-2023-Financial-Results-and-Business-Updates