

May 11, 2022



Pieris Pharmaceuticals Reports First Quarter 2022 Financial Results and Provides Corporate Update

Company To Host an Investor Conference Call On Wednesday, May 11, 2022 At 8:00 Am EDT

BOSTON, MA / ACCESSWIRE / May 11, 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, reported financial results for the first quarter of 2022 ended March 31, 2022, and provided an update on the Company's recent and anticipated future developments.

"Pieris and our partners have made steady progress across the pipeline over the past quarter, and we are reiterating guidance on both cinrebafusp alfa phase 2 data in HER2-high gastric cancer in 2023 and PRS-220 clinical initiation this year. With IND acceptance for PRS-344/S095012, enrollment continues as planned and, separately, we are expecting an IND filing for PRS-342/BOS-342 in the next 12 months. At the same time, geopolitical and pandemic-driven challenges are affecting enrollment on certain programs. We are announcing a heightened risk to maintaining current guidance on reporting topline results for PRS-060/AZD1402 this year, despite AstraZeneca's continued commitment to execute on this program. Additionally, more time is needed for the enrollment of the HER2-low arm for cinrebafusp alfa. Notwithstanding these challenges, with our efficient program funding strategies and committed alliance partners, Pieris can advance its core assets with sufficient cash reach beyond the efficacy readout for PRS-060/AZD1402, which will be a significant milestone for us," said Stephen S. Yoder, President and Chief Executive Officer of Pieris.

- **PRS-060/AZD1402 and AstraZeneca Collaboration:** Enrollment continues for part 2a (efficacy of 1 mg and 3 mg cohorts) and part 1b (safety of 10 mg cohort) of the multi-center, placebo-controlled phase 2a study of dry powder inhaler-formulated PRS-060/AZD1402, an IL-4 receptor alpha inhibitor under development in collaboration with AstraZeneca for the treatment of moderate-to-severe asthma. Given the geopolitical situation, along with broader challenges amidst an ongoing pandemic, there is a heightened risk that more time will be required to deliver the topline study results by the end of the year as planned. AstraZeneca is currently in the process of conducting a thorough timeline reforecast and working on strategies to mitigate any potential delays. 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):** Enrollment continues in the two-arm, multicenter, open-label phase 2 study of cinrebafusp alfa, a 4-1BB/HER2 Anticalin-based bispecific for the treatment of HER2-expressing gastric cancer. The first arm of the 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. The Company is reiterating its guidance and expects to report data from this arm in 2023. The second arm of the study is evaluating the efficacy, safety, and tolerability of cinrebafusp alfa in combination with tucatinib in patients with HER2-low gastric cancer. The Company is revising its guidance and now expects to report data from this arm next year due to slower than anticipated enrollment.
- **PRS-344/S095012 and Servier Collaboration:** Enrollment continues and now includes the U.S., where Pieris holds exclusive commercialization rights, in the phase 1/2 study of PRS-344/S095012, a 4-1BB/PD-L1 Anticalin-based bispecific for the treatment of solid tumors that Pieris is developing in collaboration with Servier. Pieris also will receive royalties on any ex-U.S. sales for this program. Additionally, Servier is continuing development of PRS-352/S095025, an OX40/PD-L1 bispecific, for which the companies recently presented preclinical data at the AACR Annual Meeting 2022. PRS-352/S095025 has demonstrated superior potency to anti-PD-L1 and combination OX40 and PD-L1 therapy benchmarks in different in vitro assays, inhibits the PD-1/PD-L1 pathway with comparable potency to anti-PD-L1 antibodies, stimulates human CD4 T cells, drives T cell stimulation in ex vivo cynomolgus monkey assays, and demonstrated an antibody-like PK profile in vivo.
- **PRS-220:** PRS-220, a proprietary inhaled Anticalin protein targeting connective tissue growth factor for the treatment of IPF, remains on track to enter a phase 1 trial in healthy volunteers this year.
- **PRS-342/BOS-342:** Boston Pharmaceuticals continues to advance PRS-342/BOS-342, a 4-1BB/GPC3 bispecific, towards the clinic, with an IND filing expected within the next 12 months.

First Quarter Financial Update:

Cash Position - Cash, cash equivalents and investments totaled \$100.3 million for the quarter ended March 31, 2022, compared to a cash and cash equivalents balance of \$117.8 million for the quarter ended December 31, 2021. The decrease is due to funding operations in 2022. The Company believes reported cash is sufficient to fund operations into the fourth quarter of 2023.

R&D Expense - R&D expenses were \$14.1 million for the quarter ended March 31, 2022, compared to \$16.6 million for the quarter ended March 31, 2021. The decrease is due to lower program costs, as work related to the Company's sponsored phase 1 trial of PRS-060/AZD1402 was largely complete in 2021, and due to lower manufacturing costs for cinrebafusp alfa. These lower costs were partially offset by higher clinical costs for cinrebafusp alfa and higher clinical and manufacturing costs for PRS-344/S095012. Separately, higher personnel costs due to higher headcount were partially offset by a reduction in consulting and other professional service costs.

G&A Expense - G&A expenses were \$4.4 million for the quarter ended March 31, 2022,

compared to \$4.1 million for the quarter ended March 31, 2021. The increase was driven primarily by higher non-cash amortization of deferred costs related to collaboration revenue earned and partially offset by slightly lower legal and audit costs.

Other Income - For the quarter ended March 31, 2022, \$2.1 million of grant income was recorded on PRS-220.

Net Loss - Net loss was \$5.1 million or \$(0.07) per share for the quarter ended March 31, 2022, compared to a net loss of \$4.2 million or \$(0.07) per share for the quarter ended March 31, 2021.

Conference Call:

Pieris management will host a conference call beginning at 8:00 AM EDT on Wednesday, May 11, 2022, to discuss the first quarter financial results and provide a corporate update. Individuals can join the call by dialing (888) 428-7458 (US & Canada) or (862) 298-0702 (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; the receipt of royalty payments provided for in our collaboration agreements; making IND filings or achieving other milestones related to our programs, including PRS-060/AZD1402, PRS-220, cinrebafusp alfa, PRS-344/S095012, PRS-352/S095025 and PRS-342/BOS-342; 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 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 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
 (unaudited, in thousands)

	March 31, 2022	December 31, 2021
Assets:		
Cash and cash equivalents	\$ 83,737	\$ 117,764
Short term investments	16,531	-
Accounts receivable	1,644	3,313
Prepaid expenses and other current assets	9,837	6,548
Total current assets	<u>111,749</u>	<u>127,625</u>
Property and equipment, net	18,849	19,122
Operating lease right-of-use assets	3,844	3,909
Other non-current assets	2,673	2,904
Total Assets	<u>\$ 137,115</u>	<u>\$ 153,560</u>
Liabilities and stockholders' equity:		
Accounts payable	\$ 4,496	\$ 8,609
Accrued expenses	14,075	16,836
Deferred revenue, current portion	20,913	25,116
Total current liabilities	<u>39,484</u>	<u>50,561</u>
Deferred revenue, net of current portion	30,819	38,403
Operating lease liabilities	13,362	13,841

Total Liabilities	83,665	102,805
Total stockholders' equity	53,450	50,755
Total liabilities and stockholders' equity	<u>\$ 137,115</u>	<u>\$ 153,560</u>

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

	Three months ended March 31,	
	2022	2021
Revenues	\$ 10,988	\$ 15,633
Operating expenses		
Research and development	14,066	16,562
General and administrative	4,379	4,130
Total operating expenses	18,445	20,692
Loss from operations	(7,457)	(5,059)
Interest (expense) income	(3)	3
Grant income	2,130	-
Other income	229	884
Loss before income taxes	(5,101)	(4,172)
Net loss	<u>\$ (5,101)</u>	<u>\$ (4,172)</u>
Basic and diluted net loss per share	<u>\$ (0.07)</u>	<u>\$ (0.07)</u>
Basic and diluted weighted average shares outstanding	<u>73,711</u>	<u>56,297</u>

SOURCE: Pieris Pharmaceuticals, Inc. Pieris Pharmaceuticals, Inc.

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