

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): August 4, 2022**

**PIERIS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Nevada  
(State or other jurisdiction of  
Incorporation)

001-37471  
(Commission  
File Number)

30-0784346  
(IRS Employer  
Identification No.)

255 State Street, 9th Floor  
Boston, MA  
(Address of principal executive offices)

02109  
(Zip Code)

**Registrant's telephone number, including area code: 857-246-8998**

N/A

**(Former name or former address, if changed since last report.)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	PIRS	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02 Results of Operations and Financial Condition.**

On August 4, 2022, Pieris Pharmaceuticals, Inc. (the “Company”) issued a press release announcing certain financial results for the quarter ended June 30, 2022. A copy of the press release issued by the Company is furnished as Exhibit 99.1 to this report.

The information set forth under this “Item 2.02. Results of Operations and Financial Condition,” including Exhibit 99.1 furnished hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

---

**Item 7.01 Regulation FD Disclosure.**

Furnished hereto as Exhibit 99.2 is the August 2022 Investor Presentation of the Company.

The information set forth under this “Item 7.01. Regulation FD Disclosure,” including Exhibit 99.2 furnished hereto, shall not be deemed “filed” for any purpose, and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing except as shall be expressly set forth by specific reference in such filing.

---

**Item 9.01 Financial Statements and Exhibits.**

(d) *Exhibits.*

99.1 [Press Release, dated August 4, 2022.](#)

99.2 [Investor Presentation, dated August 2022.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

---

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PIERIS PHARMACEUTICALS, INC.

Dated: August 4, 2022

/s/ Tom Bures

Tom Bures

Chief Financial Officer

## PRESS RELEASE

### PIERIS PHARMACEUTICALS REPORTS SECOND QUARTER 2022 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON  
THURSDAY, AUGUST 4, 2022 AT 8:00 AM EDT

- **Adjustments to PRS-060/AZD1402 phase 2 study design boost enrollment rate and facilitate a topline readout by 3Q23**
- **Cinrebafusp alfa (PRS-343) demonstrating clinical benefit in HER2-expressing gastric cancer patients, but Company will cease enrollment to focus its resources**
- **First-in-human regulatory submission for PRS-220 achieved, with first subject dosing planned following regulatory clearance**
- **Escalation of PRS-344/S095012 in collaboration with Servier continues**
- **AstraZeneca extends research collaboration, focusing on two discovery-stage programs with Pieris retaining co-development and U.S. co-commercialization options on both programs**
- **Strategic pipeline prioritization results in cash reach to the second quarter of 2024**

**BOSTON, MA, August 4, 2022** - *Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS)*, a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin<sup>®</sup> technology platform for respiratory diseases, cancer, and other indications, reported financial results for the second quarter of 2022 ended June 30, 2022, and provided an update on the Company's recent and anticipated future developments.

"AstraZeneca's deep support of PRS-060/AZD1402 and the Anticalin platform continues and has resulted in thoughtful adjustments to the PRS-060/AZD1402 phase 2a study design, allowing us to enroll patients amidst the challenges presented by COVID-19 precautions, as well as an extension of our research collaboration for two earlier-stage programs," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "Since the PRS-060/AZD1402 phase 2 study will take more time to enroll than originally planned, we have made the difficult but necessary decision to discontinue cinrebafusp alfa (PRS-343), despite showing clear single-agent activity in phase 1 and meaningful clinical benefit in the ongoing phase 2 study in HER2-expressing gastric cancer patients. We will continue the cost-effective development of PRS-344/S095012, our 4-1BB/PD-L1 bispecific co-developed with Servier, and PRS-220, our fully proprietary inhaled CTGF antagonist that has the generous grant support from the Bavarian government, through key clinical readouts over the next twelve months. With a more focused pipeline and co-funding mechanisms in place for our most advanced assets, we are better positioned to deliver on our overall pipeline objectives in 2023, retain a leadership position in both inhaled respiratory medicines and 4-1BB biology, and now project that our cash runway extends into the second quarter of 2024."

- **PRS-060/AZD1402 and AstraZeneca Collaboration:** AstraZeneca continues to enroll 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 Pieris is developing with AstraZeneca for the treatment of moderate-to-severe asthma. AstraZeneca conducted a reforecast of the study, which has taken into account the global challenges of recruiting for respiratory clinical trials caused by the continued impact of the COVID-19 pandemic, is broadening enrollment criteria to facilitate recruitment of the study, and plans to focus on the 3 mg cohort for the efficacy readout. Topline results are now expected to be reported by the third quarter of 2023. Upon delivery of these results, Pieris may choose to exercise its co-development option. Separately, Pieris will have a future option to co-commercialize PRS-060/AZD1402 in the United States. Beyond PRS-060/AZD1402, Pieris continues to work on two discovery-stage programs with AstraZeneca, for which the research term was recently extended. Pieris retains co-development and U.S. co-commercialization options for these two programs.
  - **Cinrebafusp Alfa (PRS-343):** Cinrebafusp alfa, a 4-1BB/HER2 Anticalin-based bispecific, has demonstrated clinical benefit in phase 1 studies, including single-agent activity in a monotherapy setting, and in the phase 2 study in HER2-expressing gastric cancer, giving the Company confidence in its broader 4-1BB franchise. However, Pieris will cease further enrollment in the
-

ongoing two-arm, multicenter, open-label phase 2 study as part of a strategic pipeline prioritization to focus its resources.

- **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 Anticalin-based bispecific for the treatment of solid tumors for which Pieris holds full U.S. rights and will receive royalties on ex-U.S. sales by Servier. The companies expect to initiate expansion cohorts in jointly-vetted indications next year. Additionally, Servier is continuing development of PRS-352/S095025, an OX40/PD-L1 bispecific.
- **PRS-220:** Pieris has submitted the first regulatory filing for PRS-220, a proprietary inhaled Anticalin protein targeting connective tissue growth factor for the treatment of idiopathic pulmonary fibrosis. The Company expects to dose the first healthy volunteer in a phase 1 study later this year and to report the outcome from the study next year.
- **PRS-342/BOS-342:** Boston Pharmaceuticals continues to advance PRS-342/BOS-342, a 4-1BB/GPC3 bispecific, towards the clinic, with phase 1 expected to begin in the first half of 2023.
- **Seagen Collaboration:** Seagen continues development of two undisclosed bispecific programs as part of its immuno-oncology collaboration with the Company. Pieris has a U.S. co-promotion option for one program in the collaboration.

#### **Second Quarter Financial Update:**

**Cash Position** – Cash, cash equivalents, and investments totaled \$80.9 million for the quarter ended June 30, 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 the first half of 2022. With the wind down of the cinrebafusp alfa phase 2 trials, along with the expectation of modest near-term development milestones, the Company believes operations are sufficiently funded into the second quarter of 2024.

**R&D Expense** - R&D expenses were \$11.9 million for the quarter ended June 30, 2022, compared to \$15.8 million for the quarter ended June 30, 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, as well as due to lower manufacturing costs across all later-stage respiratory and immuno-oncology programs, lower collaboration license fees, and lower consulting costs. These lower costs were partially offset by higher clinical costs for PRS-344/S095012, higher manufacturing and pre-clinical costs for earlier stage programs, and an increase in personnel costs.

**G&A Expense** - G&A expenses were \$4.1 million for the quarter ended June 30, 2022, compared to \$4.2 million for the quarter ended June 30, 2021. The period-over-period decrease was driven primarily by lower professional service costs and lower facilities costs, partially offset by higher travel expenses.

**Other Income** - For the quarter ended June 30, 2022, \$1.2 million of grant income was recorded with respect to PRS-220 compared to \$0.8 million for the quarter ended June 30, 2021. The increase is due to higher levels of activity as the Company plans to initiate a phase 1 study for PRS-220 this year.

**Net Loss** - Net loss was \$10.3 million or \$(0.14) per share for the quarter ended June 30, 2022, compared to a net loss of \$15.5 million or \$(0.25) per share for the quarter ended June 30, 2021.

#### **Conference Call:**

Pieris management will host a conference call beginning at 8:00 AM EDT on Thursday, August 4, 2022, to discuss the second quarter financial results and provide a corporate update. Individuals can join the call by dialing (800) 285-6670 (Toll Free US & Canada) or (713) 481-1320 (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](http://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](http://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; the potential for Pieris' development programs such as PRS-060/AZD1402, 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 and/or milestone payments provided for in our collaboration agreements; making IND filings or achieving other milestones related to our programs, including PRS-060/AZD1402, PRS-220, 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 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 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](http://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.

**Investor Relations Contact:**

Pieris Pharmaceuticals, Inc.  
Maria Kelman  
Executive Director, Investor Relations  
+1 857 362 9635  
[kelman@pieris.com](mailto:kelman@pieris.com)

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

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



---

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

	June 30, 2022	December 31, 2021
<b>Assets:</b>		
Cash and cash equivalents	\$ 54,257	\$ 117,764
Short term investments	26,679	—
Accounts receivable	1,264	3,313
Prepaid expenses and other current assets	8,704	6,548
<b>Total current assets</b>	<b>90,904</b>	<b>127,625</b>
Property and equipment, net	17,430	19,122
Operating lease right-of-use assets	3,617	3,909
Other non-current assets	2,358	2,904
<b>Total Assets</b>	<b>\$ 114,309</b>	<b>\$ 153,560</b>
<b>Liabilities and stockholders' equity:</b>		
Accounts payable	\$ 1,898	\$ 8,609
Accrued expenses	10,785	16,836
Deferred revenue, current portion	22,863	25,116
<b>Total current liabilities</b>	<b>35,546</b>	<b>50,561</b>
Deferred revenue, net of current portion	22,063	38,403
Operating lease liabilities	12,335	13,841
<b>Total Liabilities</b>	<b>69,944</b>	<b>102,805</b>
Total stockholders' equity	44,365	50,755
<b>Total liabilities and stockholders' equity</b>	<b>\$ 114,309</b>	<b>\$ 153,560</b>

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,	
	2022	2021	2022	2021
Revenues	\$ 3,698	\$ 3,285	\$ 14,686	\$ 18,918
<b>Operating expenses</b>				
Research and development	11,947	15,800	26,013	32,362
General and administrative	4,081	4,246	8,460	8,376
<b>Total operating expenses</b>	16,028	20,046	34,473	40,738
<b>Loss from operations</b>	(12,330)	(16,761)	(19,787)	(21,820)
Interest income	132	3	129	6
Grant income	1,184	796	3,314	796
Other income (expense), net	676	464	905	1,348
<b>Net loss</b>	\$ (10,338)	\$ (15,498)	\$ (15,439)	\$ (19,670)
Basic and diluted net loss per share	\$ (0.14)	\$ (0.25)	\$ (0.21)	\$ (0.33)
Basic and diluted weighted average shares outstanding	74,125	61,905	73,919	59,116

# PIERIS PHARMACEUTICALS



*CORPORATE PRESENTATION*  
*August 2022*

*SUPERIOR MEDICINES THROUGH EFFICIENT BIOLOGY*



# Forward-Looking Statements

This presentation 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 presentation that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the timing for initiation of clinical trials of PRS-220; whether PRS-220 will provide a clinical benefit in the treatment of IPF and PASC-related fibrosis; the receipt of royalty and/or milestone payments provided for in our collaboration agreements; 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 Company's cash resources, 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, PRS-344/S095012, PRS-352/S095025, PRS-342/BOS-342, and PRS-400; our continued progress in the areas of co-stim bispecifics and inhaled therapeutics; the therapeutic potential of our Anticalin platform; the potential addressable market for our product candidates; and the advancement of and funding for 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 or geo-political issues, including the conflict in Ukraine; and market conditions. These forward-looking statements are made as of the date of this presentation, 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](http://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 subsequent Quarterly Reports on Form 10-Q.

# Executive Summary

## Proven Discovery Platform

- Protein therapeutics that exploit biology validated by mAbs yet are engineered for focused activity at disease locus
- Clinical benefit, reduced side effects, increased convenience

## Two Focus Areas

- Oral inhaled antagonists for respiratory disease
- Locally activated immuno-oncology bispecifics

## Industry & Clinical Validation

- ~\$200M since 2017 in upfronts, milestones and equity investments
- Several co-developed and out-licensed programs
- Demonstrated clinical activity for both focus areas

## Value Proposition

- Third asset expected to be in the clinic by year-end 2022
- All clinical assets are funded ~50% or more by partners or grants
- Retained US or WW rights for each of the three clinical programs
- Key updates for each of the three clinical programs in 2023



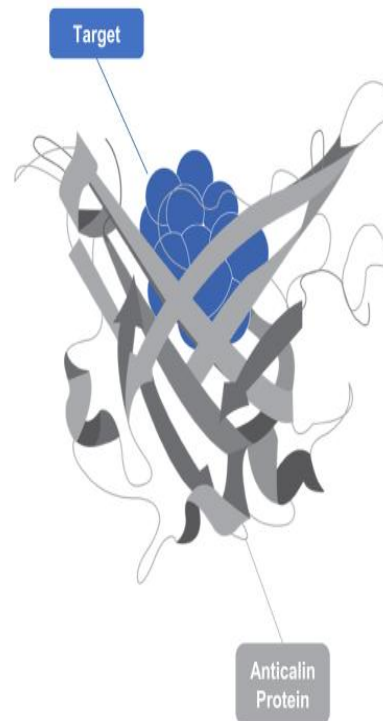
# Anticalin<sup>®</sup> Proteins as Therapeutic Modalities

## A Novel Therapeutic Class with Favorable Drug-Like Properties

- **Human** – Derived from lipocalins (human extracellular binding proteins)
- **Small** – Monomeric, monovalent, small size (~18 kDa vs. ~150kDa mAbs)
- **Stable** – Inhalable delivery
- **Simple** – Bi/multispecific constructs
- **Proprietary** – Strong IP position on platform and derived products

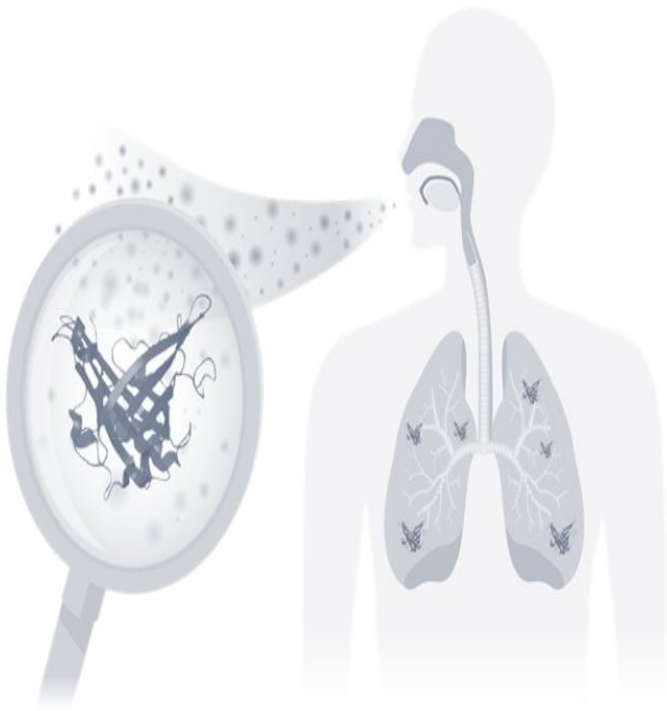
## Translational Science Expertise to Deploy Platform in Meaningful Way

- Immunology expertise underpins IO and respiratory focus
- A leader in 4-1BB and costim biology
- Patient stratification efforts for improved stratification and novel targets in, e.g., asthma

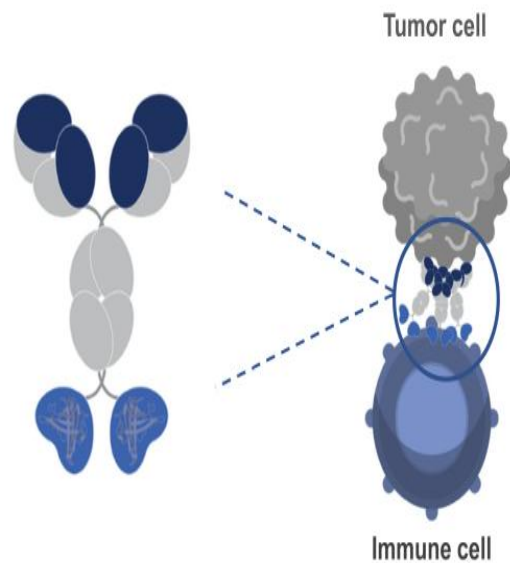


# Two-fold Focus of Anticalin Platform Deployment

Inhalable formulations to treat respiratory diseases locally








Bispecifics for local immune agonism to treat cancer





# Validating Partnerships & Non-Dilutive Capital

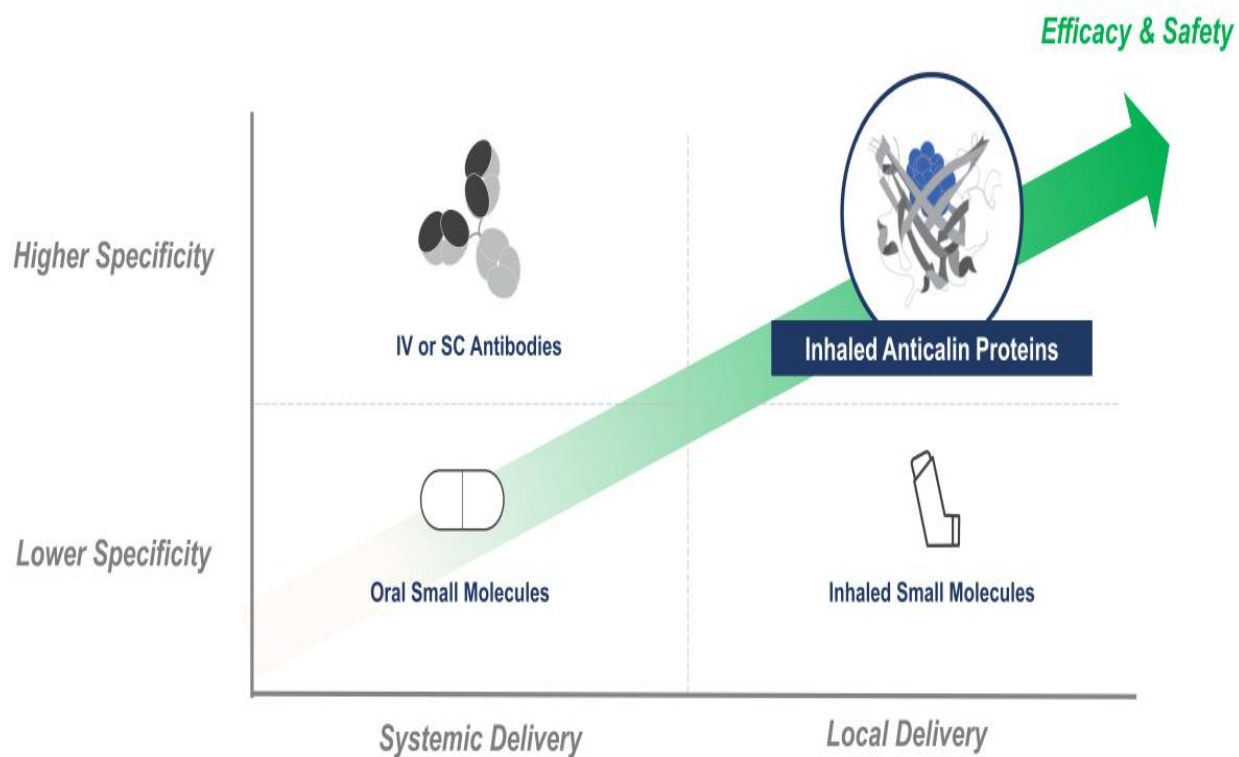
	Number of Programs	Cash to Date	Cash Potential*
	Three (all with co-dev)*	\$70.5M	>\$5B plus royalties
 <small>A Member of the Roche Group</small>	Two	\$20M	>\$1.4B plus royalties
	Two (one co-dev program)	~\$41M	~\$220M plus royalties
	Three (one with U.S. copromotion option)**	\$35M	\$1.2B plus royalties
	One	\$10M	~\$350M

\*As of July 2022, there are three programs, each with a co-dev/U.S. co-commercialization option






\*\* Two active bispecific programs with a base option for an additional one

\*As of June 30, 2022

# Combined Potential Advantages of Higher Specificity with Local Delivery



# Respiratory Pipeline

Program	Target	Indication	Discovery	Preclinical	Phase 1	Phase 2	Partner
PRS-060/AZD1402*	IL4Rα	Asthma	Phase 2a fully sponsored by AZ; co-dev option				AstraZeneca 
PRS-220	CTGF	IPF, PF-ILD, PASC-PF#	>50% grant-funded‡				
AstraZeneca Programs**	n.d.	n.d.					AstraZeneca 
PRS-400	n.d.	n.d.					
Genentech (GENE1)	n.d.	n.d.					Genentech <small>A Member of the Roche Group</small>

#IPF - Idiopathic Pulmonary Fibrosis, PF-ILD - Progressive Fibrosing Interstitial Lung Diseases, PASC-PF - Post-Acute sequelae of SARS-CoV-2 infection (PASC) Pulmonary Fibrosis (PF)

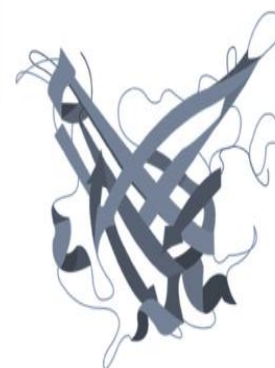
‡~\$17 million grant from the Bavarian government to evaluate PRS-220 in PASC-PF covers more than half of early-stage and phase 1 development costs of PRS-220

\*Pieris has separate co-development and U.S. co-commercialization options on PRS-060/AZD1402

\*\*Pieris has separate co-development and U.S. co-commercialization options for the two additional programs partnered with AstraZeneca

# PRS-060/AZD1402: Inhaled IL-4R $\alpha$ Antagonist

Candidate	PRS-060/AZD1402
Function/MoA	Inhibiting IL4-R $\alpha$ (disrupts IL-4 & IL-13 signaling)
Indications	Moderate-to-severe asthma
Development	Phase 2a in moderate asthmatics
Commercial Rights	Co-development and U.S. co-commercialization options with gross margin share or royalties



PRS-060/AZD1402

# PRS-060/AZD1402 Phase 2a Study

## Part 1 (Safety)

**Participant Population:** Moderate asthmatics controlled on ICS/LABA  
**Primary Endpoint:** Safety and tolerability compared to placebo from baseline until follow-up (approximately 56 days)  
**Doses:** 1 mg (completed), 3 mg (completed), 10 mg (enrolling)

## Part 2 (Efficacy)

**Participant Population:** Moderate uncontrolled asthmatics on ICS/LABA with blood EO count of  $\geq 150$  cells/ $\mu$ L and FeNO  $\geq 25$  ppb at screening  
**Primary Endpoint:** Improvement of FEV1 at four weeks relative to placebo  
**Doses\*:** 1 mg (enrolling), 3 mg (enrolling)

Safety initiated Q1 2021; efficacy initiated Q1 2022

Dry powder formulation, administered b.i.d. over four weeks on top of standard-of-care therapy (medium dose ICS with LABA)

Study is sponsored, conducted, and funded by AstraZeneca



\*1 mg dose cohort will cease enrolling with protocol amendments; 3 mg dose cohort will be the focus of the topline readout



## DPI Formulation of PRS-060/AZD1402 Passed Safety Review

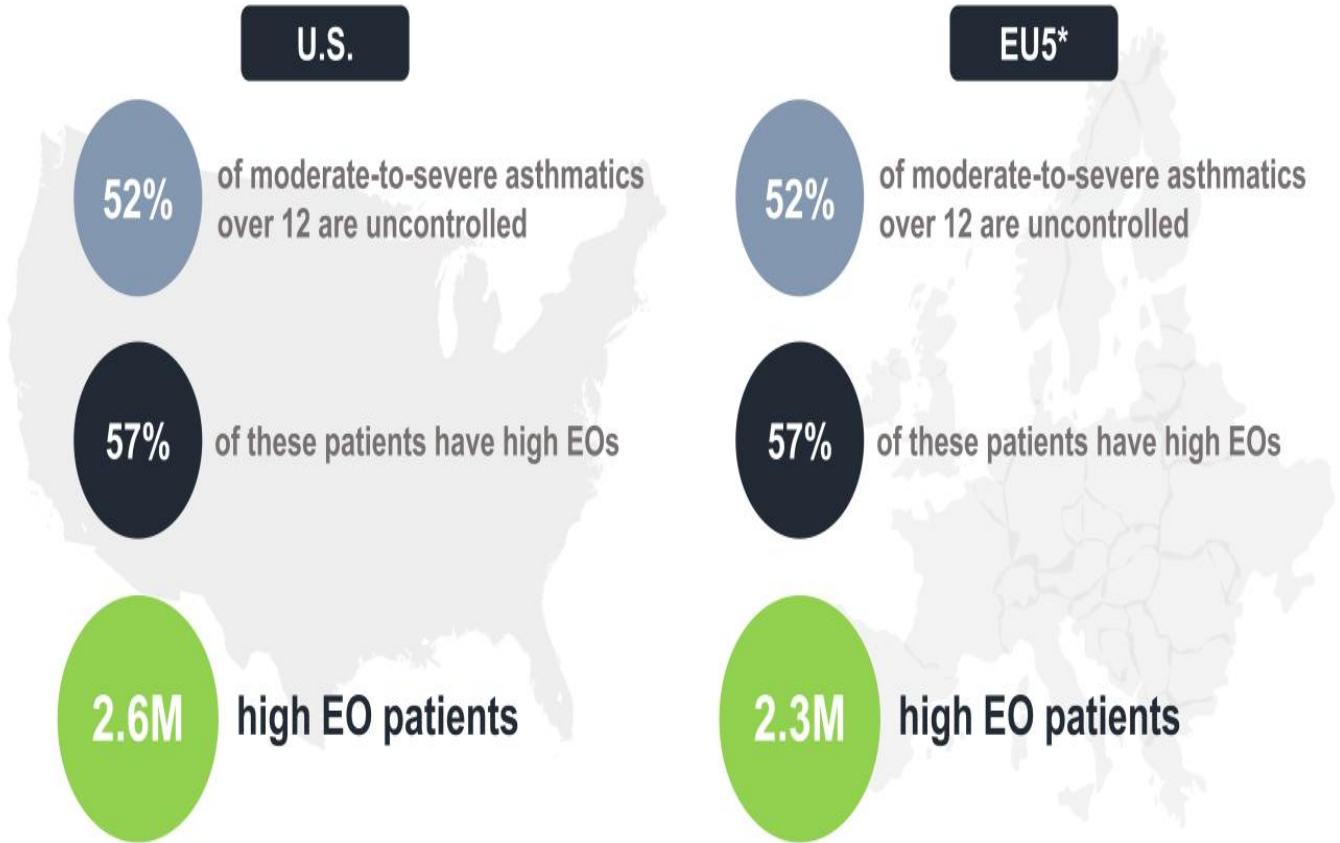
31 moderate asthmatics controlled on standard-of-care therapy (medium dose ICS with LABA) were dosed twice daily over four weeks randomized across two dose levels and placebo (1:1:1)

Safety review successfully completed for two dose levels (1mg and 3mg), triggering efficacy portion of study for those same doses in participants with moderate asthma uncontrolled on medium dose ICS-LABA

Safety review performed of the following (compared to placebo):

- Incidence of adverse events
- Changes in laboratory markers (immune biomarkers, clinical chemistry, and hematology)
- Forced expiratory volume in 1 second (FEV1)
- Pharmacokinetics

# Significant Market Opportunity in High EO Moderate-to-Severe Asthma

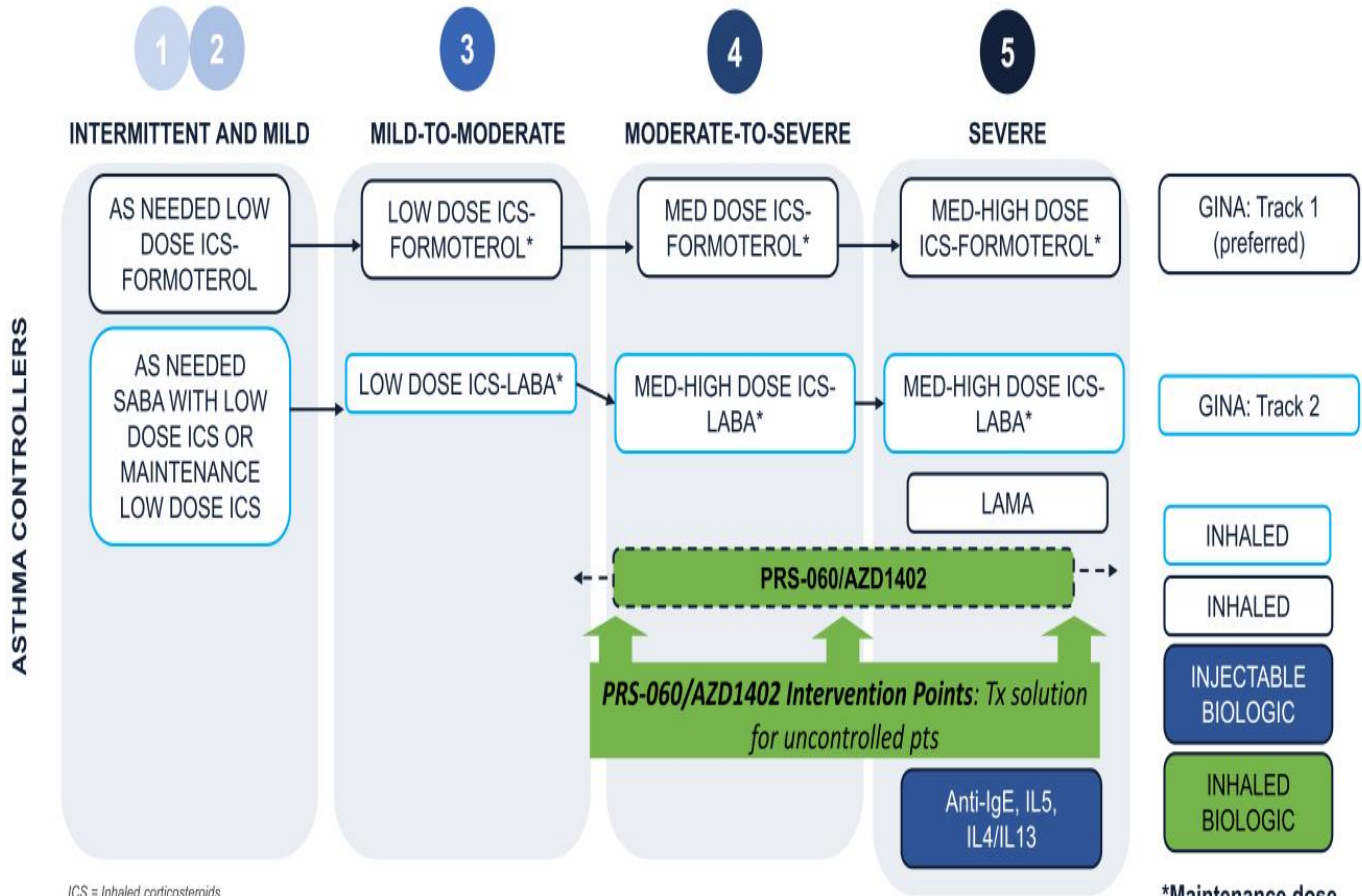


\*United Kingdom, Germany, France, Spain and Italy  
All numbers reflect 2022 estimates.

Sources: Artisan Healthcare Consulting analysis (2022), including the following: CDC, Journal of Asthma and Allergy, The Journal of Allergy and Clinical Immunology, International Society of Pharmacoepidemiology



# Potential Large Market Opportunity in Moderate-to-Severe Asthma not Addressed by ICS/LABA before Injectable Biologics



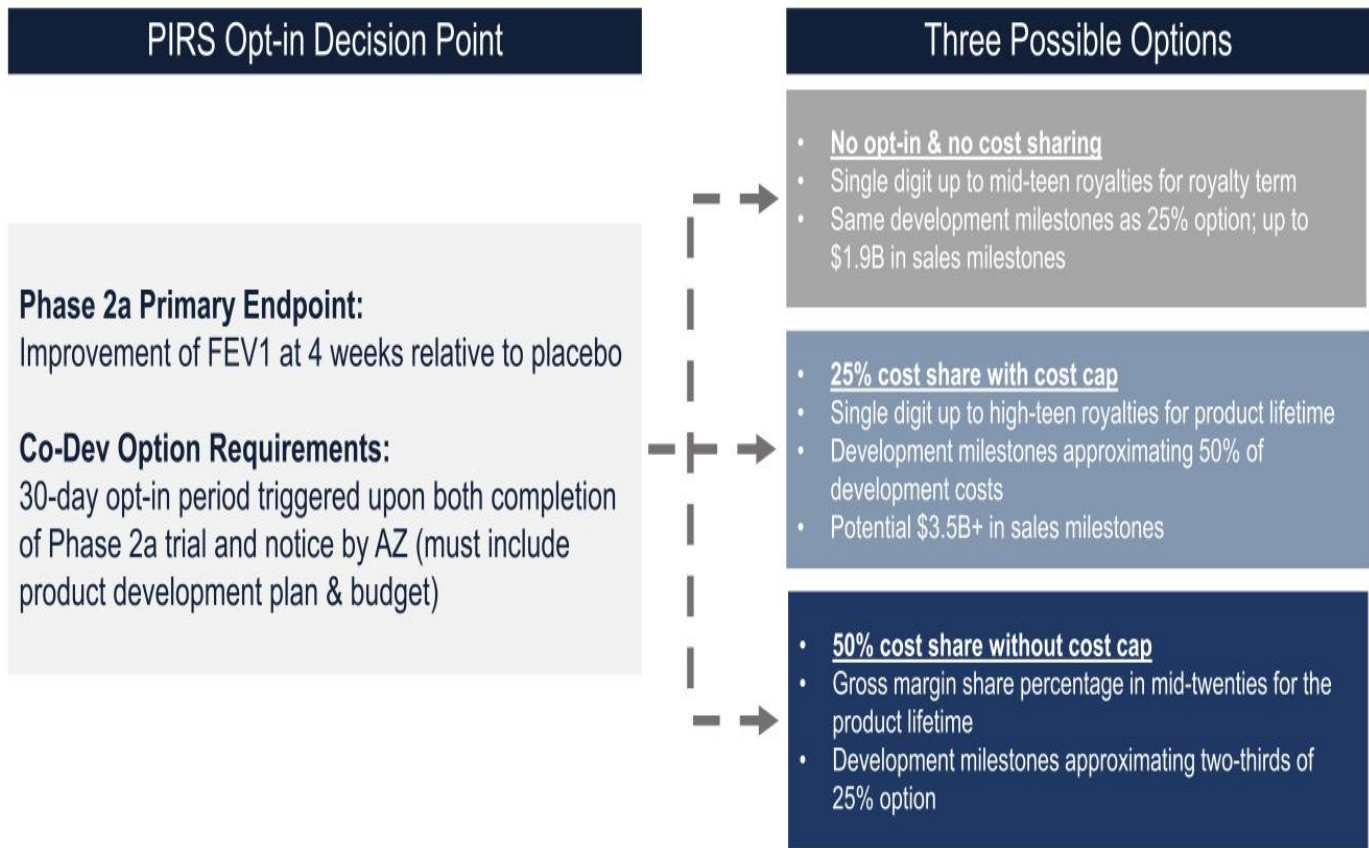
ICS = Inhaled corticosteroids  
 SABA = Short-acting  $\beta_2$  adrenergic receptor agonists  
 LABA = Long-acting  $\beta_2$  adrenergic receptor agonists  
 LAMA = Long-acting muscarinic antagonists

Global Initiative for Asthma (GINA) Steps (2021)





# Co-Development Options for PRS-060/AZD1402



# PRS-220: Inhaled CTGF Antagonist

Candidate	PRS-220
Function/MoA	Inhibiting CTGF/CCN2
Indications	IPF, PF-ILD and PASC-PF*
Development	Entering phase 1 in healthy subjects this year
Commercial Rights	Fully proprietary



PRS-220

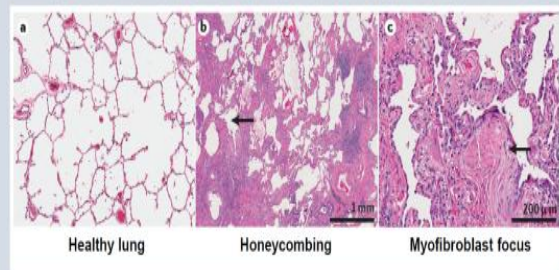
\*IPF - Idiopathic Pulmonary Fibrosis

\*PF-ILD - Progressive Fibrosing Interstitial Lung Diseases

\*PASC-PF - Post-Acute sequelae of SARS-CoV-2 infection (PASC) Pulmonary Fibrosis (PF)

# IPF: High Unmet Medical Need and Significant Commercial Opportunity

**PF – a chronic lung disease:**  
ultimately fatal lung disease of unknown cause characterized by progressive scarring of the interstitial lung tissue



Martinez, Nature Rev Dis Primer, 2017

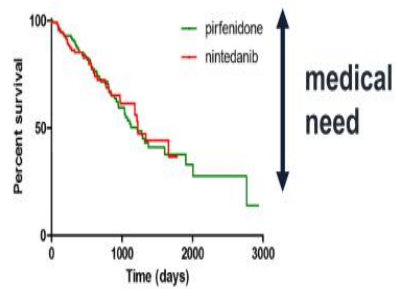
3 to 5 years

median survival from the time of diagnosis

*Hopkins, European Respiratory Journal, 2016*

2

approved therapies nintedanib & pirfenidone providing modest benefit with significant side effects



Adapted from Cameli, Frontiers in Molecular Biosciences, 2020

>\$3B

current market in sales

Significant need for well-tolerated and effective therapies

# Inhaled Delivery of PRS-220: A Novel Approach to Modulate CTGF Biology with Best-in-Class Potential

Potential key points of differentiation of inhaled PRS-220 compared to systemically delivered CTGF antagonists:

## More Efficient Target Saturation

- Avoidance of systemic CTGF sink (in blood)
- Significantly higher affinity with superior binding profile





## Superior Lung Biodistribution

- Local delivery to the site of the disease in the lung via inhalation
- Increased concentration

## Increased Convenience

- Inhalation at home compared to regular visits to infusion centers for i.v. administrations

# Immuno-Oncology Pipeline

Program	Target	Indication	Discovery	Preclinical	Phase 1	Phase 2	Partner
PRS-344/ S095012	4-1BB/PD-L1	n.d.	~50% co-dev cost share				
PRS-352/ S095025	OX40/PD-L1	n.d.					
Seagen programs <sup>†</sup>	Co-stim Agonist	n.d.					
PRS-342/ BOS-342	4-1BB/GPC3	n.d.					

<sup>†</sup> Two active bispecific programs in collaboration with Seagen, with Pieris retaining a U.S. co-promotion option in one of the programs



# 4-1BB & The Advantages of Anticalin-based Bispecifics

## High-value target

- 4-1BB activation can drive massive proliferation and improved cytotoxic profile of tumor-specific T cells
- 4-1BB activation significantly increases mitochondrial load, improving metabolic fitness and overall survival of T cells

## Historical challenges of systemic mAbs

- Despite showing clinical activity, systemically active mAbs caused unmanageable hepatic toxicity and were discontinued

## Local activation solution

- Pieris' bispecifics are designed to efficiently activate 4-1BB on T cells and NK cells outside the liver to avoid hepatic toxicity and drive improved therapeutic window
- Earlier clinical studies validated this mode of action: well-tolerated and single-agent activity in heavily pre-treated patients

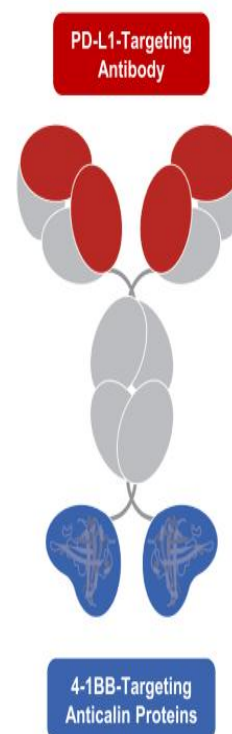
## 4-1BB-based Bispecific Achieved Clinical POC in Early Clinical Studies

First 4-1BB-based bispecific in the clinic (cinrebafusp alfa) provided key validation of multi-program 4-1BB franchise

- ✓ Acceptable safety profile observed at all doses tested with no dose-limiting toxicities
- ✓ Clinical benefit at active dose levels ( $\geq 2.5$  mg/kg), including confirmed complete response and several confirmed partial responses
- ✓ Dose-dependent immune activation and 4-1BB modulation in both HER2-high and HER2-low expressing patients
- ✓ Durable anti-tumor activity in heavily pre-treated patient population (5+ line on average), including "cold" tumors

## PRS-344/S095012: Building on Localized MoA of Cinrebafusp Alfa

Candidate	PRS-344/S095012
Function/MoA	Localized 4-1BB agonism with PD-L1 antagonism
Indications	N.D.
Development	Phase 1 (in co-dev with Servier)
Commercial Rights	Full U.S. commercial rights; royalty on ex-U.S. sales

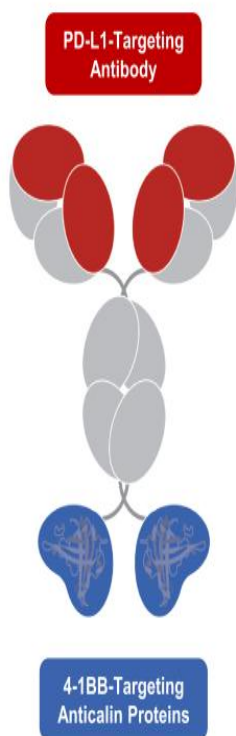




# PRS-344/S095012: Why 4-1BB/PD-L1

*PRS-344/S095012 is designed to activate 4-1BB on tumor-specific T cells when bridging to PD-L1-expressing tumors and dendritic cells*

*Molecule designed to drive potent 4-1BB agonism with an optimal therapeutic window*



Affinity	Binds with 5nM affinity to 4-1BB (lower than competitors) with 7-fold higher affinity to PD-L1 (0.6nM)
Valency	Bivalent 4-1BB inactive peripherally but potent activation potential when clustered on PD-L1-positive cells
Geometry and flexibility	Empirically tested multiple bispecific prototypes for best effect with objective of recreating natural immune synapse
4-1BB epitope	Ligand independent to avoid disrupting peripheral immune surveillance (safety) while facilitating ligand engagement when drug-bound (efficacy)

## Financial Overview (as of 6/30/22)



>\$175M non-dilutive capital from partnerships since 2017

~\$17M<sup>1</sup> grant announced in 2021

255 State Street  
Boston, MA 02109  
USA

Zeppelinstraße 3  
85399 Hallbergmoos  
Germany



Nasdaq: PIRS

IR: [kelman@pieris.com](mailto:kelman@pieris.com)  
BD: [bd@pieris.com](mailto:bd@pieris.com)  
[www.pieris.com](http://www.pieris.com)

*SUPERIOR MEDICINES THROUGH EFFICIENT BIOLOGY*



