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): May 25, 2022

PIERIS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Nevada	**001-37471**	**30-0784346**
(State or other jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

255 State Street, 9th Floor	**02109**
Boston, MA	
(Address of principal executive offices)	**(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 7.01 Regulation FD Disclosure.

Furnished hereto as Exhibit 99.1 is the May 2022 Investor Presentation of the Company.

The information set forth under this "Item 7.01. Regulation FD Disclosure," including Exhibit 99.1 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 Investor Presentation, dated May 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: May 25, 2022

/s/ Tom Bures
Tom Bures
Chief Financial Officer

PIERIS PHARMACEUTICALS

CORPORATE PRESENTATION
May 2022

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; whether the combination of cinrebafusp alfa with other therapies could address a high medical need in HER2 gastric cancer patients who do not respond to traditional HER2-targeted therapies; whether the effects of the combination of cinrebafusp alfa with other therapies seen in preclinical studies will be observed in clinical trials; the receipt of royalty 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, cinrebafusp alfa, 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 potential addressable market for our product candidates; 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 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, 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

Superior Medicines via Efficient Biology	• Protein therapeutics that exploit biology validated by mAbs yet are engineered for focused activity at disease locus • Improved activity, reduced side effects, increased convenience
Two Focus Areas	• Oral inhaled antagonists for respiratory disease • Locally activated immuno-oncology bispecifics • Four clinical stage assets expected by year-end, with three programs at least half-funded by partners/grant income
Supportive Partnerships	• ~$200M since 2017 in upfronts, milestones and equity investments • Several co-developed and out-licensed programs • Clinical supply for combination studies and development expertise

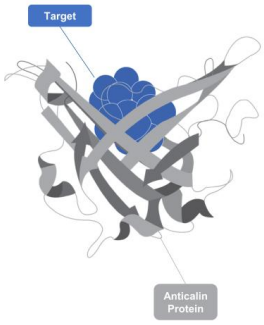
Anticalin® Proteins as Therapeutic Modalities

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** – Broad IP position on platform and derived products

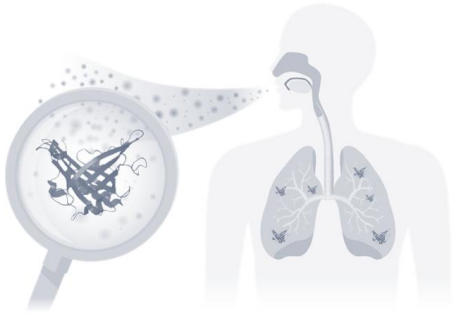
Translational Science Expertise to Deploy Platform in Meaningful Way

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

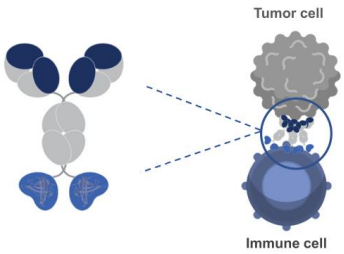


Two-fold Focus of Anticalin Platform Deployment

Inhalable formulations to treat respiratory diseases locally



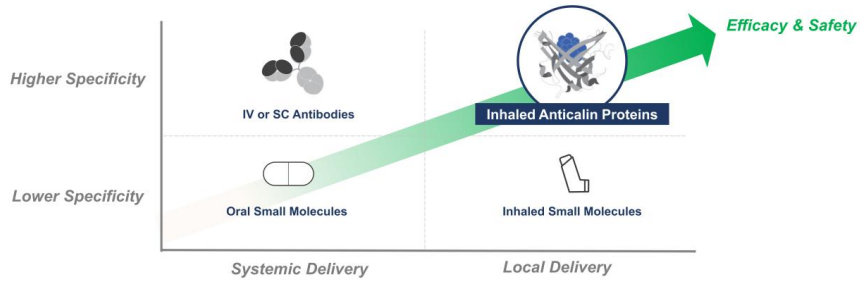
Bispecifics for local immune agonism to treat cancer



Validating Partnerships & Non-Dilutive Capital

AstraZeneca	• PRS-060/AZD1402 (co-dev option) + 3 additional programs • Upfront & milestones to date: $70.5M • Eligible for over $5B in potential milestone payments plus royalties
Genentech A Member of the Roche Group	• 1 respiratory program + 1 ophthalmology program • Upfront & milestones to date: $20M • Eligible for $1.4B in potential milestone payments plus royalties
SERVIER	• PRS-344/S095012 & PRS-352/S095025 • Upfront & milestones to date: ~$41M • Eligible for ~$230M in potential milestone payments plus royalties
Seagen	• 3-program IO bispecific partnership • Upfront & milestones to date: $35M • Eligible for $1.2B in potential milestone payments plus royalties
BOSTON pharmaceuticals	• Boston Pharmaceuticals holds exclusive license for PRS-342/BOS-342 • Upfront & milestones to date: $10M • Eligible for ~$353M in potential milestone payments and royalties

Inhaled Anticalin Proteins are a Promising Strategy for the Treatment of Respiratory Diseases



Pieris Strategy	Local, specific, and more efficient targeting of disease-relevant pathways in the lung via inhaled delivery of Anticalin proteins

Respiratory Pipeline

Program	Target	Indication	Discovery	Preclinical	Phase 1	Phase 2	Partner
PRS-060/AZD1402*	IL4Rα	Asthma	Phase 2a fully sponsored by AZ				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

#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 U.S. co-development and co-commercialization options on PRS-060/AZD1402*
***Pieris has U.S. co-development options for two of three additional programs partnered with AstraZeneca*

PRS-060/AZD1402: Inhaled IL-4Rα Antagonist

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

PRS-060/AZD1402

PRS-060/AZD1402 Progressed into Efficacy Portion of Phase 2a

Part 1 (Safety)	✓ Part 1a: 1mg + 3 mg Dose ❑ Part 1b: 10 mg Dose	**Participant Population:** Moderate asthmatics controlled on ICS/LABA **Primary Endpoint:** Safety and tolerability compared to placebo from baseline until follow-up (approximately 56 days) **# of Participants:** ~45 (randomized: 1:1:1 for part 1a; 2:1 for part 1b)
Part 2 (Efficacy)	❑ Part 2a: 1mg + 3 mg Dose ❑ Part 2b: 10 mg Dose	**Participant Population:** Moderate uncontrolled asthmatics on ICS/LABA with blood EO count of ≥ 150 cells/µL and FeNO ≥ 25 ppb at screening* **Primary Endpoint:** Improvement of FEV1 at four weeks relative to placebo **# of Participants:** ~300 (randomized: 1:1:1 for part 2a; 2:1 for part 2b)

Parts 1b & 2a initiated 1Q 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

*In addition to uncontrolled asthmatics with threshold EO count and FeNO profile, there are other enrollment criteria associated with part 2 not in part 1, including FEV1, and a different ACQ score.

DPI Formulation of PRS-060/AZD1402 Passed Safety Review

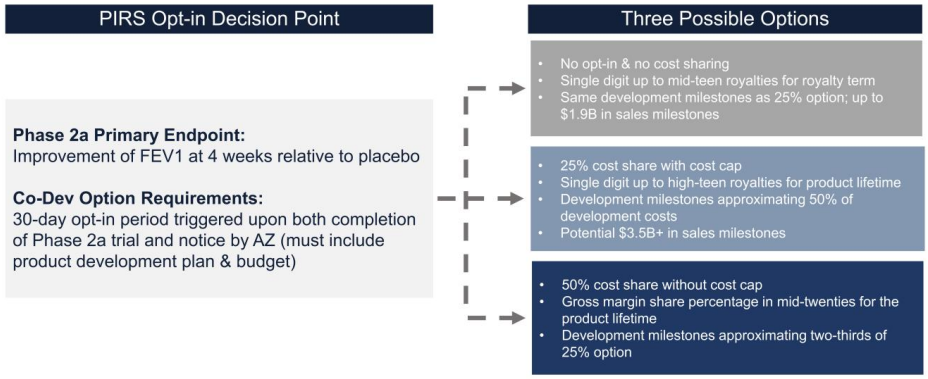
31 moderate asthmatics controlled on standard-of-care therapy (medium dose ICS with LABA) were dosed twice daily over four weeks randomized across two dose levels and placebo (1:1:1)

Safety review successfully completed for two dose levels (part 1a), triggering efficacy study (part 2a) in participants with 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

Co-Development Options for PRS-060/AZD1402



PRS-220: Inhaled CTGF Antagonist

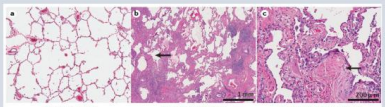
Candidate	PRS-220
Function/MoA	Inhibiting CTGF/CCN2
Indications	IPF and PASC-PF*
Development	Entering phase 1 in healthy subjects this year
Commercial Rights	Fully proprietary

PRS-220

*Idiopathic pulmonary fibrosis (IPF) and post-acute sequelae of SARS-CoV-2 infection pulmonary fibrosis (PASC-PF)

IPF: High Unmet Medical Need and Significant Commercial Opportunity

IPF is a chronic, progressive, and ultimately fatal lung disease of unknown cause characterized by chronic lung inflammation and progressive scarring (fibrosis) of the tissues between the alveoli of the lung



Martinez, Nature Rev Dis Primer, 2017

3 to 5 million people affected worldwide with increasing global incidence, with ~130K affected in the US each year[1,2]

2 to 5 years mean survival from the time of diagnosis[2]

>$3B current market in sales

Currently approved treatments provide modest benefit, in addition to having side effects that require management

1 – Glassberg, American Journal of Managed Care, 2019
2 – Meltzer & Noble, Orphanet Journal of Rare Diseases, 2008

PRS-220: Inhaled Solution

CTGF has been clinically validated with a systemically administered mAb but leaves significant room for improvement and differentiation

The only CTGF inhibitor in clinical trials for IPF is a monoclonal antibody administered by IV infusion, 30 mg/kg every three weeks

The objective of PRS-220 is to more efficiently engage a clinically validated target via oral inhalation directly to the lung epithelium and interstitium

Benefits of inhaled administration:

- Inhaled administration eliminates the need for additional clinic visits required for systemic drug administration
- Direct administration into the lungs may result in more efficient CTGF inhibition in the site of the disease
- Patients with IPF frequently take inhaled medications and thus no additional training required
- This approach supports add-on to SOC, whereas patients on SOC are excluded from current studies of reference mAb

4-1BB & the Advantages of Anticalin-based Bispecifics

High-value target	• Drives meaningful clinical benefit through proliferative, killing and durability impact on tumor-specific T cells • Improves metabolic fitness for increased survival of T cells
Historical challenges of systemic mAbs	• Despite activity, inefficient mAb approaches have led to systemic 4-1BB activation, resulting in hepatic toxicity
Local activation solution	• Bispecifics designed to efficiently activate 4-1BB on tumor-specific T cells, avoiding hepatic toxicity • Lead program is safe, well-tolerated and has single-agent activity in heavily pre-treated patients • Several 4-1BB-based follow-on programs

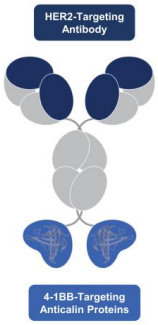
Immuno-Oncology Pipeline

Program	Target	Indication	Discovery	Preclinical	Phase 1	Phase 2	Partner
Cinrebafusp Alfa (PRS-343)	4-1BB/HER2	HER2-High GC*	Ramucirumab supplied by Eli Lilly				
		HER2-Low GC**	Tucatinib supplied by Seagen				
PRS-344/ S095012	4-1BB/PD-L1	n.d.	~50% costs covered				SERVIER
PRS-352/ S095025	OX40/PD-L1	n.d.					SERVIER
PRS-342/ BOS-342	4-1BB/GPC3	n.d.	Out-licensed				BOSTON pharmaceuticals
Seagen Programs‡	Co-stim Agonist	n.d.					Seagen

‡*3 bispecific programs in collaboration with Seagen, with Pieris retaining a US co-promotion option for one of the three programs*
** Phase 2 study includes Cinrebafusp Alfa in combination with ramucirumab and paclitaxel (HER2-high arm)*
***Phase 2 study includes Cinrebafusp Alfa in combination with tucatinib (HER2-low arm)*

Cinrebafusp Alfa (PRS-343): Lead IO Asset

Candidate	Cinrebafusp alfa (PRS-343)
Function/MoA	Tumor-targeted 4-1BB agonism and HER2 antagonism
Indications	HER2-high and HER2-low gastric cancer
Development	Phase 2
Commercial Rights	Fully proprietary



Cinrebafusp Alfa Phase 1 Summary

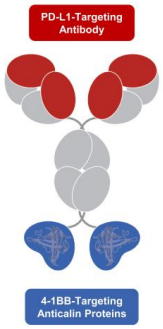
- Acceptable profile observed at all doses tested with no dose-limiting toxicities
- Clinical benefit at active dose levels (≥ 2.5 mg/kg), including confirmed complete response and several confirmed partial responses
- Dose-dependent immune activation and 4-1BB modulation in both HER2-high and HER2-low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

As lead IO program, cinrebafusp alfa provides key validation of 4-1BB franchise, including PRS-344/S095012 and PRS-342/BOS-342

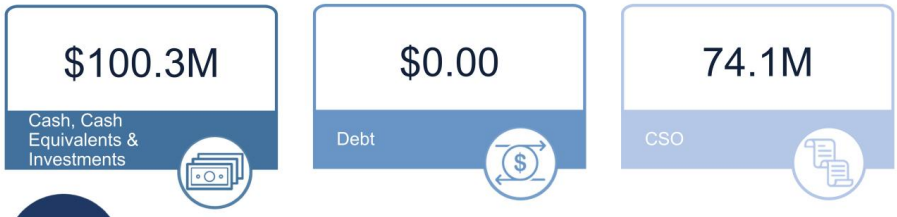
Cinrebafusp Alfa Clinical Development Plan

PRS-344/S095012: Meaningfully 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	Co-development with full U.S. commercial rights; royalty on ex-U.S. sales



Financial Overview (as of 3/31/22)



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

~$17M[1] grant announced in 2021

[1] *Calculated based on the June 25, 2021, noon buying rate of €1.00 to U.S. $1.1938*

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