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 15, 2019

PIERIS PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

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

225 State Street, 9th Floor Boston, MA	02109
(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.

Attached hereto as Exhibit 99.1 and incorporated by reference herein is the August 2019 Investor Presentation of Pieris Pharmaceuticals, Inc.

The information set forth under this "Item 7.01. Regulation FD Disclosure," including Exhibit 99.1 attached 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 August 2019.

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 15, 2019

/s/ Allan Reine

Allan Reine

Chief Financial Officer

INVESTOR PRESENTATION

AUGUST 2019

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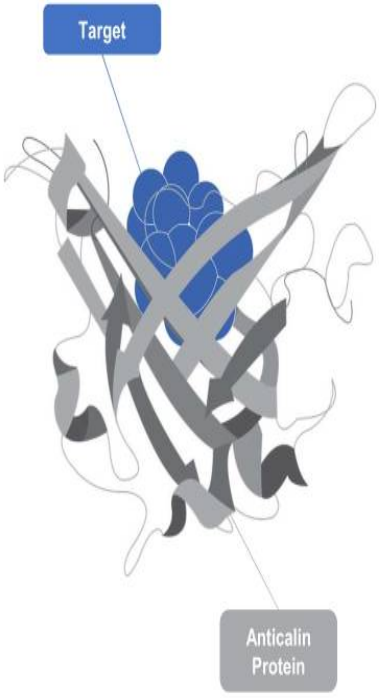
Forward Looking Statements

This presentation contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to novel technologies and methods and our business and product development plans, including the advancement of our proprietary and co-development programs into and through the clinic. 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 FDA; competition in the industry in which we operate 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 SEC available at www.sec.gov, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and the Company's Quarterly Reports on Form 10-Q.

What are Anticalin® proteins?

A Novel Therapeutic Class with Favorable Drug-Like Properties

- Derived from lipocalins (human extracellular binding proteins)
  - TLC and NGAL lipocalins used as "templates" for drug development
- Engineerable binding pocket for robust target engagement
- Monomeric, monovalent, small size (~18 kDa vs 150kDa mAbs)
- Can be formulated for inhalable delivery
- Can be formatted into novel bi/multispecific constructs
- Broad IP position



Underpinned by a Powerful Drug Discovery Platform

- Highly diverse libraries (>10^{11}) of potential drug candidates...
- Automated high-throughput drug screening technology (phage display)...
- Extensive protein engineering know-how...
- ...resulting in high hit rates, quick-to-development candidates

Company Snapshot

Pipeline Highlights

- **PRS-060:** Inhaled IL4-Rα antagonist for moderate-to-severe asthma (partnered with AstraZeneca)
- **Next-generation respiratory:** Includes 4 discovery-stage inhaled therapeutics programs (2 proprietary, 2 partnered with AstraZeneca)
- **PRS-343:** 4-1BB/HER2 bispecific for solid tumors
- **PRS-344:** 4-1BB/PD-L1 bispecific (partnered with Servier)

Anchor Partnerships

- Validation through three anchor partnerships
- $120+M in upfront payments and milestones since January 2017
- Each partnership includes options for co-development & US-focused commercialization rights
- Value-driving opt-in for PRS-060 after phase 2a completion

Inflection Points

- **Respiratory:** MAD phase 1 data, including FeNO reduction vs. placebo, for PRS-060, inhaled IL4-Rα antagonist in co-development with AstraZeneca, at ERS 2019 on Oct. 1, 2019
- **IO:** Phase 1 monotherapy data at upcoming medical meeting for PRS-343, a wholly-owned 4-1BB/HER2 bispecific
- **IO:** IND for PRS-344, 4-1BB/PD-L1 bispecific

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Pipeline

RESPIRATORY							
CANDIDATE	TARGETS	PARTNER	COMMERCIAL RIGHTS	DISCOVERY	PRECLINICAL	PHASE I	PHASE II
PRS-060	IL4-Rα	AstraZeneca	Pieris Worldwide Profit-Share Option				
Proprietary Programs	n.d.	n/a	Pieris Worldwide				
AstraZeneca Programs*	n.d.	AstraZeneca	Pieris Worldwide Profit-Share Option*				
*4 additional respiratory programs (3 active, 1 forthcoming) in collaboration with AstraZeneca, 2 of which carry co-development and co-commercialization options for Pieris							

IMMUNO-ONCOLOGY							
CANDIDATE	TARGETS	PARTNER	COMMERCIAL RIGHTS	DISCOVERY	PRECLINICAL	PHASE I	PHASE II
PRS-343	HER2/4-1BB	n/a	Pieris Worldwide				
	+ Anti-PD-L1	n/a					
PRS-344	PD-L1/4-1BB	SERVIER	Pieris U.S. Rights				
Servier Programs†	n.d.	SERVIER	Pieris U.S. Option†				
Proprietary IO Programs	n.d.	n/a	Pieris Worldwide				
Seattle Genetics Programs‡	n.d.	SeattleGenetics	Pieris U.S. Option‡				
†4 additional IO bispecific programs in collaboration with Servier, with Pieris retaining US rights for 2 of 5 programs							
‡3 bispecific programs (1 active, 2 forthcoming) in collaboration with Seattle Genetics, with Pieris retaining US rights for 1 program							

OTHER DISEASE AREAS							
CANDIDATE	TARGETS	PARTNER	COMMERCIAL RIGHTS	DISCOVERY	PRECLINICAL	PHASE I	PHASE II
PRS-080	Hepcidin	ASKA	Major Markets Ex-ASKA Territories				

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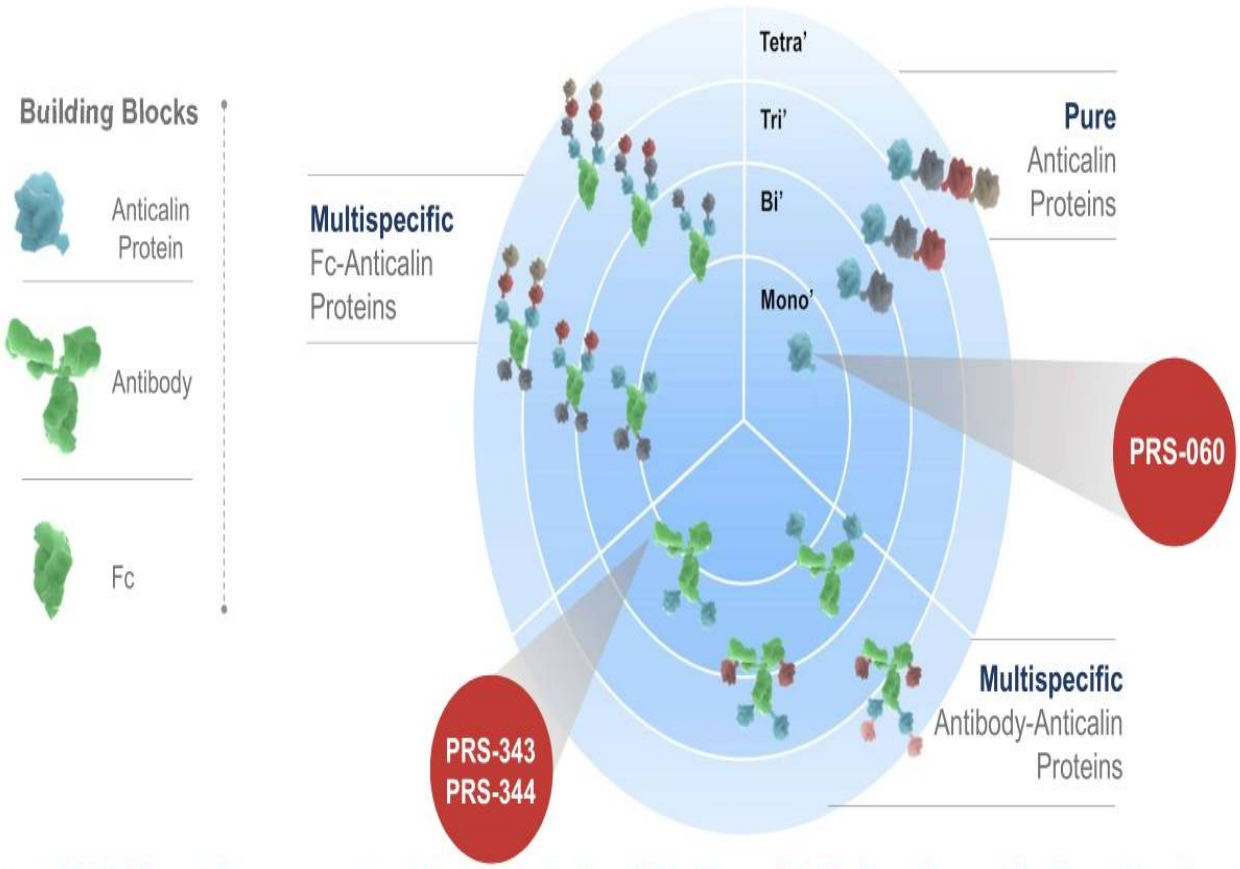
Key Value Driver:
Unique Formatting of Anticalin Protein-Based Drugs



Potent Multi-Target Engagement • Novel Inhaled and Multispecific MoA • Favorable Drug-like Properties

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Partnerships

AstraZeneca

- PRS-060 + 4 additional novel inhaled Anticalin protein programs
- Retained co-development and co-commercialization (US) options on PRS-060 and up to 2 additional programs
- $57.5M upfront & 2017 milestone
- ~$2.1B in milestone potential, plus double-digit royalties
- AZ funds all PRS-060 development costs through post-phase 2a co-development opt-in decision
- Access to complementary formulation and device know-how for inhaled delivery

SERVIER

- PRS-344: PD-L1/4-1BB antibody-Anticalin bispecific
- 5-program deal (all bispecific fusion proteins)
- Pieris retains option for full U.S. rights for 3 out of 5 programs
- ~$31M upfront payment, ~$1.8B milestone potential
  - ✓ Two preclinical milestones achieved for PRS-344
- Up to low double-digit royalties on non-co-developed products

SeattleGenetics®

- 3-program partnership based on tumor-localized costimulatory bispecific fusion proteins
- Pieris retains opt-in rights for 50/50 global profit split and U.S. commercialization rights on one of the programs
- $30M upfront payment, ~$1.2B milestone potential
- Up to double-digit royalties on non-co-developed products

Strong Partners • Significant Cash Flow • Retained Commercial Rights

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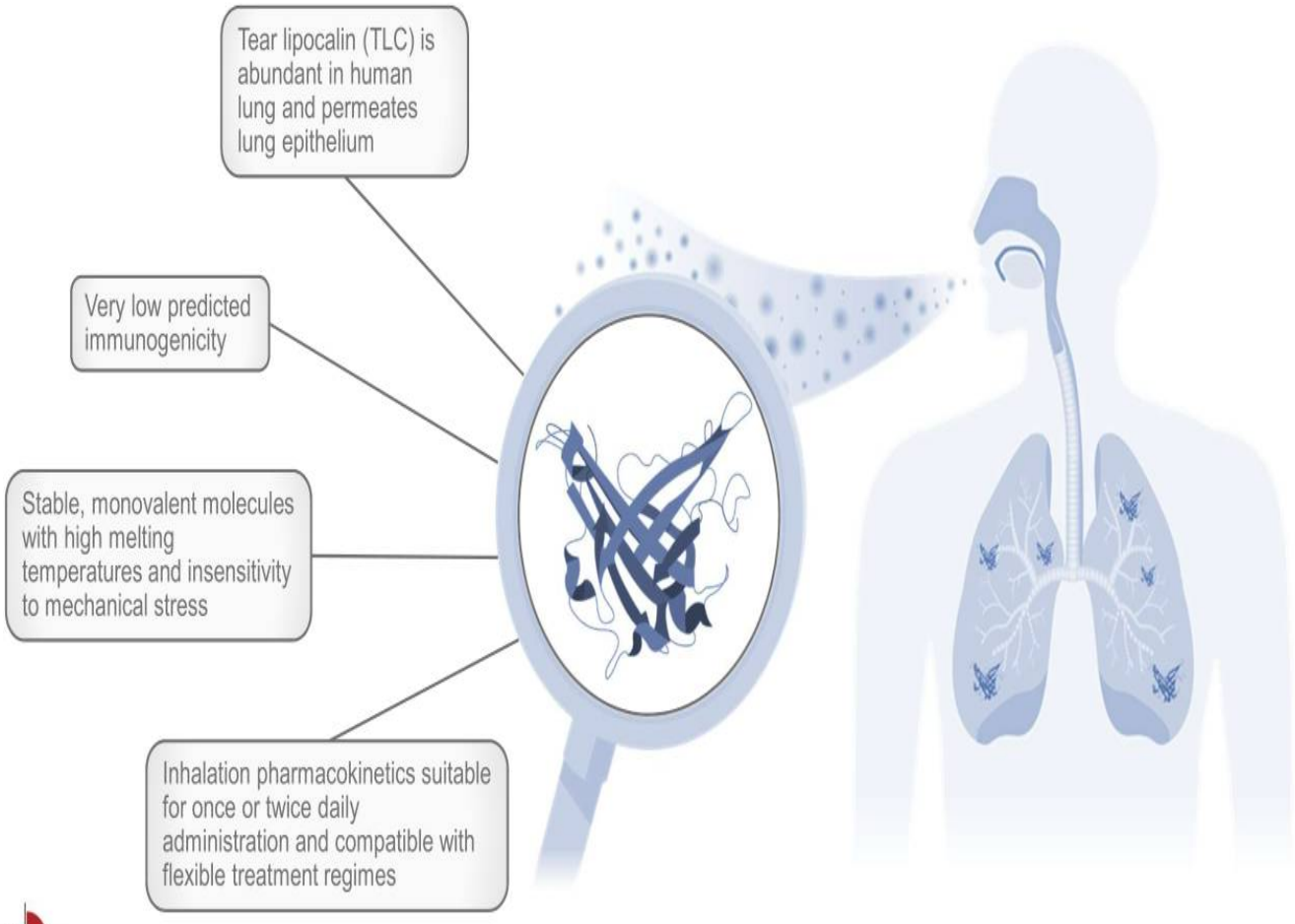
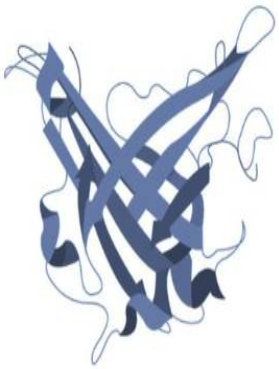
Anticalin Technology Advantages: Differentiated Respiratory Platform



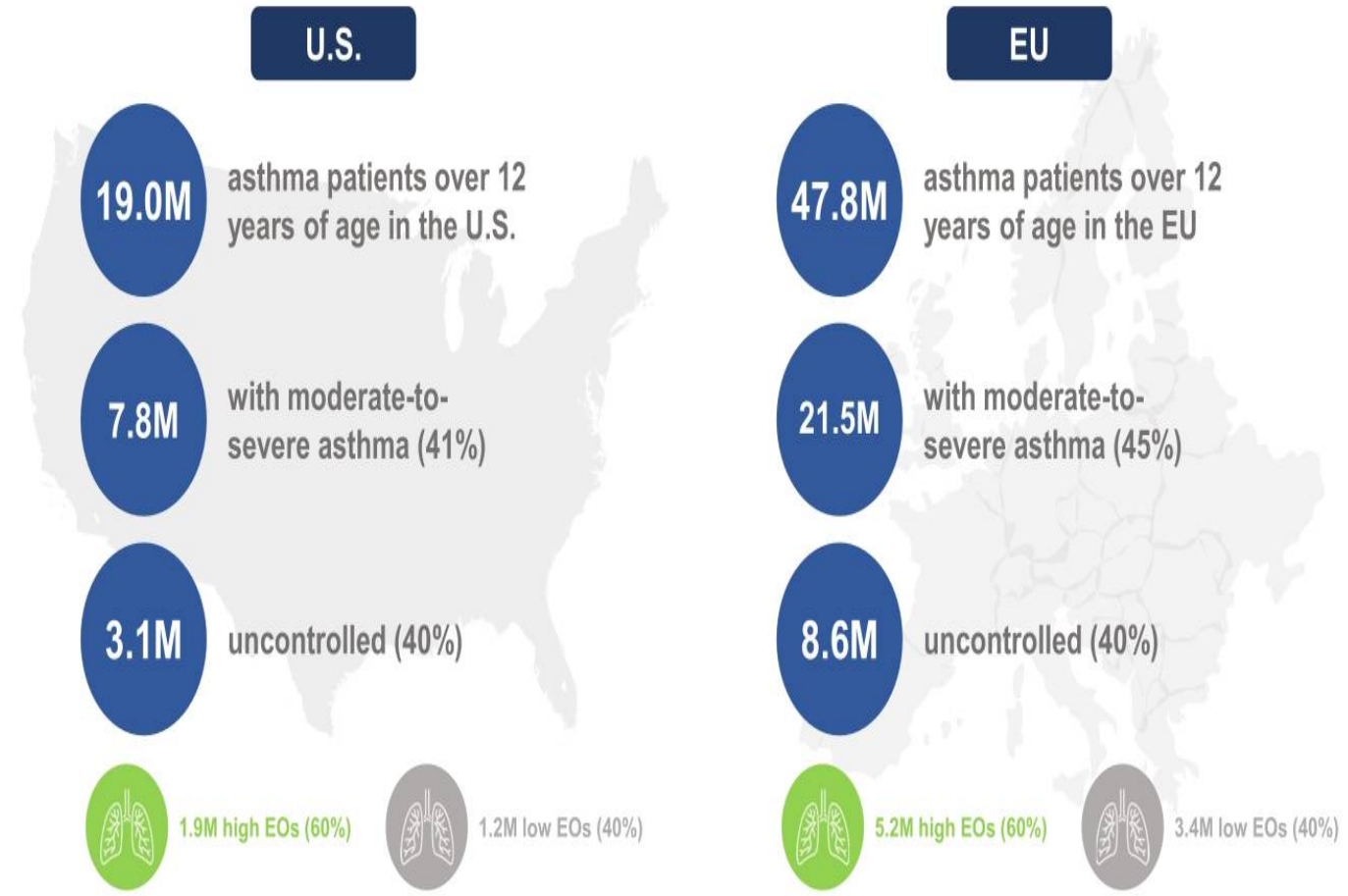
PRS-060: IL-4Rα Antagonist

Candidate	PRS-060
Function/MoA	Inhibiting IL4-Rα (disrupts IL-4 & IL-13 signaling)
Indications	Moderate-to-severe asthma
Development	Phase 1 multiple-ascending dose trial ongoing
Commercial Rights	Co-development and U.S. co-commercialization rights, including gross margin share



PRS-060

Moderate-to-Severe Asthma Market Opportunity



All numbers reflect 2016 estimates.

Source: Artisan Healthcare Consulting analysis, including the following: CDC, Eurostat, Rabe (2004), Cazzoletti (2007), Colice (2012), Hekking (2015).

IL-4Rα: Best-in-Class Efficacy for Uncontrolled Asthma

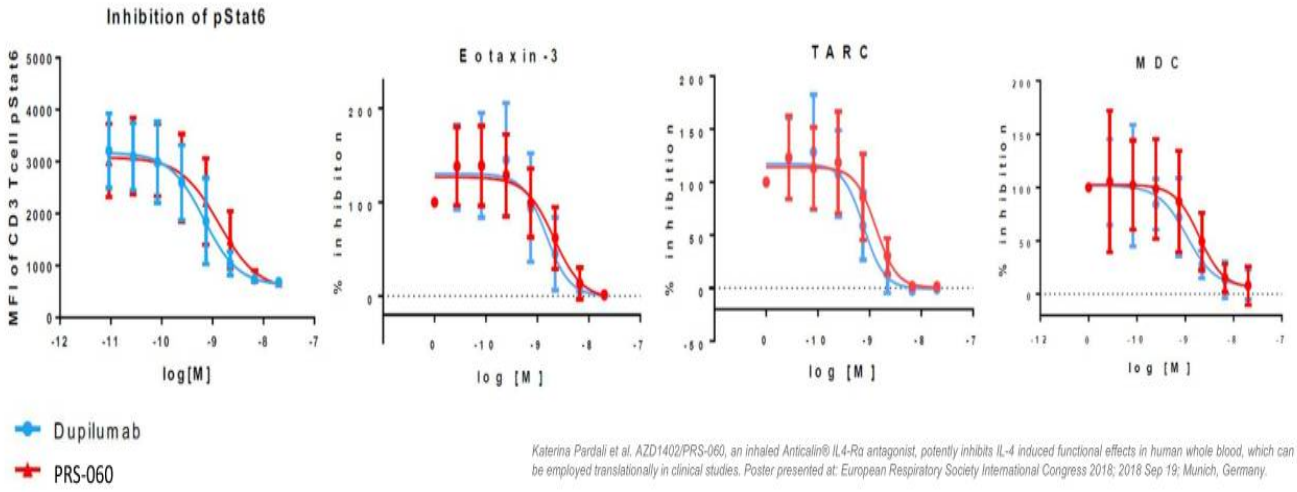
Superior data on lung function improvement, exacerbation reduction and steroid-sparing effects across all indicated biologics therapies

Approved Intervention	FeNO	Exacerbation Rate	FEV_1
Anti-IL-4Rα (dupilumab)	**Stat. sig. reduction in all comers, normalizes in ~70% of FeNO high patients, no increase following ICS/LABA withdrawal**	**High EO: 67% reduction on label (87% in Phase II)**	**Significant Change: 0.25L-0.32L in high EO population**
Anti-IL-5 (benralizumab, mepolizumab, rezlizumab)	No change	51-53% on label for benralizumab and mepolizumab	Minimal change: 0.08L-0.16L
Anti-IgE (omalizumab)	No change	43% in post-approval pediatric study (not analyzed in registrational studies)	No change

PRS-060 Potency Similar to that of Dupilumab

PRS-060 reduces levels of pSTAT6, Eotaxin-3, TARC and MDC comparably to dupilumab

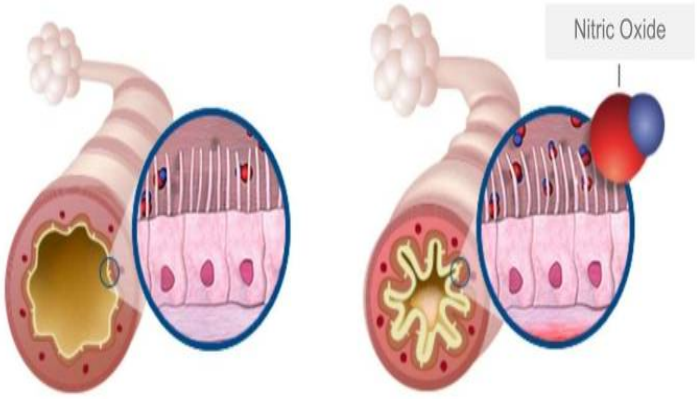
Drug	IC_{50} [nM] pSTAT6	IC_{50} [nM] Eotaxin-3	IC_{50} [nM] TARC	IC_{50} [nM] MDC
PRS-060	1.3	2.1	1.3	2.0
Dupilumab	0.8	1.5	0.8	1.1



Katerina Pardali et al. AZD1402/PRS-060, an inhaled Anticalin® IL4-Rα antagonist, potently inhibits IL-4 induced functional effects in human whole blood, which can be employed translationally in clinical studies. Poster presented at: European Respiratory Society International Congress 2018; 2018 Sep 19; Munich, Germany.

FeNO is a Validated Biomarker in Allergic Asthma Interventions

Elevated fractional exhaled nitric oxide (FeNO) is a marker of allergic asthma



Normal epithelial cells release minimal NO

During airway inflammation, activated epithelial cells increase production of NO

Biologics that have demonstrated a meaningful reduction in FeNO (dupilumab, tezepelumab) have subsequently produced clinically-significant improvements in lung function and superior exacerbation improvements versus drugs that had no on effect FeNO

Dupilumab was recently approved by the EMA for severe asthma in patients with either high EOs OR high FeNO

We are exploring FeNO reduction versus placebo in a multi-dose ascending phase 1 study of PRS-060

Positive FeNO data from this study would support continued development to assess the potential to improve lung function (FEV1) in uncontrolled asthmatics

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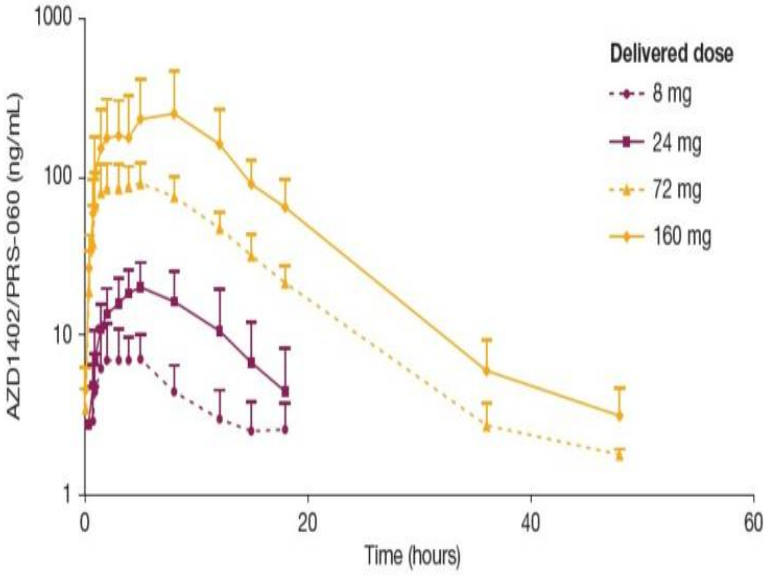
PRS-060 Phase I Single Ascending Dose Trial

Safe and well-tolerated in healthy volunteers at nominal dose levels (0.25mg to 400mg) with no SAEs reported or ADAs detected

PK profile showed slow & prolonged absorption into systemic circulation after inhalation, with mean t½ ranging from 4.1 hours to 6.2 hours across all cohorts

Dose-dependent inhibition of pSTAT6 confirms robust target engagement

PK profile of PRS-060 after inhalation confirms desired rapid serum clearance observed in preclinical studies



Ingmar Bruns et al. First-in-human data for the inhaled IL-4Rα antagonist AZD1402/PRS-060 reveals a promising clinical profile for the treatment of asthma. Poster presented at: 2019 American Thoracic Society Annual Meeting; 2019 May 22; Dallas, Texas.

-pieris-

PRS-060 Phase I Multiple Ascending Dose Trial

Strategic Objectives	Ascertain PK/PD with a reliable biomarker to confirm local target engagement and inform Phase II dosage regimen
Trial Design Highlights	Dosing patients with mild asthma with elevated FeNO levels (>35 ppb), to receive inhaled PRS-060 or pbo b.i.d.* over a 10-day period

*q.d. on Day 10

Initiated in July 2018

Evaluating safety, tolerability, PK, PD and will also evaluate FeNO reduction vs. placebo

Measuring safety, tolerability and FeNO changes days 1-10,17 and 40

Pieris is sponsoring the trial, AstraZeneca is reimbursing Pieris for all associated costs

Data will be presented at ERS 2019 on October 1, 2019

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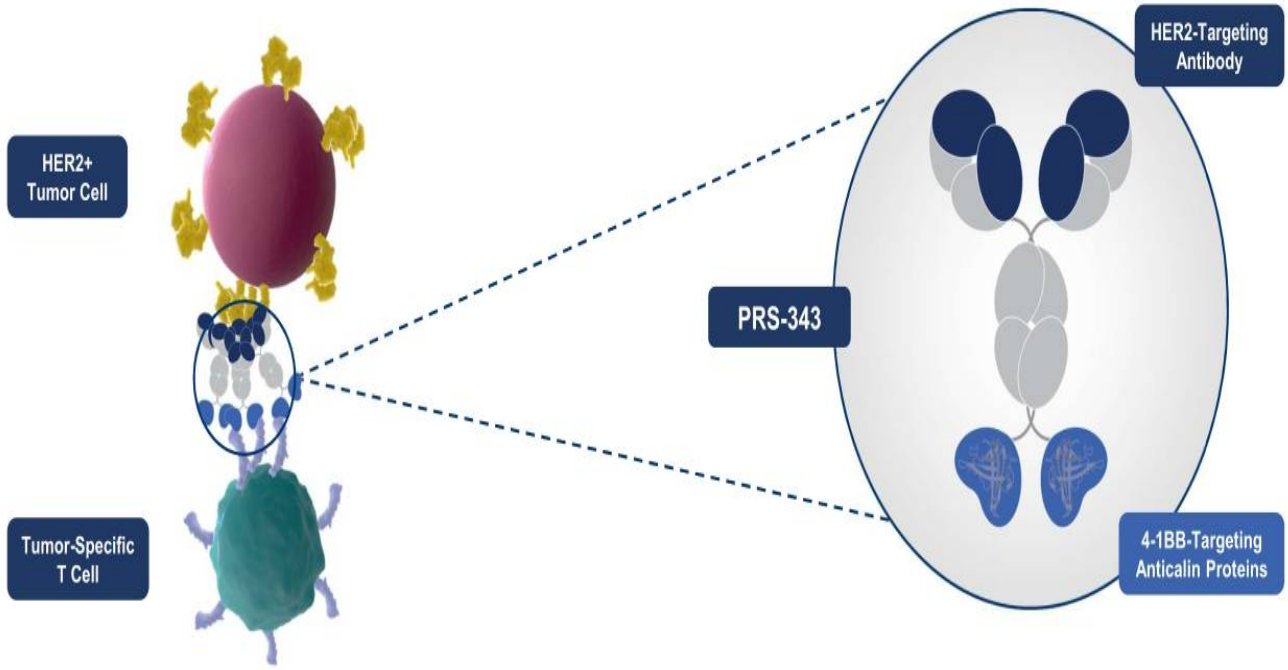
PRS-343: 4-1BB/HER2 Bispecific

Candidate	PRS-343
Function/MoA	Tumor-targeted 4-1BB agonism, HER2 antagonism
Indications	HER2+ solid tumors
Development	Phase 1 ongoing
Commercial Rights	Fully proprietary

4-1BB (CD137): Validated Target in Need of Appropriate Drug

- Marker for tumor-specific T cells in TME
- Ameliorates T-cell exhaustion & critical for T-cell expansion
- Drives anti-tumor cytolytic activity
- Drives central memory T-cell phenotype

Systemically agonizing 4-1BB mAb (urelumab) has shown clinical activity yet caused significant toxicity



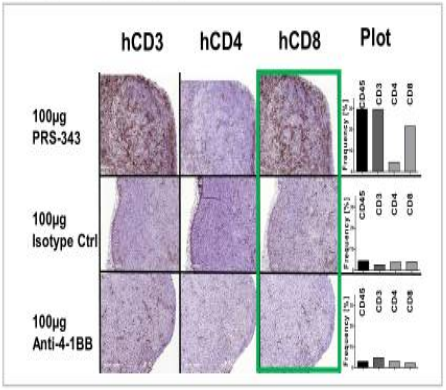
PRS-343 was designed for TME-specific 4-1BB activation*

*4-1BB *trimerization* required for activation

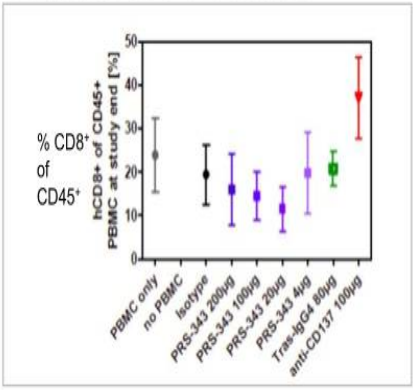
PRS-343 Shows Localized Activity and Differentiation in Humanized Mouse Model

	CD8⁺ Proliferation in TME	Peripheral CD8⁺ Proliferation	Systemic Toxicity
PRS-343	Yes	No	No
4-1BB mAb	No	Yes	Yes
Isotype Control	No	No	No

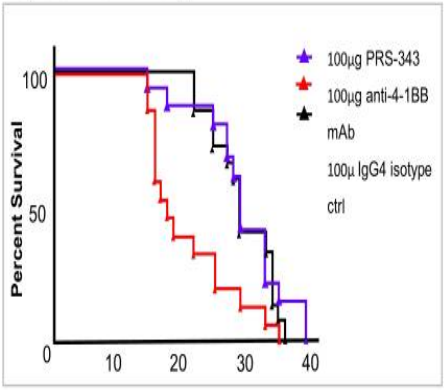
CD8⁺ Proliferation in TME



Peripheral CD8⁺ Proliferation



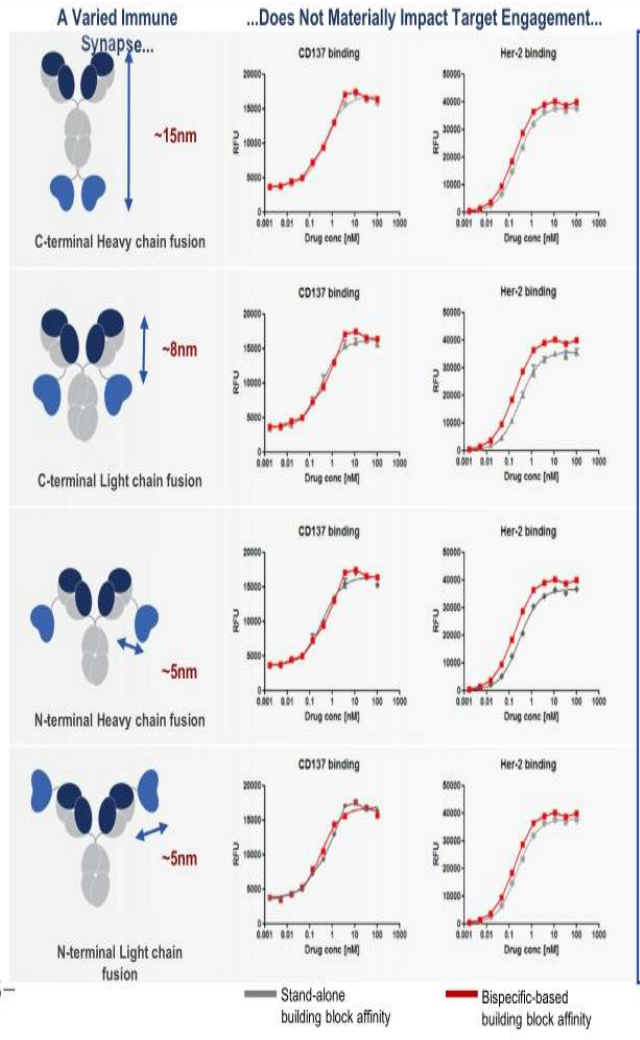
Systemic Toxicity

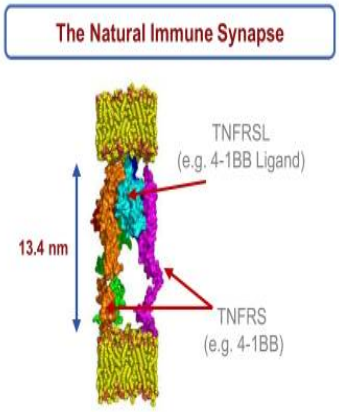


Experimental Design:

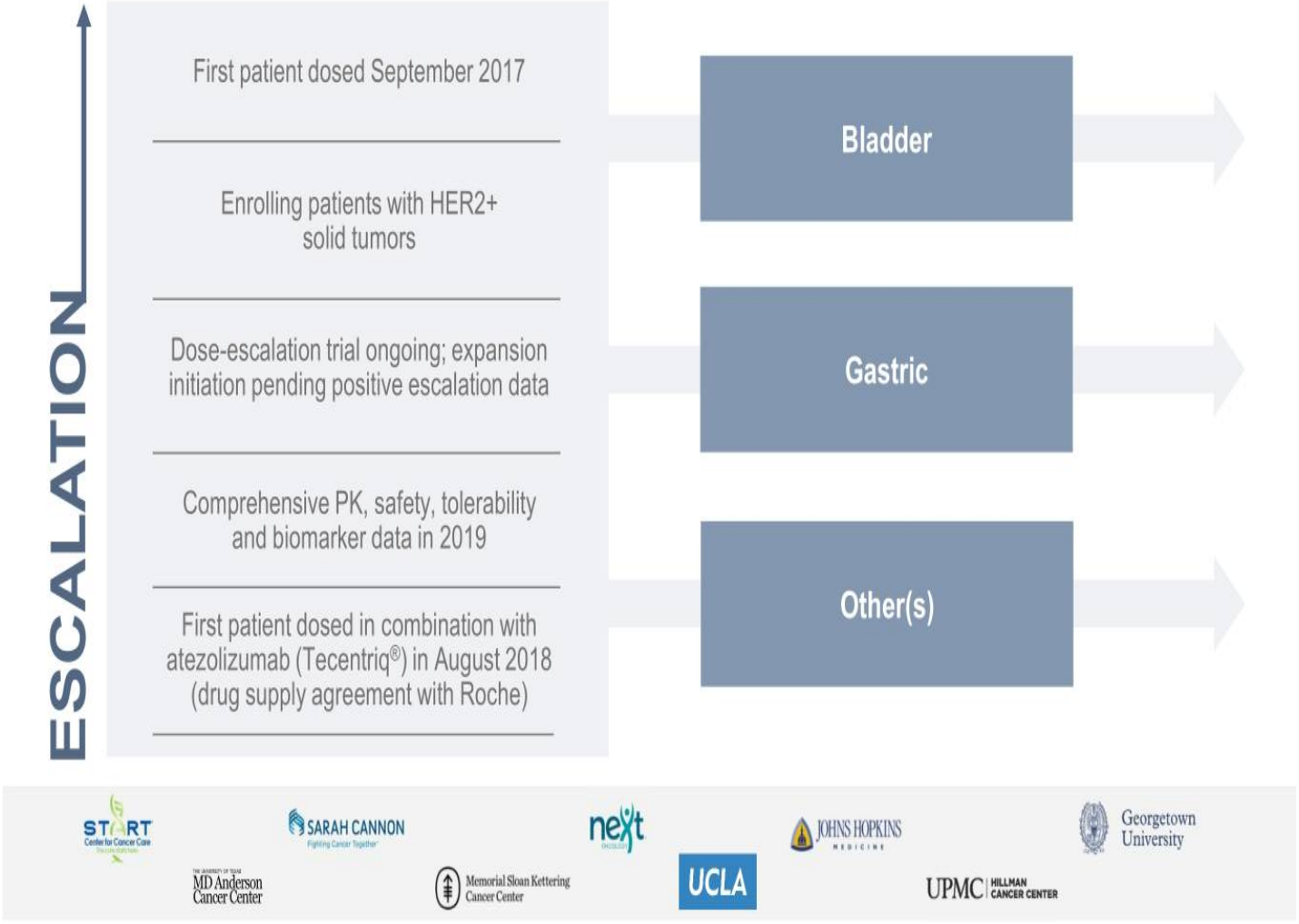
- SKOV-3 tumor cells grafted onto immune-deficient mice and grown to predetermined volume
- Human PBLs + control or PBLs + PRS-343 administered

Anticalin Technology Advantages: Well-Equipped for Targeted IO Agonism





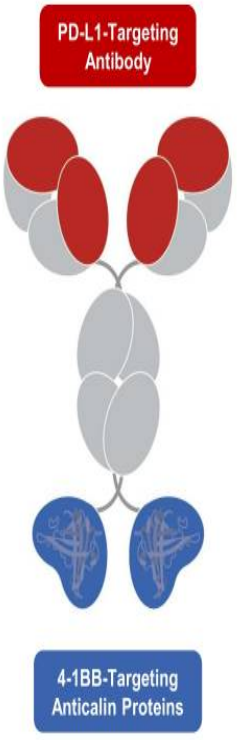
PRS-343 Phase 1 Escalation and Expansion Trials



START Center for Cancer Care · SARAH CANNON Fighting Cancer Together · next Oncology · JOHNS HOPKINS MEDICINE · Georgetown University · MD Anderson Cancer Center · Memorial Sloan Kettering Cancer Center · UCLA · UPMC HILLMAN CANCER CENTER

PRS-344: 4-1BB/PD-L1 Bispecific

Candidate	PRS-344
Function/MoA	Localized 4-1BB agonism with PD-L1 antagonism
Indications	N.D.
Development	2019 IND expected (in co-dev with Servier)
Commercial Rights	Opt-in for co-development with full U.S. commercial rights; royalty on ex-U.S. sales



Financial Overview (As of 6/30/19)

$99.7 M	$0.0	50.9 M
Cash & Cash Equivalents	Debt	CSO

$120+ M non-dilutive capital since January 2017

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2019 Upcoming Catalysts

Respiratory: MAD phase 1 data, including FeNO reduction vs. placebo, for PRS-060, inhaled IL4-Rα antagonist in co-development with AstraZeneca, at ERS 2019 on October 1, 2019

IO: Phase 1 monotherapy data at upcoming medical meeting for PRS-343, a wholly-owned 4-1BB/HER2 bispecific

IO: IND for PRS-344, 4-1BB/PD-L1 bispecific

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NASDAQ: PIRS