

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

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**FORM 8-K**

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**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 8, 2018**

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

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**Nevada**  
(State of  
Incorporation)

**001-37471**  
(Commission  
File Number)

**EIN 30-0784346**  
(IRS Employer  
Identification No.)

**255 State Street, 9th Floor**  
**Boston, MA 02109**  
**United States**  
(Address of principal executive offices, including zip code)

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

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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))

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 May 2018 Deutsche Bank Health Care Conference presentation of Pieris Pharmaceuticals, Inc.

The information set forth under this “Item 7.01. Regulation FD Disclosure,” including the exhibit attached 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 9.01 Financial Statements and Exhibits**

(d) *Exhibits.*

99.1 [Deutsche Bank Health Care Conference Presentation, dated May 2018.](#)

**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 8, 2018

/s/ Allan Reine

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Allan Reine

Chief Financial Officer



# Deutsche Bank Health Care Conference Presentation

May 2018  
(Nasdaq: PIRS)

## Forward Looking Statements

This press release 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](http://www.sec.gov), including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and the Company's Quarterly Reports on Form 10-Q.

## Anticalin Proteins – A Novel Therapeutic Class



### Features

Derived from lipocalins  
(human epithelial proteins)

Engineerable binding pocket

Engineerable scaffold

Small size (1/8<sup>th</sup> the size of a mAb)

### Benefits

No observed  
immunogenicity to date

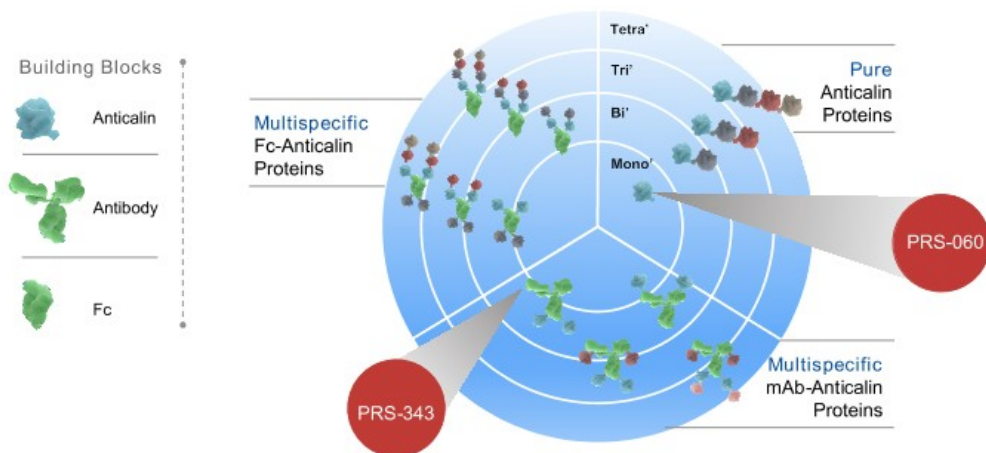
Potent target engagement

Unique bi/multispecific fusion  
proteins

Enhanced delivery, e.g.,  
Inhaled therapeutics

*Our pipeline addresses clinically-validated targets in new ways by leveraging unique features of the Anticalin<sup>®</sup> protein drug class, effectively taking reduced target biology risk*

# Anticalin-based Drug Candidates can be Tailored to Multiple Formats



Potent Multi-target Engagement • Novel MoA • Favorable Drug-like Properties



## Financial Update (12/31/17)

(in millions)

Cash & Cash Equivalents (proforma)*	\$172.4
Debt	\$0.0
2017 Opex	\$39.3
CSO	45.0

\*Includes \$82.6 in cash and equivalents at year end plus \$12.5 from AstraZeneca, \$47.3 net from equity raise, \$30 due from Seattle Genetics, and excludes YTD operating cash expenses

## 2018 Anticipated Milestones

Core Clinical	<ul style="list-style-type: none"> <li>• PRS-343: Initial safety and PD data in 2H18</li> <li>• PRS-060: First-in-human data in 2H18</li> </ul>
Non-Core Clinical	<ul style="list-style-type: none"> <li>• PRS-080: Phase IIa data in 2H18 (safety, PK, hemoglobin change post 5QW dosing)</li> </ul>
Next-Generation Pipeline	<ul style="list-style-type: none"> <li>• Advance multiple programs in immuno-oncology and respiratory</li> </ul>

## Pipeline Highlights

	DISCOVERY	PRECLINICAL	PHASE I	PHASE II
PRS-080				✓
PRS-343			✓	
PRS-060			✓	
Servier	✓	✓		
PRS-300's	✓	✓		
AZ	✓			
SeaGen	✓			

Two IO INDs Planned in 2019

Advance additional respiratory programs under the AstraZeneca alliance in 2018



# Immuno-oncology Franchise



## Proprietary Clinical

- PRS-343: First-in-class bispecific to preferentially activate T cells in the tumor microenvironment (TME)
- Committed to advancing several additional tumor-localized costimulatory bispecific fusion proteins

## Servier Alliance

- 5-program deal (all bispecific fusion proteins)
- Pieris retains full U.S. rights for 3 out of 5 programs
- \$31M upfront payment, \$1.8B milestone potential
- Up to low double-digit royalties on non-codev products

## Seattle Genetics Collaboration

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



# PRS-343: Why did we Design This?



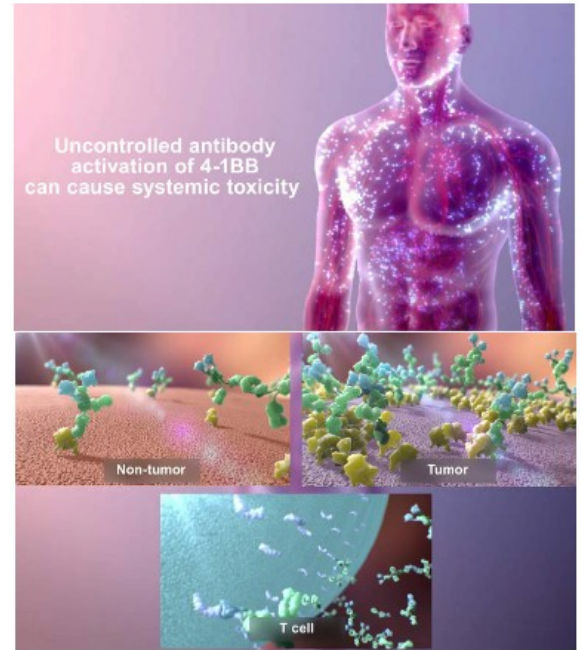
HER2-targeting antibody



4-1BB-targeting Anticalin proteins

4-1BB systemically agonizing antibody has shown mono-therapy efficacy yet significant toxicity in the clinic (narrow therapeutic window)

PRS-343 preferentially agonizes 4-1BB in the TME by using its anti-HER2 component to drive drug clustering and, therefore, 4-1BB cross-linking



## PRS-343 Targets Local Biology

### 4-1BB (CD137) – Key Costimulatory Target

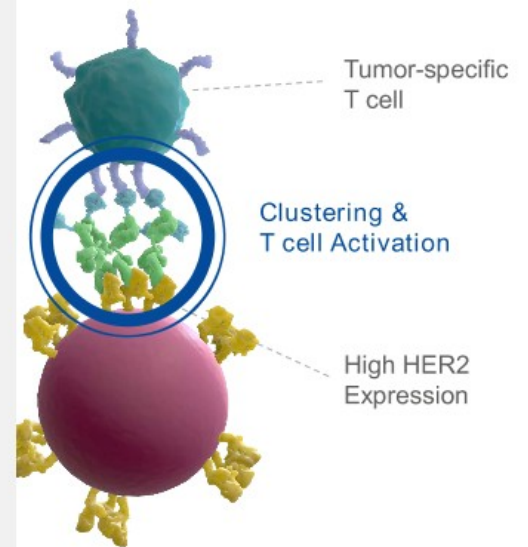
- Marker for tumor-specific T cells in TME
- Ameliorates T cell exhaustion
- Critical for T cell expansion
- Induces anti-tumor cytolytic activity
- Drives central memory T cell differentiation for sustained response

### HER2 – Strongly Validated Tumor Target

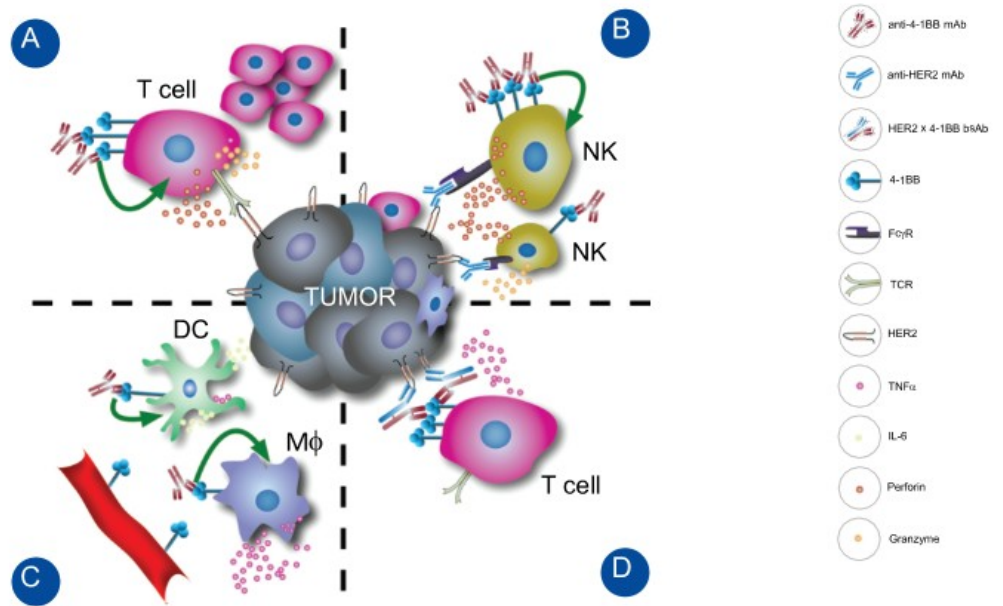
- Restricted expression on normal tissue
- Multiple HER2+ tumors with high-unmet need
  - Bladder, Gastric, Breast and several others
  - Mediates drug mobilization and immune receptor activation within the tumor bed



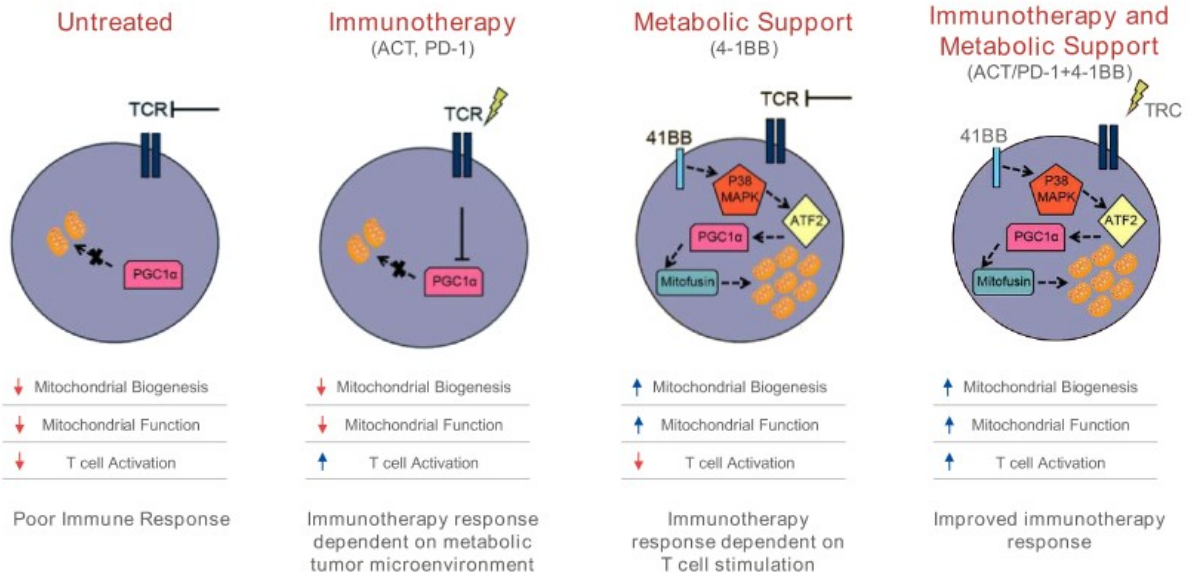
### T cell costimulation in TME



# Multifunctional Immunomodulatory Effects of 4-1BB Therapy

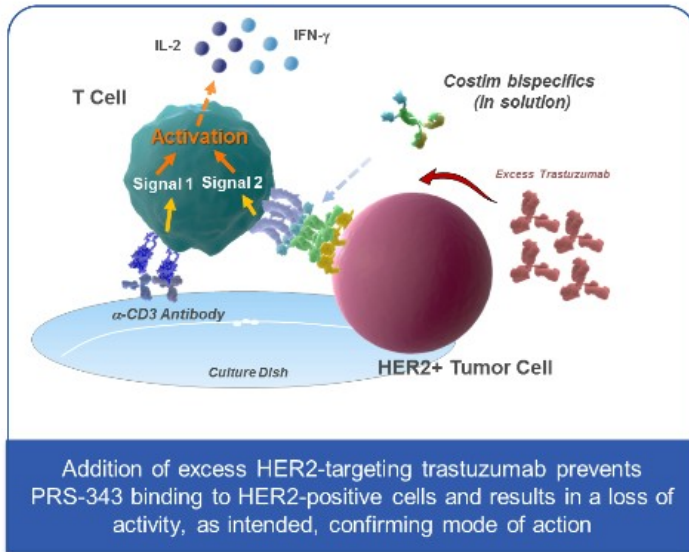


# 4-1BB Costimulation Induces T Cell Mitochondrial Function and Biogenesis Enabling Cancer Immunotherapeutic Responses: Reversing the Exhausted Phenotype

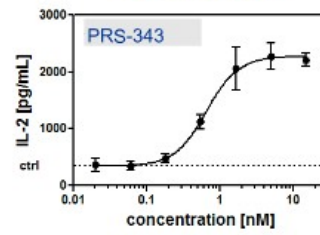




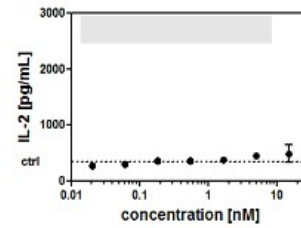
# PRS-343: T Cell Activation is HER2 Target-Dependent



PRS-343-mediated T Cell activation



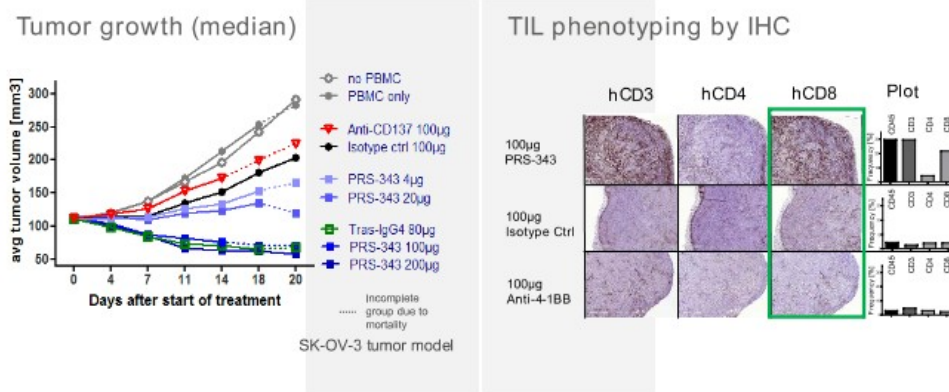
PRS-343 + excess trastuzumab





## PRS-343 Shows Bifunctional Activity – Dose-dependent Tumor Growth Inhibition & CD8(+)TIL Expansion in HER2+ Ovarian Cancer Model

- PRS-343 shows dose-dependent tumor growth inhibition in HER2-sensitive model
- PRS-343 leads to strong and dose-dependent lymphocyte infiltration in tumors; monospecific anti-HER2 mAb (IgG4 backbone) inhibits tumor growth but lacks this immuno-stimulatory activity
- Monospecific anti-4-1BB benchmark mAb shows insignificant response compared to isotype control and no significant tumor infiltration of lymphocytes

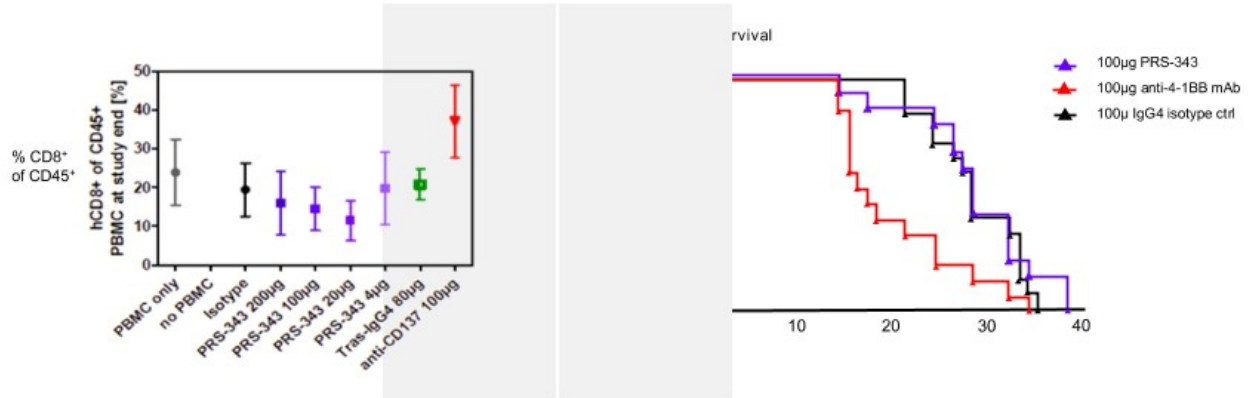






## PRS-343 Avoids Unwanted Effect of Peripheral T Cell Activation, Unlike Systemically Agonistic 4-1BB Antibody

- Toxicity observed with anti-4-1BB mAb likely corresponds to indiscriminate peripheral T cell activation
- Unlike PRS-343, anti-4-1BB benchmark mAb shows accelerated graft-versus-host-disease with significant mortality in line with literature data<sup>1</sup>



<sup>1</sup>Sanmamed et al., Cancer Res. 2015 Sep 1;75(17):3466-78.

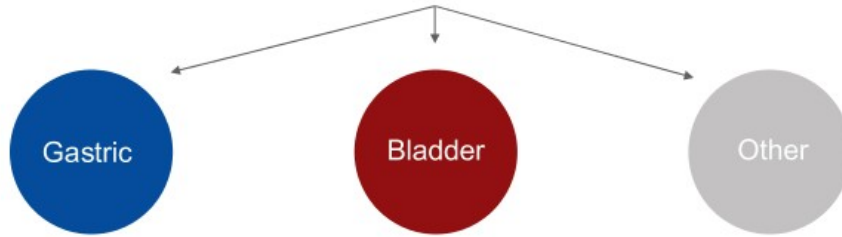
# PRS-343 | First-in-Patient Trial



## Phase I Trial (Initiated 3Q17)

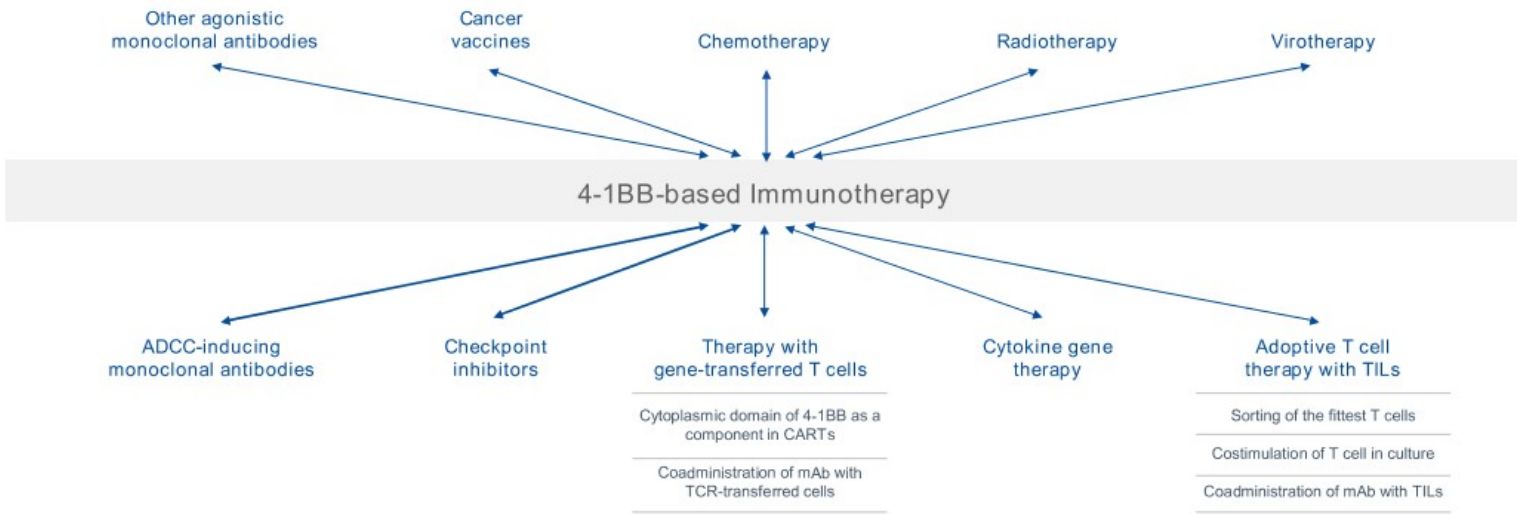
- Dose Escalation Phase
- Enrolling HER2+ cancer patients
- Started with single patient cohorts (modified 3+3 design)
- Determine maximum tolerated and/or efficacious dose level
- Biopsy driven biomarker analyses
- Initial safety and PD data 2H18

## Expansion Phase



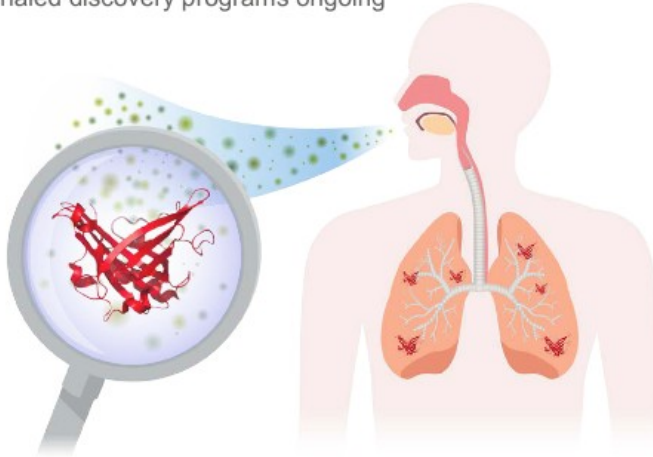
# Multiple Synergies Between 4-1BB and Other Therapeutic Modalities Have Been Demonstrated with in vivo Cancer Models

Landscape of potentially synergistic interactions based on the combination of 4-1BB-based and other anticancer therapeutics. Arrows represent described combinations.



# Novel Inhaled Biologics Platform: Targeting Lung Diseases Locally

- PRS-060 (Part of AstraZeneca alliance)
  - First-in-class inhaled IL-4Ra antagonist for asthma
  - Phase 1a SAD initiated in 4Q17
  - Pieris retains opt-in for co-development/co-commercialization rights in the US
- Proprietary inhaled discovery programs ongoing



AstraZeneca 

## Alliance Highlights

5 committed novel inhaled Anticalin protein programs

Including lead asthma program PRS-060 (IL-4Ra)

Retained co-development and co-commercialization (US) options on PRS-060 and up to 2 additional programs

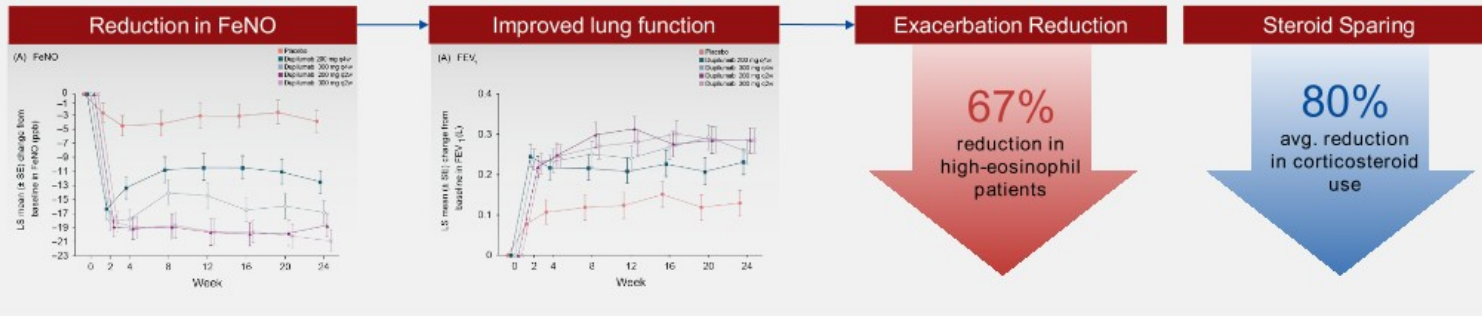
\$57.5M upfront & Phase I MS in 2017; up to ~\$2.1B in milestones, plus double-digit royalties

Access to complementary formulation and device know-how for inhaled delivery

# PRS-060 for Uncontrolled Asthma: Why did we Design This?

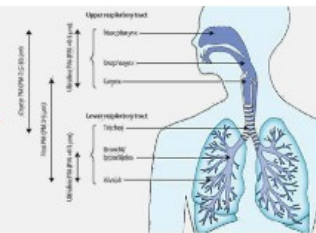
## What We Know

Regeneron/Sanofi's dupilumab (systemically administered anti-IL-4Ra antibody) has demonstrated the following:



## What We Are Testing

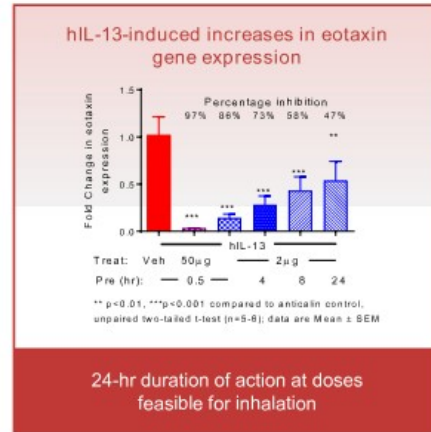
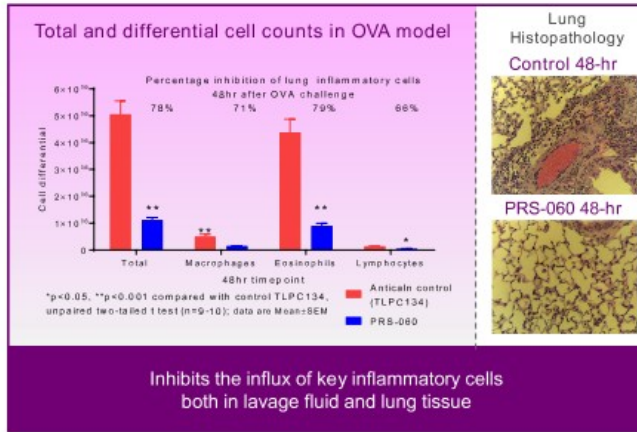
- Is this a local phenomenon?
- First-in-man study underway



# PRS-060 is a Localized IL-4Ra Antagonist for Uncontrolled Asthma

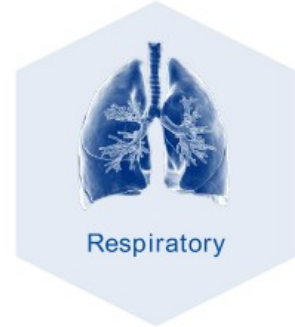


- First inhaled Anticalin protein to potently engage the highly validated asthma target, IL-4Ra
- Localized target engagement in lung tissue supports a rationale for a convenient, low-dose, low-cost alternative to systemically administered antibodies
- Preclinical in vivo PoC for pulmonary delivery at doses supportive of daily administration



## Pieris Investment Opportunity

- An industry-validated class of novel therapeutics
  - Anticalin proteins
  - \$120+M in upfront payments and milestones since January 2017
- Potentially transformative, wholly owned IO program
  - Clinical-stage, tumor-targeted 4-1BB bispecific
- High-value, inhaled targeted respiratory program
  - Clinical-stage inhaled IL-4Ra antagonist
  - partnered with AstraZeneca – retained co-dev/US comm rights
- All three anchor partnerships include US-focused commercialization rights
- Robust IND engine that has yielded several clinical-stage candidates with excellent drug-like properties





Pieris Pharmaceuticals, Inc.

Corporate HQ: 255 State Street, 9th Floor, Boston, MA 02109, USA

R&D Hub: Freising, Germany (Munich)



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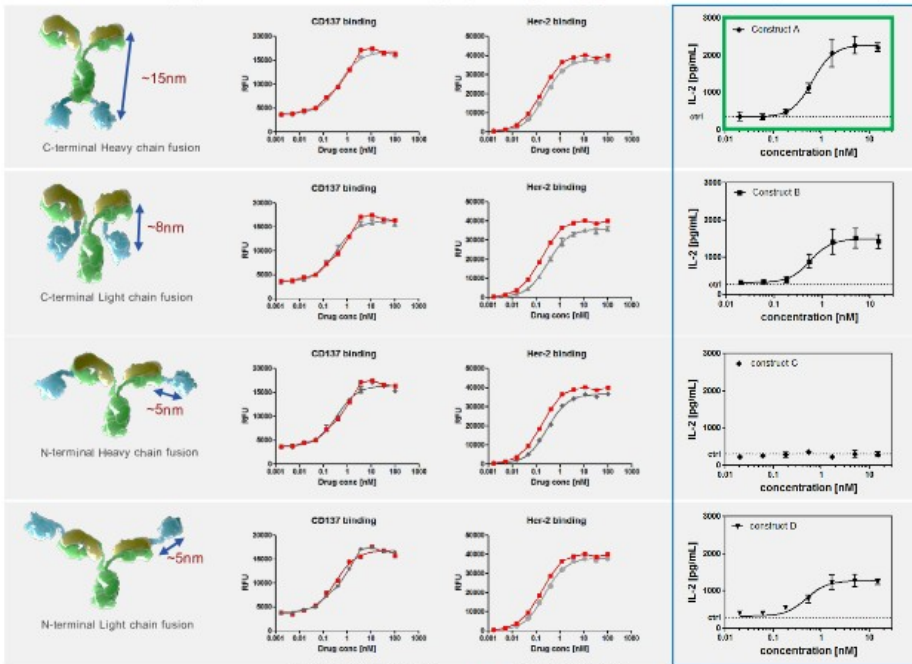
# Appendix



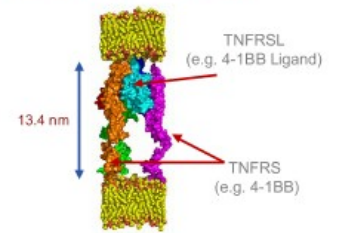
# Bispecific Geometry Impacts Immune Synapse, Efficacy



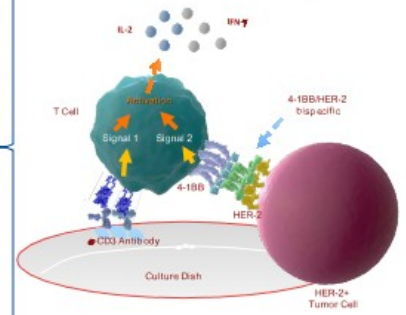
A Varied Immune Synapse... ... Does Not Materially Impact Target Engagement... ...But Impacts Efficacy



The Natural Immune Synapse



Efficacy Experimental Design



— Stand-alone building block affinity — Bispecific-based building block affinity

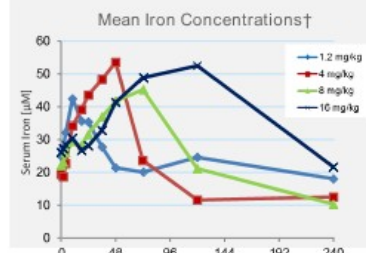
# PRS-080 Shows Consistent Effects in Healthy Volunteers & CKD5 Patients – Ongoing Ph IIa Study will Evaluate Hemoglobin



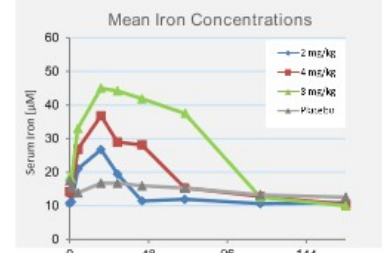
- In both healthy volunteers and CKD5 patients, PRS-080
  - Was safe and well-tolerated
  - Showed a dose-proportional increase of PK parameters (data not shown)
  - Demonstrated dose-dependent PD effects on serum iron and TSAT
  - Led to an immediate dose-dependent decrease in circulating free hepcidin (data not shown)
- A Phase IIa trial is underway in Germany and Czech Republic
  - Planning 5 QW infusions in ESRD FID anemia patients
  - Two dose cohorts: 4 mg/kg and 8 mg/kg body weight (4 drug; 2 placebo per cohort)
  - Safety, tolerability hemoglobin (Hb) and reticulocyte concentration of Hb as endpoints
  - If data are positive, Pieris will seek to out-license beyond Japan



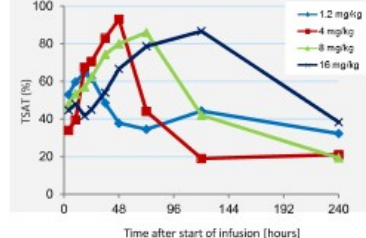
Ph I SAD in Healthy Volunteers\*



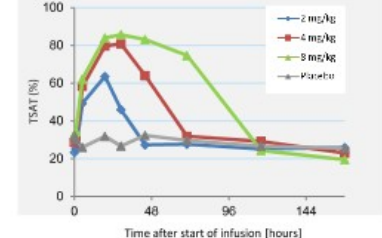
Ph Ib SAD in CKD5 patients\*\*



Mean TSAT (%)†



Mean TSAT (%)




\* Presented at 57th ASH Conference December 2015  
 † Subjects achieving iron response > 34.5 µM (avg. 3 out of 6 subjects / dose cohort)


\*\* Presented at 54th ERA-EDTA Conference June 2017  
 N=24 (6 patients per dose cohort, 6 patients on placebo)

# Management and Board

## Executive Management Team



Stephen Yoder, J.D.  
President & CEO




Louis Matis, M.D.  
SVP, Chief Development Officer




Allan Reine, M.D.  
SVP, Chief Financial Officer



## Board of Directors

Stephen Yoder  
President & CEO

Michael Richman  
CEO, NextCure  
Amplimmune, Chiron,  
MedImmune, MacroGenics

Jean-Pierre Bizzari, M.D.  
Director  
Celgene, Servier, Rhone-Poulenc,  
Sanofi-Aventis

Christopher Kiritsy  
CEO, Arisaph Pharmaceuticals  
Kos Pharmaceuticals

Ann Barbier, M.D., Ph.D.  
CMO, Translate Bio

Steven Prelack  
SVP & COO, VetCor  
Aerpio, Galectin Therapeutics,  
BioVex Group

Julian Adams, Ph.D.  
President & CEO, Gamida Cell  
Clal BioTech Industries, Ltd., Infinity,  
Millennium Pharm., LeukoSite Inc.

James Geraghty  
Director  
Third Rock Ventures, Sanofi, Genzyme,  
Bain and Company

