

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): September 11, 2017

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

Nevada  
(State of Incorporation)

001-37471  
(Commission  
File Number)

EIN 30-0784346  
(IRS Employer  
Identification No.)

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

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

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 an investor presentation of Pieris Pharmaceuticals, Inc.

The information set forth under this “Item 7.01. Regulation FD Disclosure,” including the exhibits 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 Investor Presentation of Pieris Pharmaceuticals, Inc., dated September 2017.

**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.

Dated: September 11, 2017

**PIERIS PHARMACEUTICALS, INC.**

By: /s/ Allan Reine  
Name: Allan Reine  
Title: Chief Financial Officer

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EXHIBIT INDEX

Exhibit No.	Description
99.1	<a href="#">Investor Presentation of Pieris Pharmaceuticals, Inc., dated September 2017.</a>





# Investor Presentation

September 2017

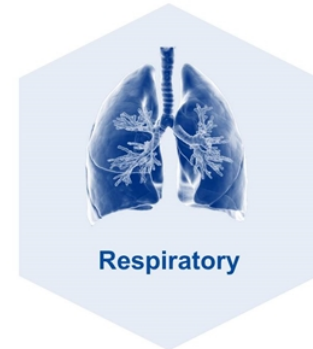


## Forward Looking Statements

Statements in this presentation that are not descriptions of historical facts are forward-looking statements that are based on management's current expectations and assumptions and are subject to risks and uncertainties. In some cases, you can identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" or the negative of these terms or other comparable terminology. Factors that could cause actual results to differ materially from those currently anticipated include, without limitation, risks relating to the results of our research and development activities, including uncertainties relating to the discovery of potential drug candidates and the preclinical and clinical testing of our drug candidates; the early stage of our drug candidates presently under development; our ability to obtain and, if obtained, maintain regulatory approval of our current drug candidates and any of our other future drug candidates; our need for substantial additional funds in order to continue our operations and the uncertainty of whether we will be able to obtain the funding we need; our future financial performance; our ability to retain or hire key scientific or management personnel; our ability to protect our intellectual property rights that are valuable to our business, including patent and other intellectual property rights; our dependence on third-party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators; our ability to successfully market and sell our drug candidates in the future as needed; the size and growth of the potential markets for any of our approved drug candidates, and the rate and degree of market acceptance of any of our approved drug candidates; developments and projections relating to our competitors and our industry; our ability to establish collaborations; our expectations regarding the time which we will be an emerging growth company under the JOBS Act; our use of proceeds from this offering; regulatory developments in the U.S. and foreign countries; and other factors that are described more fully in our Annual Report on form 10-K filed with the SEC on March 30, 2017. In light of these risks, uncertainties and assumptions, the forward-looking statements regarding future events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. The forward-looking statements included in this presentation speak only as of the date hereof, and except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in our expectations.

# Pieris Investment Opportunity

- Robust pipeline of a novel class of therapeutics—Anticalin® proteins
- Potentially transformative, wholly owned, tumor-targeted 4-1BB bispecific immuno-oncology (IO) program
- Next-generation multispecifics IO platform to exploit costimulatory and checkpoint targets with novel modes of action
- First-in-class, inhaled Anticalin protein targeting IL-4Ra partnered with AstraZeneca, retaining co-dev & co-marketing rights in USA
- Novel inhaled biologics platform that may bring enormous benefits in respiratory diseases including asthma and beyond
- Validating pharmaceutical partnerships in IO, respiratory diseases, and other therapeutic areas, demonstrating platform value
  - \$80M in upfront payments in 2017, \$4.5B in milestone potential



# Anticalin Proteins – A Novel Therapeutic Class with Favorable Drug Properties

## Features

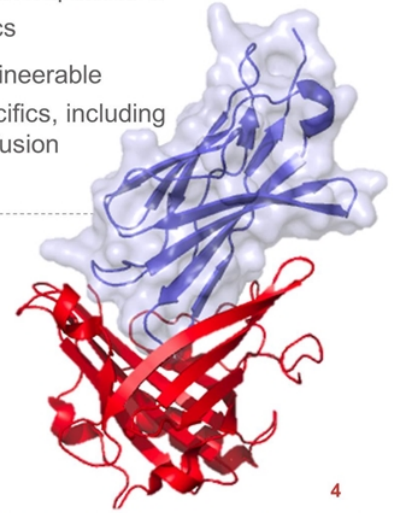
- Derived from lipocalins (human extracellular binding proteins)
  - multifunctional, non-immunogenic polypeptides
- Engineerable binding pocket
- Small size (18 kDa vs 150kDa mAbs)
- Very Stable

## Benefits

- No observed immunogenicity to date
- Potent target engagement
- Can be stand-alone therapeutics...
  - Inhaled biologics
- ...Yet are highly engineerable
  - Novel multispecifics, including mAb-Anticalin fusion proteins

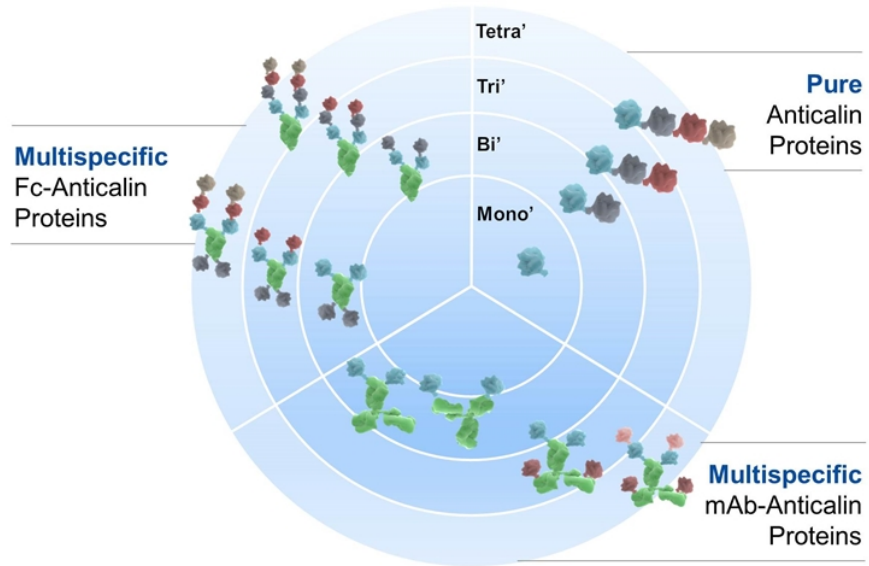
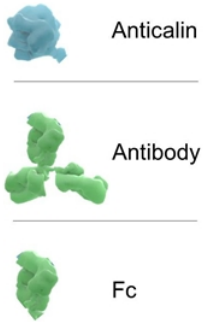
## ...Powered by Cutting Edge Platform

- Highly diverse libraries ( $>10^{11}$ ) of potential drug candidates
- Automated high-throughput drug screening technology (phage display)
  - High hit rates, quick to development candidates, versatile use
- Extensive protein engineering know-how for potentially transformative therapeutics and multispecifics



# Anticalin-based Drug Candidates Can Be Tailored to Multiple Formats

## Building Blocks



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



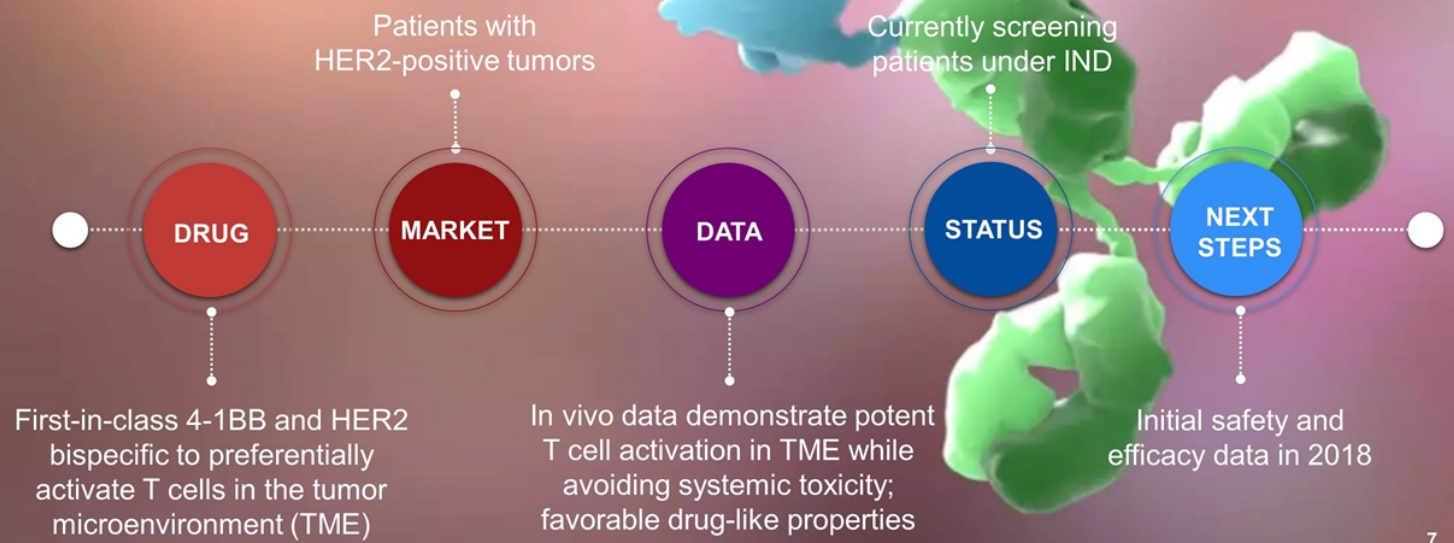
# Immuno-oncology Programs



Candidate	Target	Phase
PRS-343 (Pieris)	4-1BB/HER2 Bispecific	Phase 1
PRS-342 (Pieris)	4-1BB/GPC3 Bispecific	Preclinical
PRS-332 (Servier - Pieris)	PD-1/n.d. Bispecific	Preclinical
PRS-300s (Pieris)	n.d.	Discovery
4 Programs (Servier - Pieris)	Bispecifics	Discovery
Roche Program	n.d.	Discovery

# PRS-343 IO Drug for Solid Tumors

**100% Proprietary to Pieris**



# PRS-343 Market Opportunity



Cancer Type	Prevalence (US) <sup>1</sup>	Line of Therapy	Line of Therapy Size (%)	HER2+ Rate (%)	Addressable Population (US)
Breast Cancer	3,327,552	3 <sup>rd</sup> Line	~9 %	20 % <sup>2</sup>	59,495
Bladder Cancer	696,440	3 <sup>rd</sup> Line	~4 %	43 % <sup>3</sup>	10,705
Gastric Cancer	76,829	2 <sup>nd</sup> Line	~23 %	22 % <sup>4</sup>	3,942
Uterine (Endometrial) Cancer	710,228	1 <sup>st</sup> Line	~12 %	25 % <sup>5</sup>	20,827
Ovarian Cancer	222,060	2 <sup>nd</sup> Line	~32 %	7 % <sup>6</sup>	4,278

Additional potential tumor types include e.g. Biliary, NSCLC, Esophageal, Colorectal and Cervical Cancer

- **Multi-billion dollar market opportunity in HER2-positive cancers, well over 100K addressable patients in the US alone.**

1) Surveillance, Epidemiology, and End Results (SEER) Program 2) Schmidt, C. J Natl Cancer Inst. 2010; 3) Krüger, S. et al. Int. J. Cancer. 2002; 4) Yano et al. J Clin Oncol. 2004; 5) Livasy, CA., et al. Gyn Onc. 2006; 6) Tuefferd M, et al., PLoS ONE. 2007



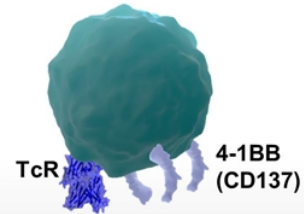
# PRS-343 is a First-in-class Bispecific TME-activated Costimulatory Agonist



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

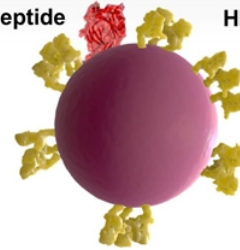
- Marker for tumor-specific T cells in TME
- Ameliorates T cell exhaustion
- Critical for T cell expansion
- Induces anti-tumor cytolytic activity
- Drives central memory T cell differentiation for sustained response

## Tumor-specific T Cell



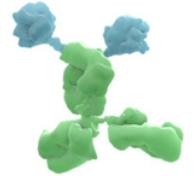
MHC-peptide

HER2



Tumor Cell

## PRS-343 4-1BB-targeting Ac



HER2-targeting mAb

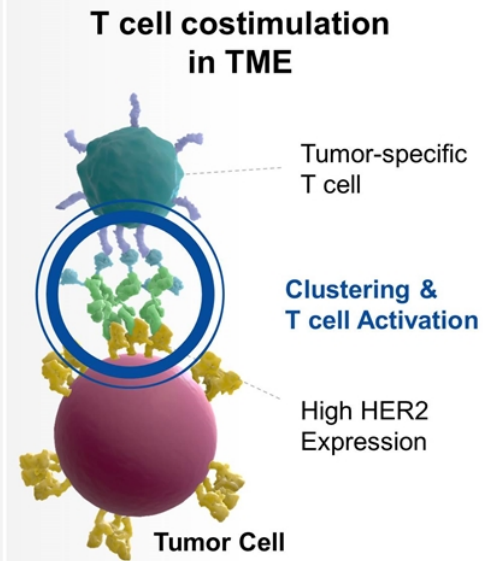
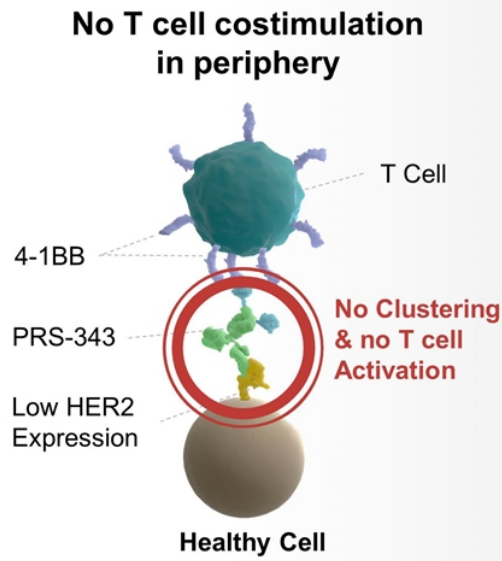
## HER2 – Strongly Validated Tumor Target

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

# Concept: Tumor-localized Costimulation with PRS-343 (Bispecific 4-1BB Engager)



- 4-1BB is activated via high-order clustering
- Tumor receptor-mediated clustering of bispecifics drives 4-1BB-mediated T cell activation
- Maintained tumor antigen specificity by T cell receptor may lead to safety advantages

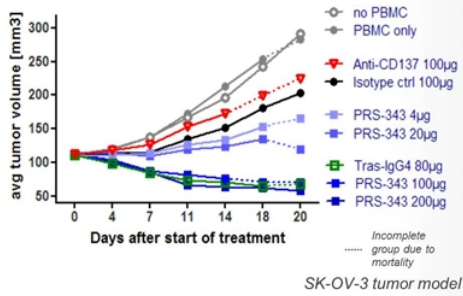


# PRS-343 Shows Bifunctional Activity – Dose-dependent Tumor Growth Inhibition & CD8(+)TIL Expansion in HER2+ Ovarian Cancer Model

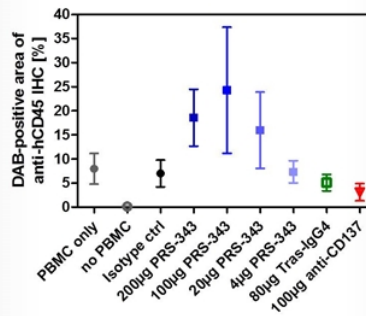


- PRS-343 shows dose-dependent tumor growth inhibition, which is dominated by anti-HER2 activity
- PRS-343 leads to strong and dose-dependent lymphocyte infiltration in tumors; monospecific anti-HER2 mAb (IgG4 backbone) lacks this activity
- Monospecific anti-4-1BB benchmark mAb shows insignificant response compared to isotype control and no significant tumor infiltration of lymphocytes

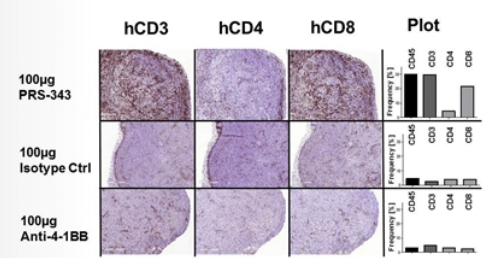
Tumor growth (Median)



TIL frequency (hCD45)



TIL phenotyping by IHC

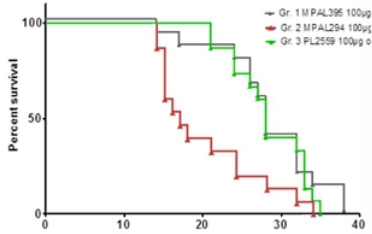


# PRS-343 Avoids Unwanted Effect of Peripheral T Cell Activation, Unlike Systemic 4-1BB Agonist mAb



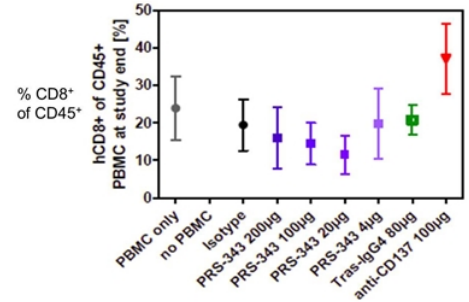
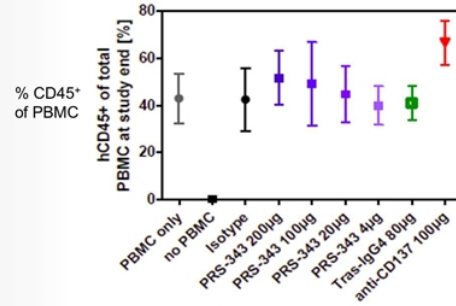
- Anti-4-1BB benchmark mAb shows accelerated graft-versus-host-disease with significant mortality in line with literature data<sup>1</sup>
- Toxicity corresponds with expansion of CD8-positive T cells in PBMC for this group

## Survival



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

## PBMC phenotyping at day 19

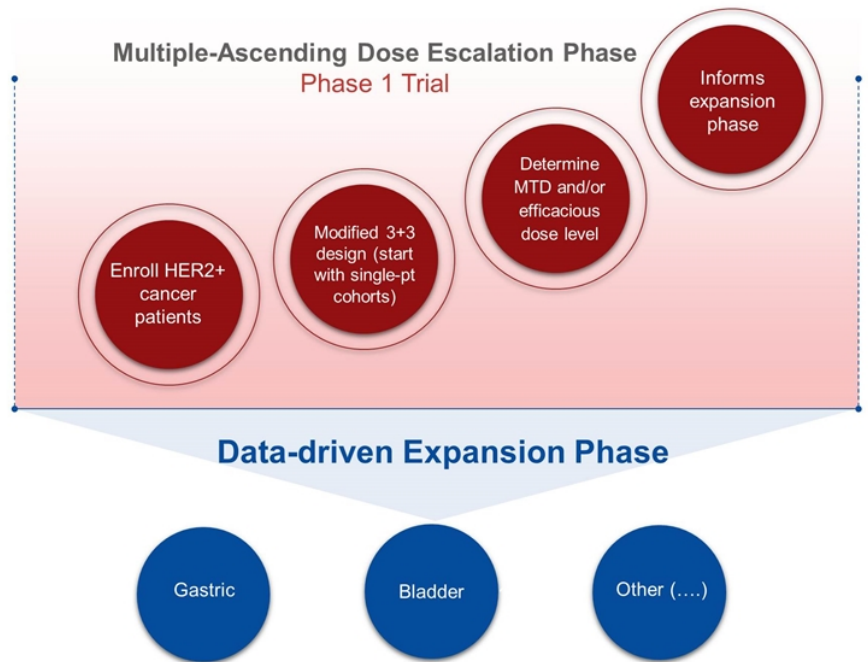


# PRS-343 First-in-Patient Clinical Trial




## PRS-343 Summary

- Demonstrated ability to activate human T cells consistent with desired mode of action
  - Potent, tumor-dependent activity
  - Differentiation over anti-4-1BB mAbs
- Favorable drug-like properties
  - CMC/manufacturing: robust titers and long-term stability
  - Low risk of immunogenicity observed ex vivo
  - Antibody-like half-life in mouse and cynomolgus monkey
  - Clean cynomolgus monkey GLP toxicity study



# Beyond PRS-343... Servier Partnership is a Transformative Alliance in Immuno-oncology



Alliance Highlights	 <b>Partner Overview</b>	<b>Strategic Implications of Partnership</b>
<p>5 committed + 3 optional novel IO programs</p> <p>Lead bispecific PRS-332 (PD-1-based)</p> <p>Retained co-development and full US commercial rights on PRS-332 and up to 3 additional programs</p> <p>~\$30M upfront, up to ~\$1.8B in milestones, low double-digit royalties</p> <p>“True Partnership” – equal voice, shared strategic vision and resources</p>	<p>France’s largest private pharmaceutical company and second largest overall (~\$4B annual sales)</p> <p>Founded in 1954</p> <p>&gt; 21,000 employees</p> <p>A commercial-stage oncology company</p> <p>Deep commitment to R&amp;D with \$1B research budget with oncology as one of its core areas</p>	<p>Validates Pieris’ unique multispecifics formats to interrogate novel biology in a highly competitive field</p> <p>Free cash flow materially extends runway and enables increased investments in proprietary pipeline</p> <p>Pieris can independently develop lead IO asset, PRS-343 (4-1BB/HER2), and is free to enter into additional IO partnerships</p>



# Next-Generation IO Therapy Strategy



**Engage immune costimulatory targets in highly novel, targeted manner with unique multispecifics, led by PRS-343 (wholly owned by Pieris)**

Establish superior therapeutic window over mAbs

Improve on benefits of leading checkpoint antagonists and other therapies

**Simultaneously block multiple immune checkpoints in one drug built on key backbone components (e.g. PD-1), led by PRS-332 (fully retained US rights)**

Demonstrate superiority to existing PD-1 mAbs

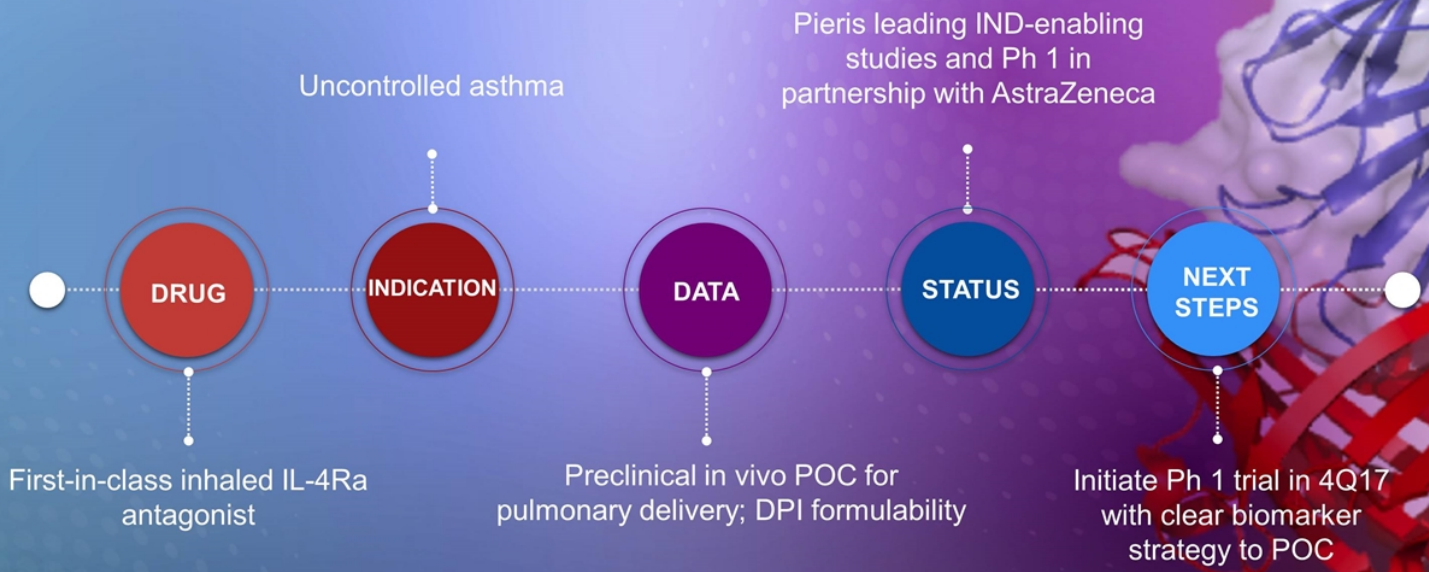
Exploit independent and fully proprietary position

**Demonstrate intra-pipeline synergy between targeted costimulatory engagement and multi-checkpoint blockade within own pipeline**

4-1BB (CD137) activation combined with PD-1 blockade expected to result in greater tumor growth inhibition than either monotherapy in preclinical studies<sup>1</sup>

**Next-Generation IO Therapies: Novel multispecifics • novel combinations • proprietary**

# PRS-060 for Asthma

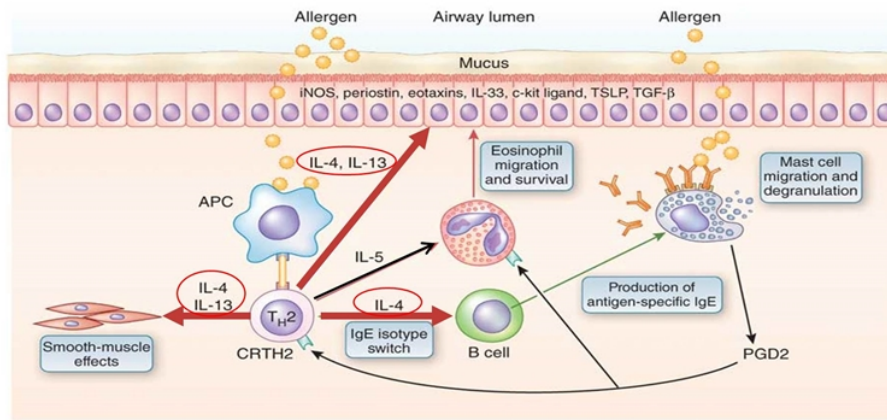






# IL-4Ra is the Broadest Established Intervention Point in the T2 Pathway

- IL-4 & IL-13 are main Th2 cytokines involved in asthma, both signal via IL-4Ra
- Anti-IL-4Ra mAb (Dupilumab) demonstrated strong activity and high response rates in moderate to severe, uncontrolled asthmatics – best-in-class among late-stage/approved biologics

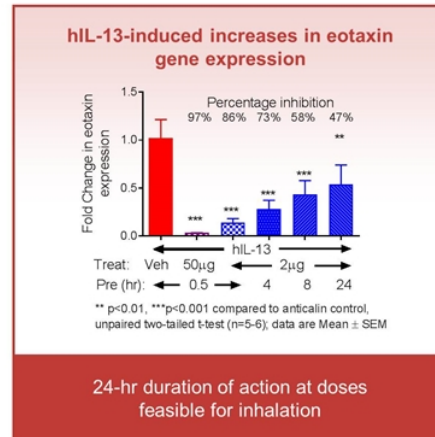
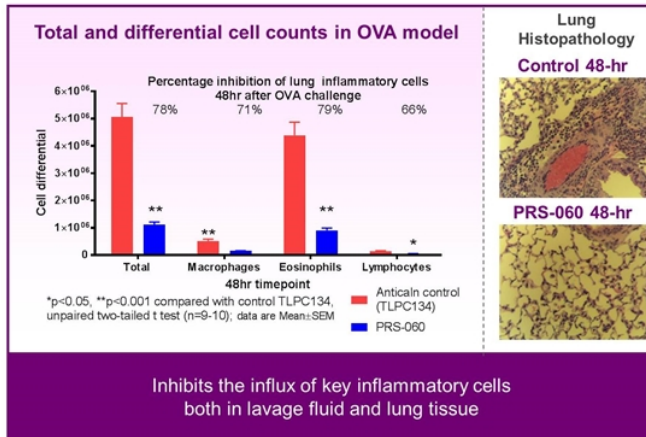


Adapted from Wenzel, Nature Medicine 18, 716–725 (2012)

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



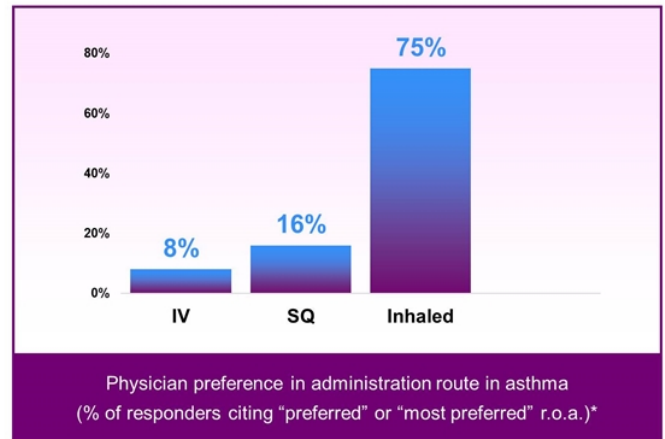
- First inhaled Anticalin protein to potently engage the highly validated asthma target, IL-4Ra
- Localized target engagement in lung tissue supports a rationale for a convenient, low-dose, low-cost alternative to systemically administered antibodies
- Preclinical in vivo POC for pulmonary delivery at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



# PRS-060 has the Potential to Transform the Use of Biologics in Uncontrolled Asthma



- A fraction of uncontrolled asthmatics are currently treated with biologics
- Uptake of biologics limited by several factors including; inconvenient in-office dosing, high price & biomarker restrictions
- PRS-060 as an inhaled protein is positioned to overcome these challenges
- An inhaled IL-4Ra blocker has the potential to become market leader and create new markets



\* Primary market research with prescribing physicians by Artisan Healthcare Consulting (on behalf of Pieris) in 2016

# PRS-060 and beyond... AstraZeneca Partnership is a Transformative Alliance in Respiratory Diseases



## Alliance Highlights

5 committed novel inhaled Anticalin proteins programs for local treatment of respiratory disease

Lead asthma program PRS-060 (IL-4Ra)

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

~\$45M upfront, up to ~\$2.1B in milestones, plus double-digit royalties

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



## Partner Overview

A world leading respiratory company

In 2016, AZ's respiratory products generated over \$4.7 billion in worldwide sales

The respiratory portfolio includes 12 marketed products, e.g. franchises such as Symbicort® and Pulmicort®

Over 40 year experience in developing medicine for respiratory diseases

## Strategic Implications of Partnership

Demonstrates high-value opportunity for locally delivered over systemically administered biologics, including potential benefits in cost, convenience, safety and efficacy

World-leading respiratory company de-risks and accelerates development of respiratory pipeline

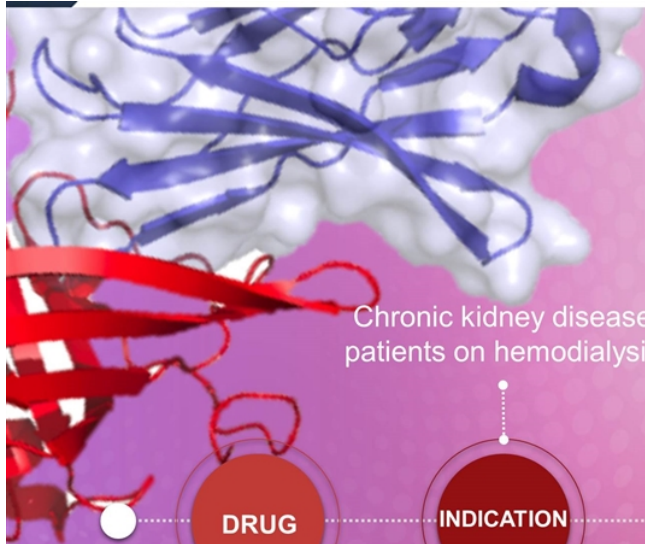
Retained co-development and US co-commercialization rights on PRS-060 and other programs provide ability to forward-integrate into a high-value market beyond IO

## Other Pipeline Programs

Candidate or Partner	Target or Indication	Phase
PRS-080 (Pieris)	Hepcidin (Anemia)	Phase Ib/IIa
Daiichi Sankyo	n.d.	Preclinical
Sanofi	<i>P. aeruginosa</i>	IND-Enabling



# PRS-080 for Anemia



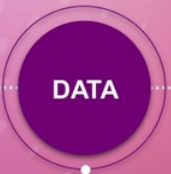
Chronic kidney disease patients on hemodialysis



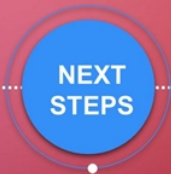
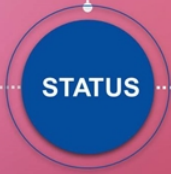
PEGylated Anticalin-based hepcidin antagonist



Well tolerated in patients, Dose-dependent PD on serum iron & TSAT and decrease in circulating free hepcidin



Option agreement for Japan+ rights with ASKA Pharmaceutical



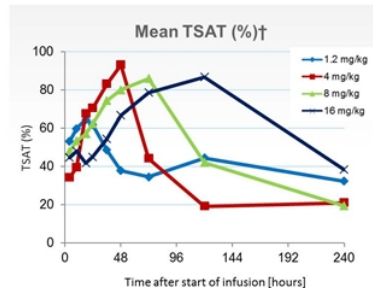
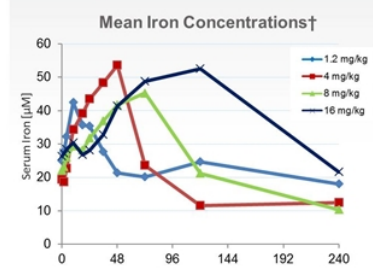
Initiate Phase IIa trial - seek partner for ROW rights after trial

# PRS-080 Shows Consistent Effects in Healthy Volunteers & CKD5 Patients



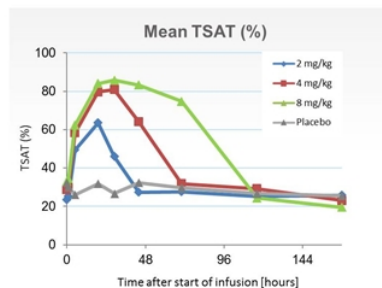
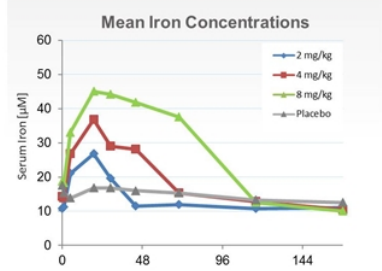
- In both healthy volunteers and CKD5 patients, PRS-080...
  - Was safe and well-tolerated
  - Showed a dose-proportional increase of PK parameters (data not shown)
  - Demonstrated dose-dependent PD effects on serum iron and TSAT
  - Led to an immediate dose-dependent decrease in circulating free Hcpicidin (data not shown)
- CTA filed with the German and Czech Republic regulatory authorities
- Begin enrolling patients for multi-dose Phase IIa in 3Q17
- Safety, tolerability hemoglobin (Hb) and reticulocyte concentration of Hb as endpoints

## Ph I SAD in Healthy Volunteers\*



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

## Ph Ib SAD in CKD5 patients\*\*



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

# Financials & Milestones





## Financial Highlights – As of June 30, 2017

<b>Cash &amp; Cash Equivalents</b> <small>(6/30 pro-forma for \$45mm up-front payment from Astra Zeneca July 2017)</small>	\$95.3M
<b>Debt</b>	\$0.0M
<b>First Half 2017 Net Loss</b>	\$18.1M
<b>First Half 2017 Operating Expenditure Burn</b>	\$15.2M
<b>Common Shares Outstanding</b>	43.8M
<b>Preferred Shares Outstanding (as-converted)</b>	5.0M
<b>Options and Warrants Outstanding</b>	11.7M

# 2017 Expected Milestones



## Immuno-Oncology

- Cornerstone Servier alliance incl. PRS-332 and full US rights
- PRS 343 IND accepted
- Progress several preclinical-stage, highly differentiated multispecifics



## Respiratory

- Cornerstone AstraZeneca alliance incl. PRS-060 and co-marketing
- PRS-060 first subject dosing 4Q17
- Initiate program on additional target within AZ alliance



## Anemia

- Regional partnership in Japan with ASKA
- Disclose Phase Ib results
- Enroll Phase IIa patients in 3Q17 and initiate ROW partnering activities

# 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*



**Claude Knopf**

*SVP, Chief Business Officer*



## Board of Directors

**Stephen Yoder**

President & CEO

**Michael Richman**

CEO, NextCure, Inc.  
Amplimune, Chiron,  
MedImmune, Macrogenics

**Jean-Pierre Bizzari, M.D.**

Director  
Celgene, Servier, Rhone-Poulenc,  
Sanofi-Aventis

**Christopher Kiritsty**

CEO  
Arisaph Pharmaceuticals  
Kos Pharmaceuticals

**Chau Khuong (Chairman)**

Partner, OrbiMed Advisors

**Steven Prelack**

SVP, COO, VetCor  
Velquest Corp., Galectin  
Therapeutics, BioVex Group

**Julian Adams, Ph.D.**

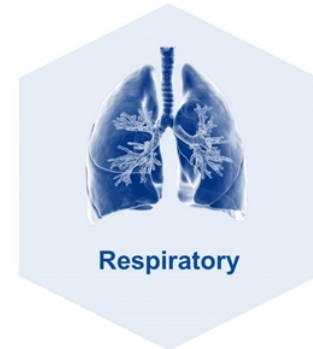
CSO & President Clal BioTech  
Industries, Ltd.,  
Infinity, Millennium Pharm.,  
LeukoSite Inc.

**James Geraghty**

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

## Pieris Investment Opportunity

- Robust pipeline of a novel class of therapeutics—Anticalin® proteins
- Potentially transformative, wholly owned, tumor-targeted 4-1BB bispecific immuno-oncology (IO) program
- Next generation multispecifics IO platform to exploit costimulatory and checkpoint targets with novel modes of action
- First-in-class, inhaled Anticalin protein targeting IL-4Ra partnered with AstraZeneca, retaining co-dev & co-marketing rights in USA
- Novel inhaled biologics platform that may bring enormous benefits in respiratory diseases including asthma and beyond
- Validating pharmaceutical partnerships in IO, respiratory diseases, and other therapeutic areas, demonstrating platform value
  - \$80M in upfront payments in 2017, \$4.5B in milestone potential





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