

**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): June 6, 2018**

---

**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 02109**  
**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 the June 2018 Jefferies Global Healthcare 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 [Jefferies Global Healthcare Conference Presentation, dated June 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: June 6, 2018

/s/ Allan Reine

Allan Reine

Chief Financial Officer



# Jefferies Global Healthcare Conference Presentation

June 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® protein drug class, effectively taking reduced target biology risk

## 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





## Financial Update (3/31/18)

(in millions)

Cash & Cash Equivalents (proforma)	\$162.2
Debt	\$0.0
2017 Opex	\$39.3
CSO	50.1

## 2018 Anticipated Milestones

Core Clinical	<ul style="list-style-type: none"> <li>• PRS-343: Initial safety and PD data; initiate PDL-1 combo study 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

# 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

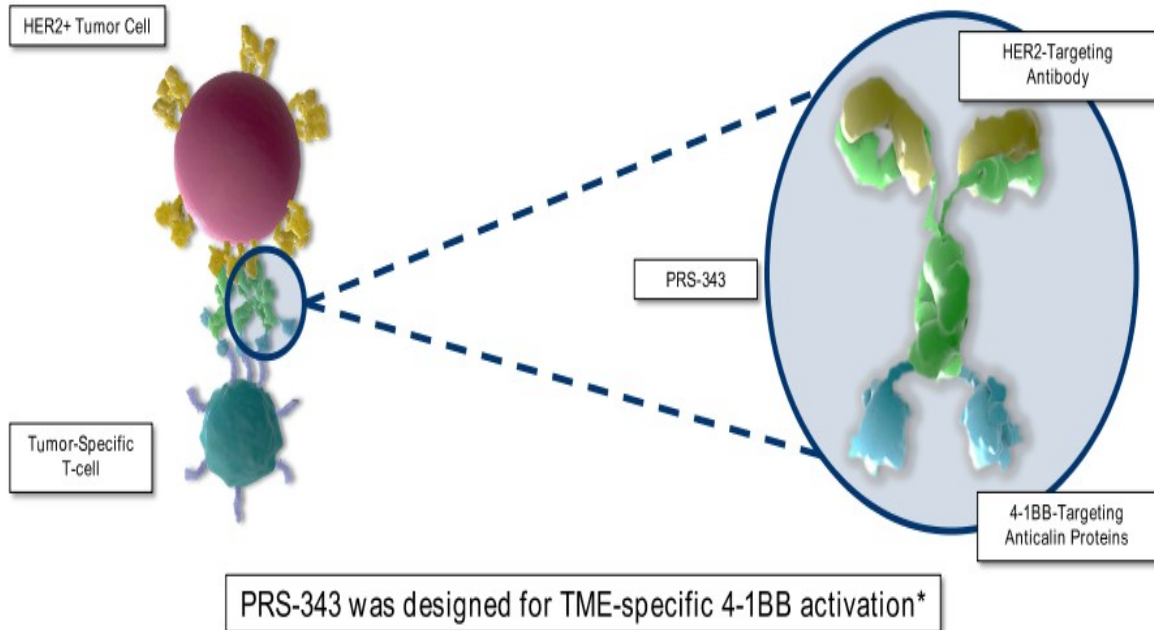
Our pipeline addresses clinically-validated targets in new ways by leveraging unique features of the Anticalin® protein drug class, effectively taking reduced target biology risk

# 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

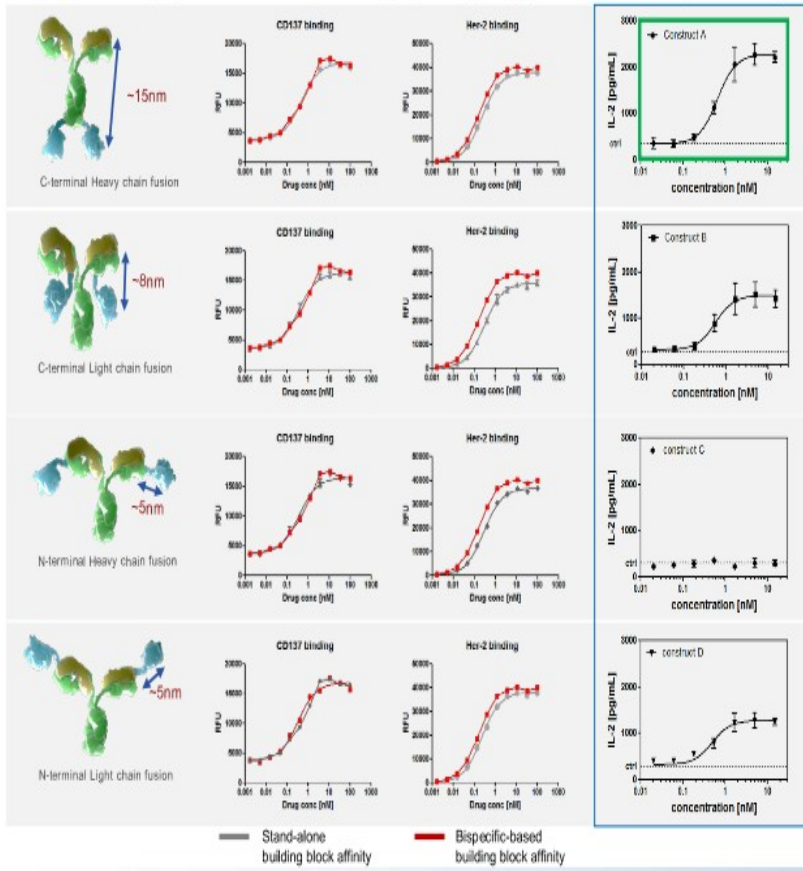


\*4-1BB trimerization required for activation 7

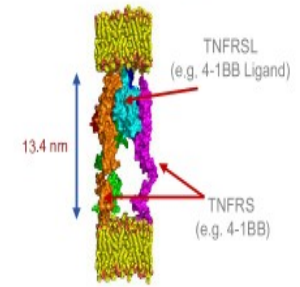
# Anticalin Platform: Well-Equipped for Targeted IO Agonism



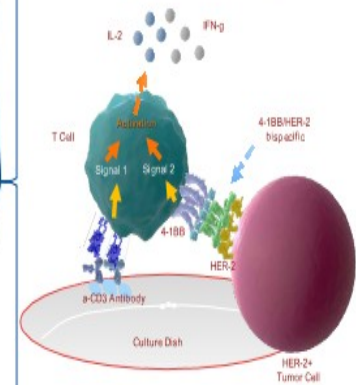
A Varied Immune Synapse... ... Does Not Materially Impact Target Engagement... ...But Impacts Efficacy



The Natural Immune Synapse



Efficacy Experimental Design

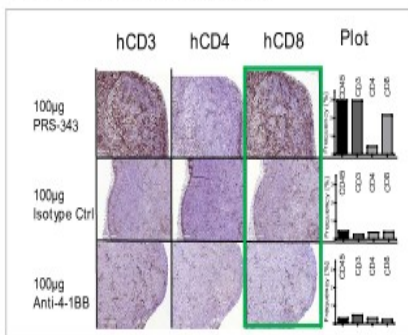


# PRS-343 Shows Localized Activity in Humanized Mouse Model

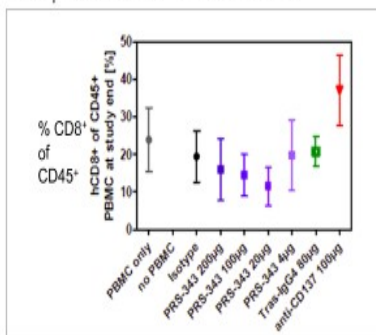


	CD8 <sup>+</sup> Proliferation in TME	Peripheral CD8 <sup>+</sup> Proliferation	Systemic Toxicity
PRS-343	Yes	No	No
4-1BB mAb	No	Yes	Yes
Isotype Control	No	No	No

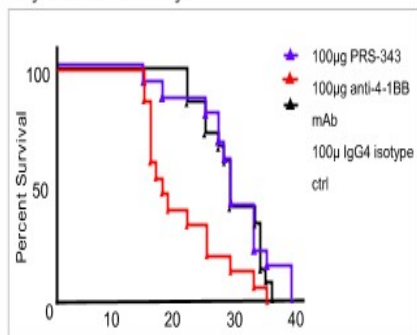
CD8<sup>+</sup> Proliferation in TME



Peripheral CD8<sup>+</sup> Proliferation

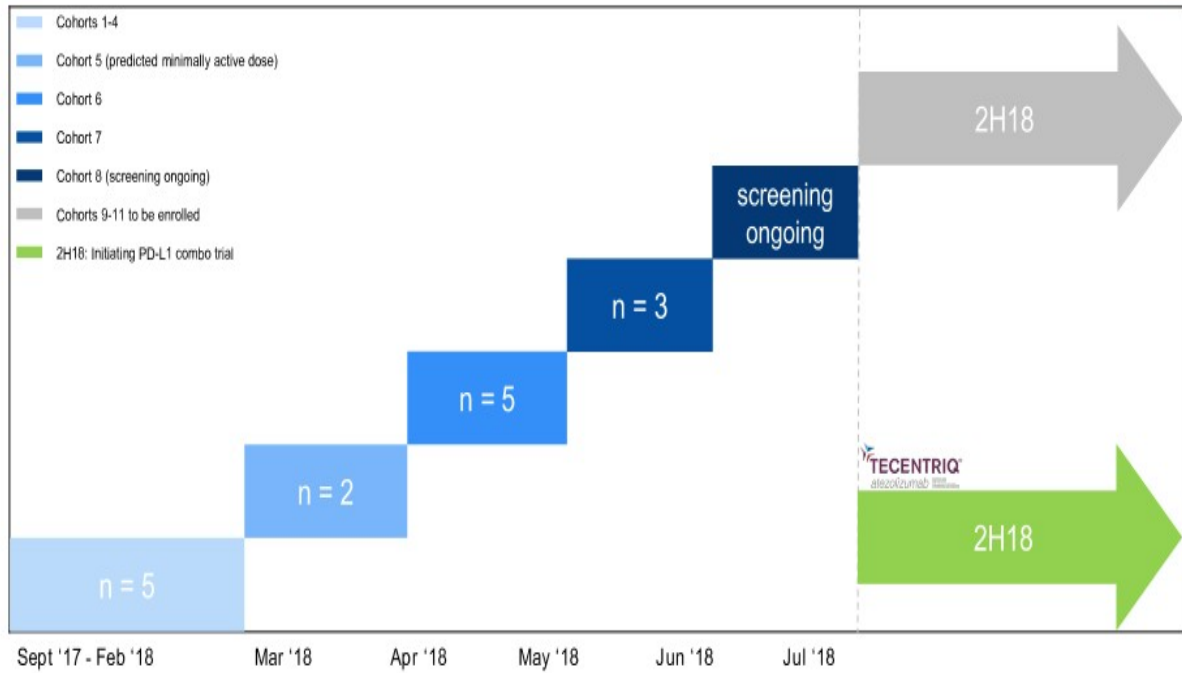


Systemic Toxicity



Experimental design: SKOV-3 tumor cells grafted onto immune-deficient mice; human PBLs + control or PBLs + PRS-343 administered once grafted tumor reaches predetermined volume

# PRS-343 Phase 1 Enrollment\*



\*Enrollment status as of 6/6

\*\*Site initiation planned

# PRS-343 Patient Recruitment Strategy for Escalation and Expansion



## ESCALATION

HER2\* all-comers to efficiently interrogate therapeutic window during escalation

### Tumor types enrolled to date\*

- Breast
- Cholangiocarcinoma
- Colorectal adenocarcinoma
- Endometrial
- Esophageal
- Gastric
- GEJ adenocarcinoma
- Pancreatic
- Vulvar carcinoma

Similar strategy to be employed for Tecentriq® combination trial

## EXPANSION

Bladder

Gastric

Other(s)



\*Enrollment status as of 6/6

# Immuno-oncology Franchise

Prioritizing PRS-343 “fast-followers” and diversified costim agonism beyond 4-1BB



## Proprietary Clinical (worldwide rights)

- 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



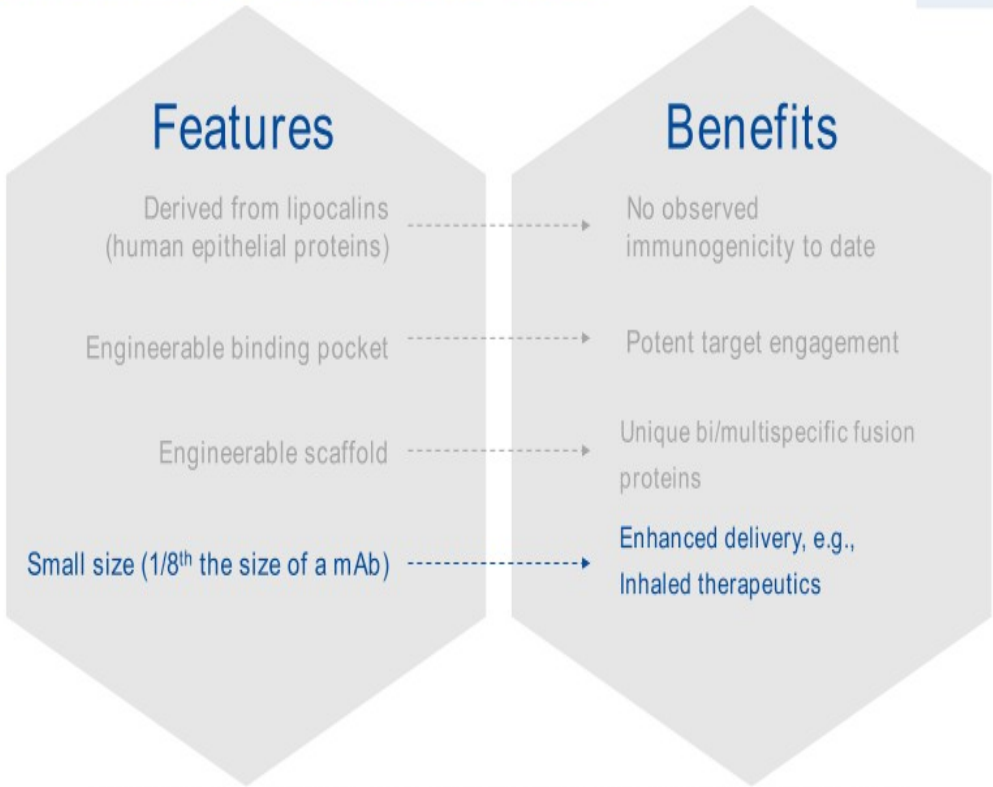
## Seattle Genetics Collaboration



- 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



# Anticalin Proteins: A Novel Therapeutic Class



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

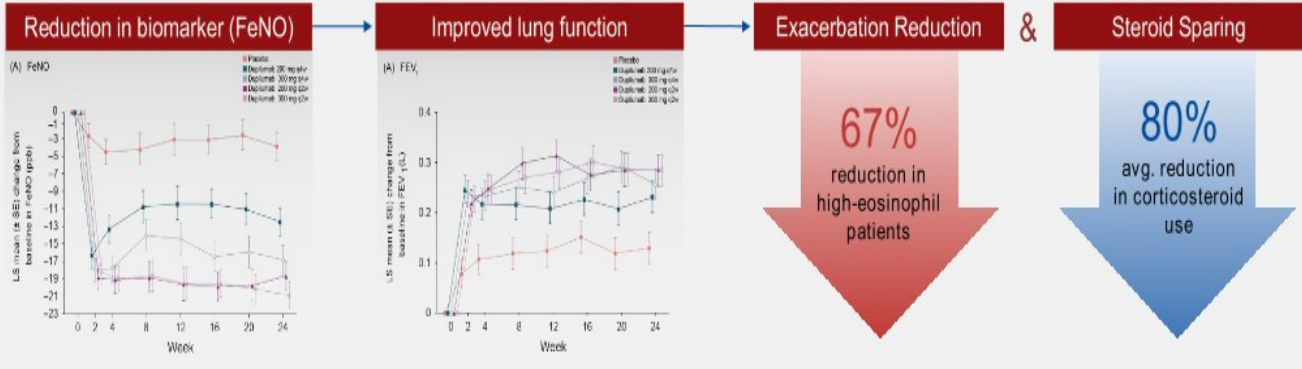
# PRS-060 is an Inhaled Drug Candidate for Uncontrolled Asthma



Why did we design this?

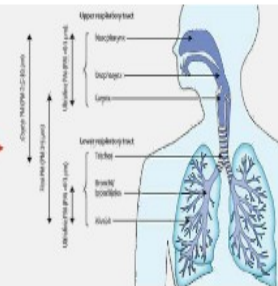
## What We Know

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



## What We Are Testing

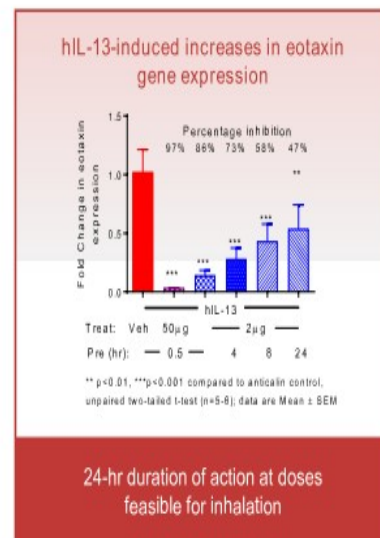
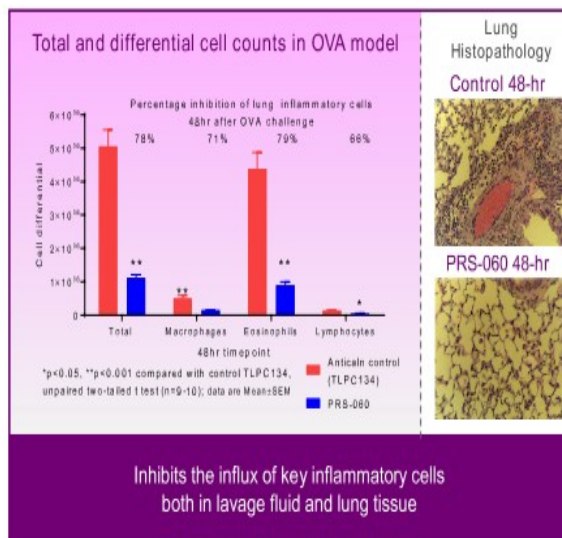
- Is this a local phenomenon? →
- First-in-man study underway via inhaled delivery



# Preclinical In Vivo PoC Support Clinical Development



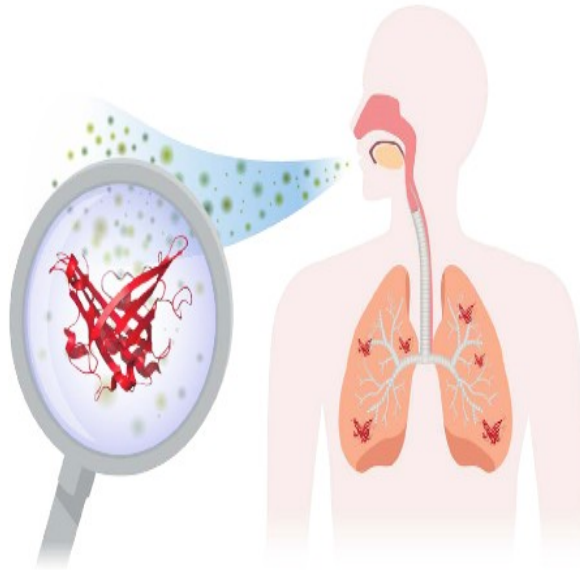
- First inhaled Anticalin protein to potently engage the highly validated asthma target, IL-4Ra
- Localized target engagement in lung tissue supports a rationale for a convenient, low-dose, low-cost alternative to systemically administered antibodies
- Preclinical in vivo PoC for pulmonary delivery at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



# AstraZeneca Provides Complementary Development Know-how



- PRS-060 (Part of AstraZeneca alliance)
  - First-in-class inhaled IL-4Ra antagonist for asthma
  - Phase1a SAD initiated in 4Q17
  - Pieris retains opt-in for co-development/co-commercialization rights in the US
- Proprietary inhaled discovery programs ongoing



## 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



Pieris Pharmaceuticals, Inc.

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

R&D Hub: Freising, Germany (Munich)



[info@pieris.com](mailto:info@pieris.com)  
[www.pieris.com](http://www.pieris.com)

# Appendix

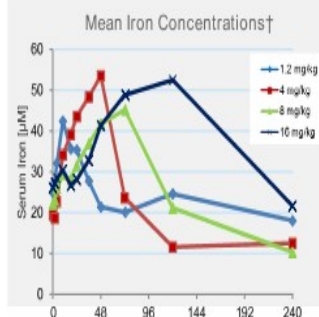


# PRS-080 Shows Consistent Effects in Healthy Volunteers & CKD5 Patients – Ongoing Ph IIa Study will Evaluate Hemoglobin

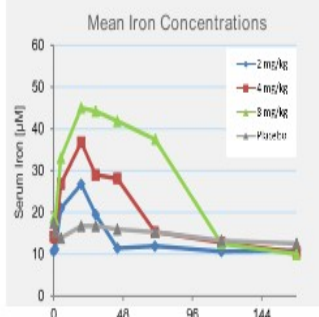


- In both healthy volunteers and CKD5 patients, PRS-080
  - Was safe and well-tolerated
  - Showed a dose-proportional increase of PK parameters (data not shown)
  - Demonstrated dose-dependent PD effects on serum iron and TSAT
  - Led to an immediate dose-dependent decrease in circulating free hepcidin (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

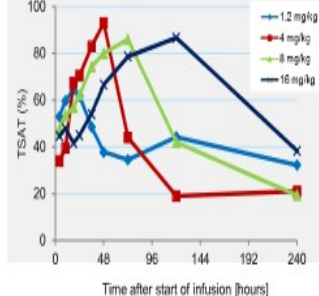
## Ph I SAD in Healthy Volunteers\*



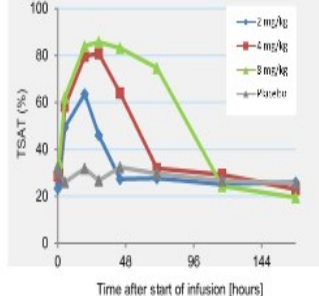
## Ph Ib SAD in CKD5 patients\*\*



## Mean TSAT (%)†



## Mean TSAT (%)




\* Presented at 57th ASH Conference December 2015  
 † Subjects achieving iron response > 34.5 µM (avg. 3 out of 8 subjects / dose cohort)

\*\* Presented at 54th ERA-EDTA Conference June 2017  
 N=24 (16 patients per dose cohort, 8 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

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

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

Christopher Kiritsy  
CEO, Arisaph Pharmaceuticals  
Kos Pharmaceuticals

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

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

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

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

Stephen Yoder  
President & CEO



