

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): March 13, 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 an investor 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 [Investor Presentation of Pieris Pharmaceuticals, Inc., dated March 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: March 13, 2018

/s/ Allan Reine

Allan Reine
Chief Financial Officer



Investor Presentation

March 2018
(Nasdaq: PIRS)

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.

Anticalin Proteins – A Novel Therapeutic Class



Features

Derived from lipocalins
(human epithelial proteins)

Engineerable binding pocket

Engineerable scaffold

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

Benefits

No observed
immunogenicity to date

Potent target engagement

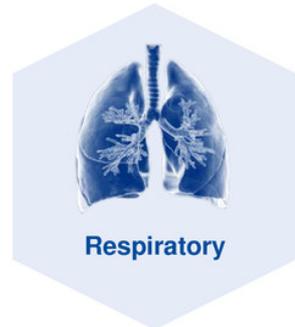
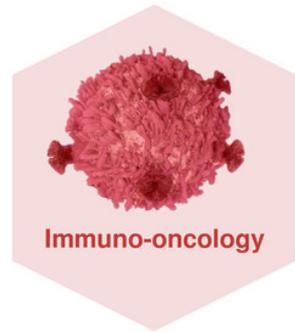
Unique bi/multispecific fusion
proteins

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

Pipeline Highlights

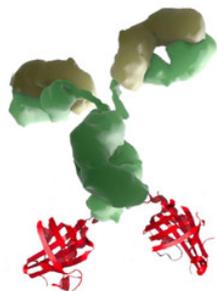
	DISCOVERY	PRECLINICAL	PHASE I	PHASE II
PRS-080				✓
PRS-343			✓	
PRS-060			✓	
Servier	✓	✓		
PRS-300's	✓	✓		
AZ	✓			
SeaGen	✓			

File two IO INDs 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



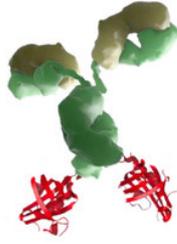
Seattle Genetics Collaboration

- 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?



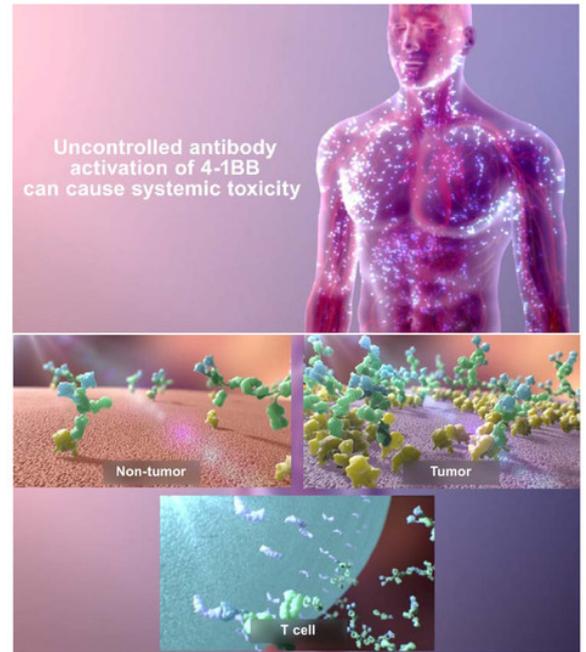
HER2-targeting antibody



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

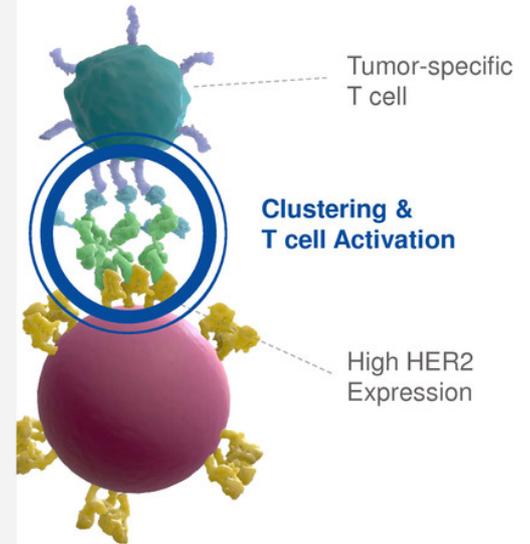
- Marker for tumor-specific T cells in TME
- Ameliorates T cell exhaustion
- Critical for T cell expansion
- Induces anti-tumor cytolytic activity
- Drives central memory T cell differentiation for sustained response

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



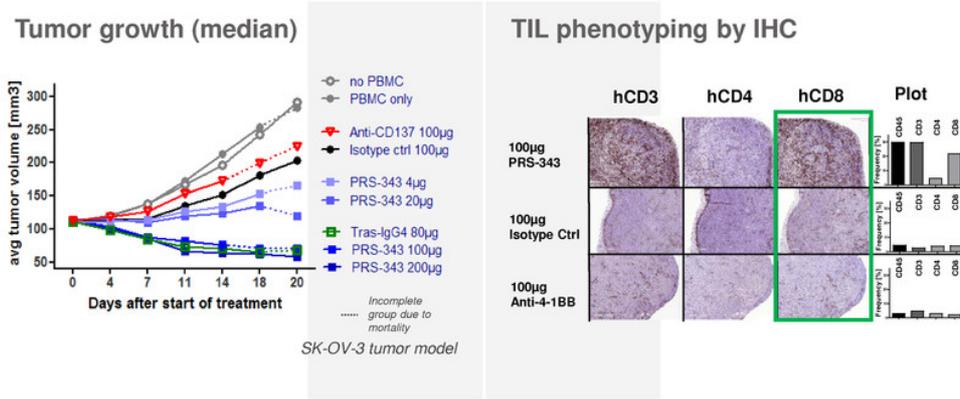
T cell costimulation in TME



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



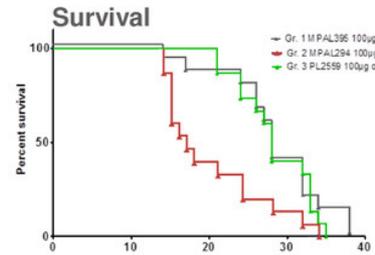
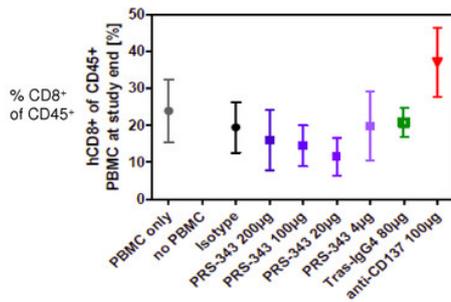
- PRS-343 shows dose-dependent tumor growth inhibition in HER2-sensitive model
- PRS-343 leads to strong and dose-dependent lymphocyte infiltration in tumors; monospecific anti-HER2 mAb (IgG4 backbone) inhibits tumor growth but lacks this immuno-stimulatory activity
- Monospecific anti-4-1BB benchmark 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 data¹



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

PRS-343 First-in-Patient Clinical Trial

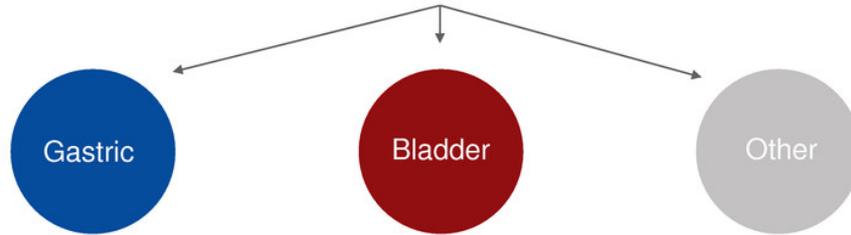


Phase I Trial (Initiated 3Q17)

Dose Escalation Phase

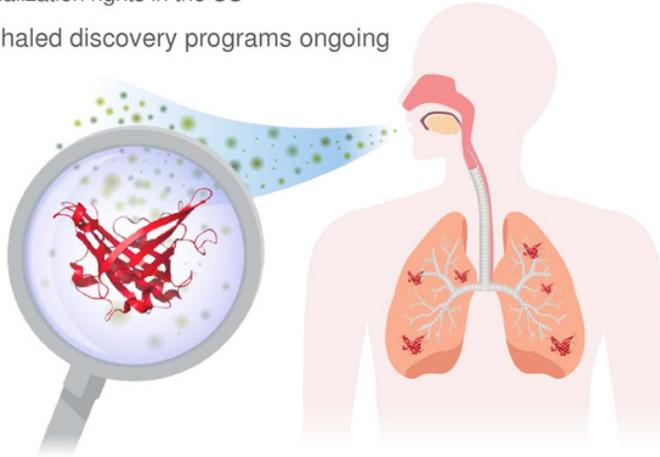
Enrolling HER2+ cancer patients
Starting with single patient cohorts (modified 3+3 design)
Determine maximum tolerated and/or efficacious dose level
Initial safety and PD data 2H18

Expansion Phase



Novel Inhaled Biologics Platform: Targeting Lung Diseases Locally

- PRS-060 (Part of AstraZeneca alliance)
 - First-in-class inhaled IL-4Ra antagonist for asthma
 - Phase I 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

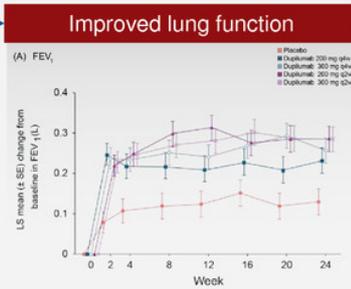
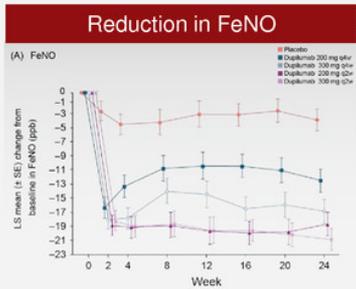
\$57.5M upfront & Phase I MS in 2017; up to ~\$2.1B in milestones, plus double-digit royalties

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:



Exacerbation Reduction

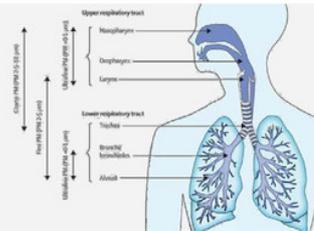
67%
reduction in
high-eosinophil
patients

Steroid Sparing

80%
avg. reduction
in corticosteroid
use

What We Are Testing

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



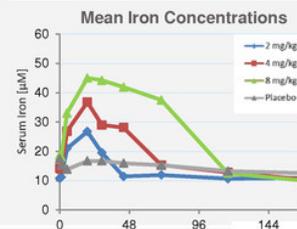
PRS-080 for Anemia – Why did we Design This?

What We Know

Hepcidin is up-regulated in functional iron deficiency anemia

Antagonizing hepcidin with single-dose PRS-080 in CKD5 patients led to Fe mobilization

Ph Ib SAD in CKD5 patients



What We Are Testing

Will antagonizing hepcidin with PRS-080 lead to a hemoglobin increase after 5 q/wk. doses?

- Phase IIa study underway testing two dose cohorts: 4mg/kg and 8mg/kg vs. placebo
- Data expected 2H18



Pieris Pharmaceuticals, Inc.

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

R&D Hub: Freising, Germany (Munich)



info@pieris.com
www.pieris.com

Back Up Slides



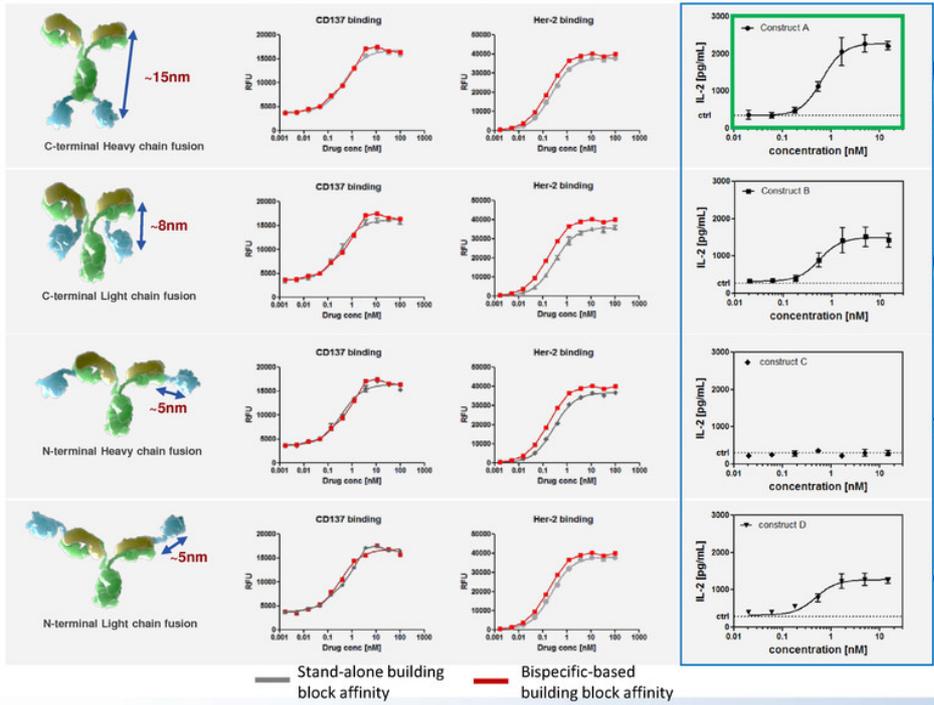
Bispecific Geometry Impacts Immune Synapse, Efficacy



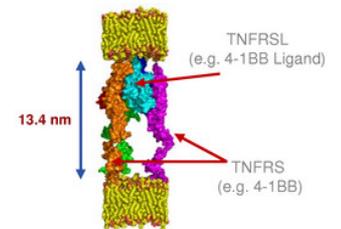
A Varied Immune Synapse...

... Does Not Materially Impact Target Engagement...

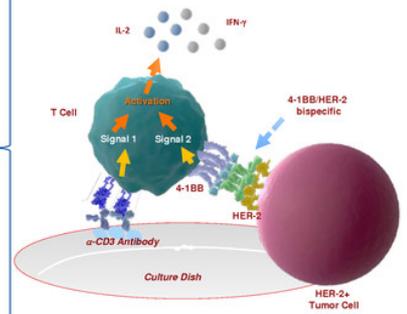
...But Impacts Efficacy



The Natural Immune Synapse



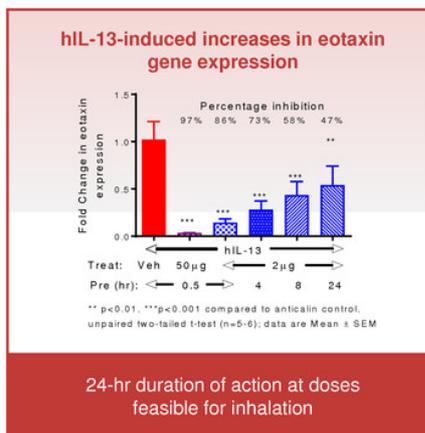
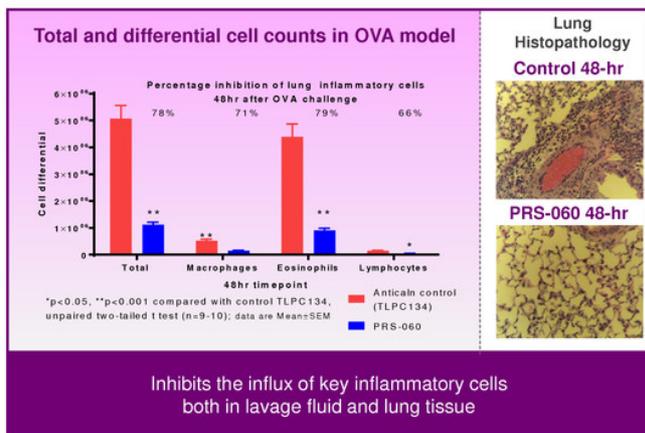
Efficacy Experimental Design



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

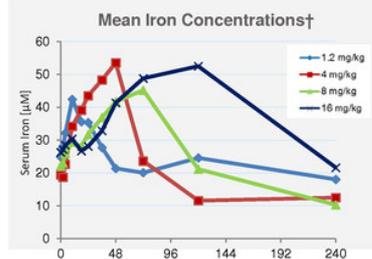


PRS-080 Shows Consistent Effects in Healthy Volunteers & CKD5 Patients – Ongoing Ph IIa Study will Evaluate Hemoglobin

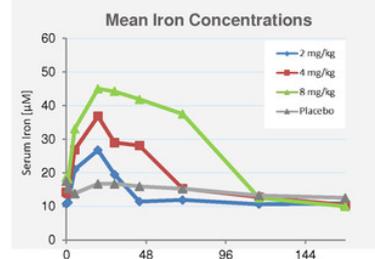


- In both healthy volunteers and CKD5 patients, PRS-080
 - Was safe and well-tolerated
 - Showed a dose-proportional increase of PK parameters (data not shown)
 - Demonstrated dose-dependent PD effects on serum iron and TSAT
 - Led to an immediate dose-dependent decrease in circulating free Hepcidin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

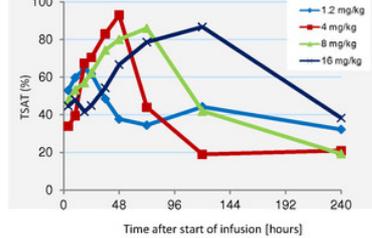
Ph I SAD in Healthy Volunteers*



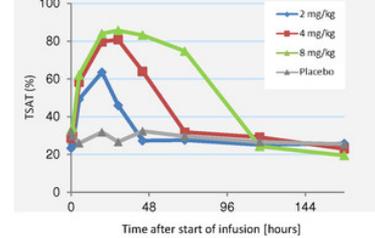
Ph Ib SAD in CKD5 patients**



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 Kirtsy
CEO, Arisaph Pharmaceuticals
Kos Pharmaceuticals

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

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

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

