# 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 22, 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 02109 United States (Address of principal executive offices, including zip code)

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

<del></del>
ck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under 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))

#### Item 7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.1 and incorporated by reference herein is a corporate 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 Corporate Presentation of Pieris Pharmaceuticals, Inc., dated March 22, 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: March 22, 2017 PIERIS PHARMACEUTICALS, INC.

By: /s/ Lance Thibault

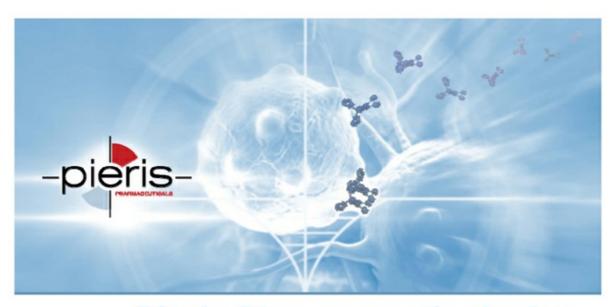
Name: Lance Thibault

Title: Acting Chief Financial Officer

#### EXHIBIT INDEX

#### Exhibit No. Description

99.1 Corporate Presentation of Pieris Pharmaceuticals, Inc., dated March 22, 2017.



# Pieris Pharmaceuticals, Inc. Nasdaq:PIRS

**27th Annual Oppenheimer Healthcare Conference** 

Stephen Yoder, President & CEO

## **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 23, 2016. 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,

## Expanding the Playing Field for Therapeutic Proteins



Novel Drug Class

#### Anticalins® - A Novel Therapeutic Protein Drug Class

- · Fully proprietary and unique
- · Excellent drug-like properties and clinical validation

Novel Modes of Action

#### Multiple Paths for Success & Risk Diversification

- · Potentially transformative immuno-oncology multispecifics PRS-343
  - TME-targeted T cell agonists / Multi-checkpoint blockade
- . Inhaled biologics may bring enormous benefits in respiratory disease PRS-060

Validation and Growth Capital

#### Partnerships and Capital to Pursue Clinical-based Inflection Points

- Transformative alliance with Servier in Immuno-oncology with fully retained US rights on several novel multispecific drug candidates for immuno-oncology
- · JP-market partnership with ASKA de-risks may accelerate time to market for PRS-080
- ~\$100 M in revenues since inception
- \$2.6 B in biodollar potential from partnerships + royalties
- \$60+ million in cash on hand provides runway into 2019 through key value inflection points on fully proprietary pipeline











Non-Confidential

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# **Diversified Immuno-Oncology** (IO) and Non-IO Product Pipeline



#### IMMUNO-ONCOLOGY PROGRAMS

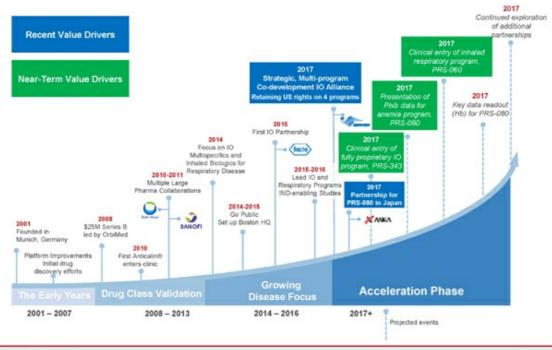
Candidate	Target	Indication	Partner	Our Commercial Rights		IND- enabling	Phase Ib/Ila
PRS-343	4-1BB/HER2 Bispecific	10		Worldwide			
PRS-342	4-1BB/GPC3 Bispecific	10		Worldwide			
PRS-300s	n.d.	10		Worldwide			
PRS-332	PD-1/n.d. Bispecific	10	* A SERVER	U.S.			
Servier 4 Programs	n.d./n.d. Bispecific	Ю	* AUMER	U.S./ Milestones & Royalties			
Roche	n.d.	Ю	Roche	Milestones & Royalties			

#### RESPIRATORY, ANEMIA AND OTHER DISEASE AREAS

Candidate	Target	Indication	Partner	Our Commercial Rights		IND- enabling	Phase I	Phase Ib/Ila
PRS-080	Hepcidin	Anemia	ASKA Pharmaceutical	Major Markets ex-Japan				
PRS-060	IL4Ra	Asthma		Worldwide				
DS-9001	PCSK9	Dyslipidemia	Dala lungo	Milestones & Royalties				
Daiichi Sankyo	n.d.	n.d.	0	Milestones & Royalties				
Sanofi	P. aeruginosa	Infectious disease	SANOFI	Milestones & Royalties				
PRS-110	cMet	Oncology	Zydus	Major Markets				

## **Experiencing an Acceleration Phase**





# Servier Immuno-Oncology Partnership pieris is a Transformative Strategic Alliance





#### Strategic Alliance Highlights

- IO co-development alliance: ~\$30M upfront, up to \$1.8B in potential milestones and low double-digit royalties
- 5 committed bispecifics, including PRS-332 (PD-1-based)
  - Potential to expand to 3 additional bispecific programs
  - Full US commercial rights on PRS-332 and up to 3 additional programs
- · A "True Partnership" equal voice with a collaborator having a shared strategic vision and resources to develop several novel IO bispecifics

#### Strategic Implications of Partnership

- · Underscores the value of Pieris' powerful multispecifics platform in IO
- Extends financial runway into 2019, through several clinical-stage value inflection points
- Fully retained rights on lead IO bispecific, PRS-343 (4-1BB/HER2)
- · Several assets within partnership provide US commercialization opportunity
- · Ability to enter into additional partnerships

## Regional Partnership with ASKA Derisks and Accelerates Development of PRS-080



#### **Alliance Highlights**

- Option deal for Japan, S. Korea and a few smaller Asian countries
- Exercisable after completion of Phase 2a study to be conducted by Pieris
- Option Fee of \$2.75M
- >\$80M in Option Exercise Fee & Milestones for 1st indication in Japan (CKD HD patients)
  - Additional Milestones in other indications and other Asian countries
- · Double-digit royalties up to mid- to high-teens

## X ASKA Pharmaceutical Co., Ltd.

#### **ASKA Company Overview**

- Independent Japanese pharma company
- Founded 1920, >800 employees
- Annual revenues: ~\$400M
- Listed on Tokyo Stock exchange
  - Market Cap: ~\$470M1
  - Largest shareholder: Takeda Pharmaceutical
- · Main therapeutic areas: Internal Medicine, Urology & Woman's Health
- Products distributed through Takeda



#### Strategic Implications of Partnership

- Further validates Anticalin® drug class and value of PRS-080, addressing a high medical need in Japan
- Enables immediate investment into manufacturing efficiencies and future drug supply
- Monetizes non-core asset in a key market (JP), improves probability of finding US/EU partner after P2a
- Facilitates Company focus on clinical development of high-value immunology assets

1: as of Feb 24, 2017

# Anticalins® Share Several Features with mAbs yet are Highly Differentiated



- Monoclonal Antibodies (mAbs) are highly successful drugs
- · Anticalins share many of the beneficial properties of mAbs yet are highly differentiated

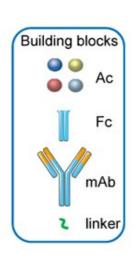
Differentiating	Antibody	Anticalin	
Human-derived	1	<b>V</b>	
Natural binding molecule		1	1
Non-immunogenic		1	1
High affinity and specificity	1	1	
Systemic delivery	√	1	
Tunable pharmacokinetics	(4)	1	
Valent- and geometry-versatile mu		1	
Inhalable		1	
Protein class exclusivity		1	
Positive freedom to operate lands		1	
Safety Related	l I	Related	

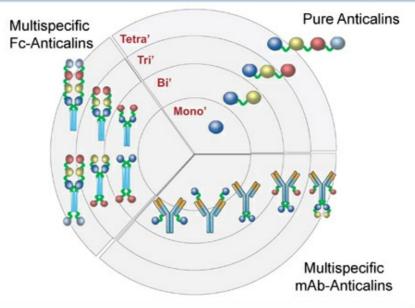


# **Anticalins in Immuno-Oncology**

## Valent- and Geometry-Versatile Multispecifics to Achieve Optimal Biology







Potent Multi-target Engagement | Novel MoA | Excellent Drug-like Properties



## PRS-343 is a First-in-Class TMEactivated Co-stim Agonist



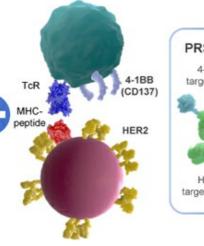
#### 4-1BB (CD137) - Key Costimulatory Target

- 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

#### 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

#### Tumor-specific T Cell

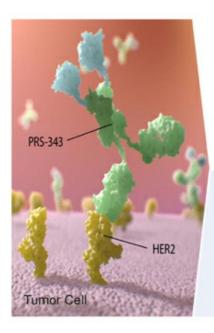




**Tumor Cell** 

# PRS-343 is a First-in-Class TMEactivated Co-stim Agonist

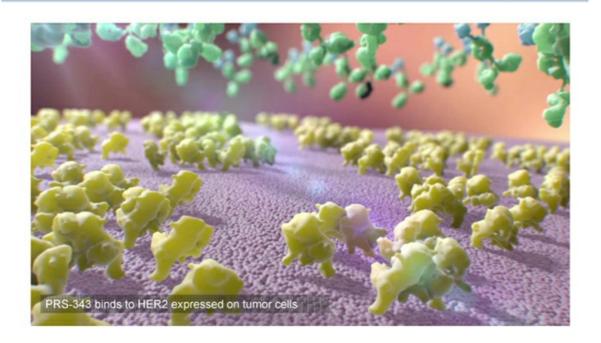




#### Tumor Target: HER2

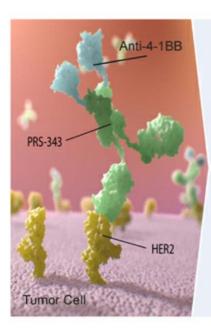
- · A highly validated tumor target
  - · Restricted expression on normal tissue
  - · Several HER2+ tumors with high-unmet
  - Mediates drug mobilization and immune receptor activation within the tumor bed

# PRS-343 Engages HER2 on Tumor Cells-pieris-



## PRS-343 is a First-in-Class TMEactivated Co-stim Agonist





#### T cell Target: 4-1BB

- · Key Costimulatory Target
  - · Marker for tumor-specific T cells in TME
  - · Critical for T cell expansion
  - · Induces anti-tumor cytolytic activity
  - Drives central memory T cell differentiation for sustained response

#### **Tumor Target: HER2**

- · A highly validated tumor target
  - · Restricted expression on normal tissue
  - · Multiple HER2+ tumors with high-unmet
  - Mediates drug mobilization and immune receptor activation within the tumor bed

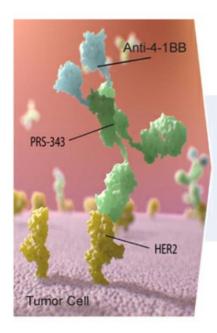
# 4-1BB Engagement by PRS-343, Alone, -pieris-**Does Not Cause T Cell Activation**





## PRS-343 is a First-in-Class TMEactivated Co-stim Agonist

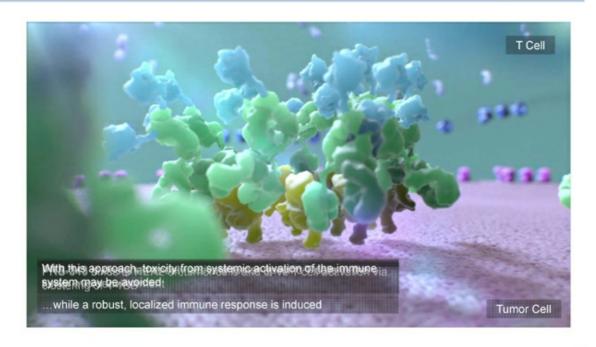




#### Potential Benefits of Pieris' Approach

- · Localized T cell activation
- Reduced T cell-mediated systemic toxicity
- Increased therapeutic index in patients unresponsive to standard of care

# HER2-mediated Clustering of PRS-343 Causes 4-1BB-mediated T Cell Activation



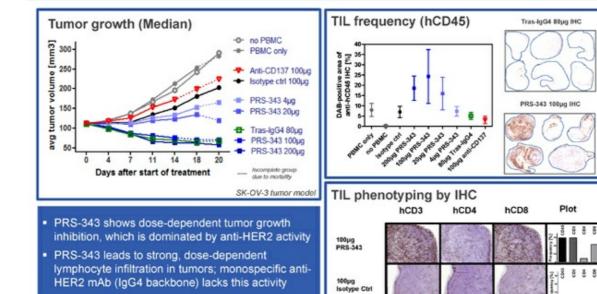
# PRS-343 – *In Vivo* Data Show High Differentiation Over mAbs (1/2)

Monospecific anti-4-1BB benchmark mAb shows

insignificant response compared to isotype control and no significant tumor infiltration of lymphocytes

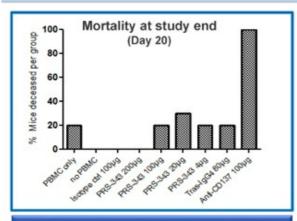


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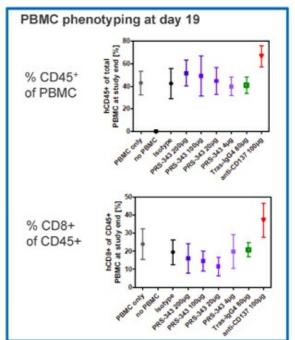


# PRS-343 – *In Vivo* Data Show High Differentiation Over mAbs (2/2)





- Anti-CD137 benchmark mAb shows accelerated GvHD with significant mortality at day 20 in line with literature data<sup>2</sup>
- Toxicity corresponds with expansion of CD8-positive T cells in PBMC for this group

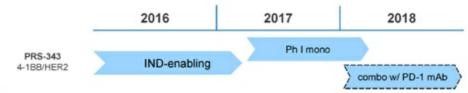


GVHD = graft vs host disease

<sup>&</sup>lt;sup>2</sup> Sanmamed et al., Cancer Res. 2015 Sep 1;75(17):3466-78.

# PRS-343 Phase 1 Initiation Planned for 1H17





- Lead drug candidate progressing through IND enabling studies
  - Demonstrated ability to activate human T cells consistent with desired mode of action
    - · Potent, tumor-dependent activation
    - Differentiation over anti-4-1BB (CD137) mAbs
  - Desired 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
- First-in-Patient Clinical Trial planned for 1H17
  - HER2+ solid tumor patients unresponsive to SOC



## PRS-343 Prioritized Indications Address High-need, Large Markets



#### **Targeted Indication Characteristics**

#### **Known Immune Component**

- · Existing tumor-infiltrating lymphocyte (TIL) repertoire
- Validated role of CD137

#### **High Medical Need**

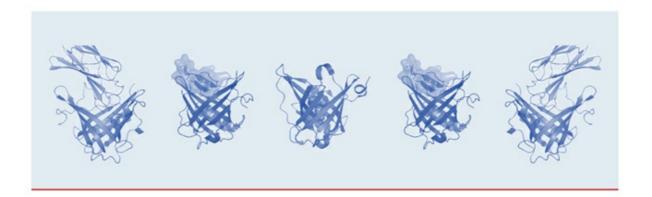
Populations where current HER2 therapies don't work

#### Straightforward Registration Path

Manageable trial size and duration with clear endpoints

Muscle- invasive Bladder Cancer	Advanced Gastric Cancer	Resistant Metastatic HER2+Breast Cancer		
1	1	1		
1	1	1		
✓	1	✓		

	Total Prevalence (2012, in .000s)					Prevalence (2012, in .000s)			
Main Indication	7MM	US	EU5	JP	Relevant Patient subset*	7MM	US	EU5	JP
Diaddersesses	837	520	247	70	Muscle-invasive 1st line, HER2+	108	67	32	9
Bladder cancer					Recurrent, platinum-failed muscle-invasive, HER2+	58	36	17	5
Gastric cancer	514	105	78	331	Advanced gastric cancer, HER2+	23	5	3	15
D	st cancer 4.221 2	2.975	1.000	0 246	Recurrent or metastatic 2nd line, HER2+	143	101	34	8
Breast cancer		2.975	1.000		Recurrent or metastatic 3rd line, HER2+	77	54	18	4
Total	5.572	3.600	1.325	647	* ex US stage distribution based on US data	409	263	105	42



# Anticalins in Respiratory Disease & Anemia

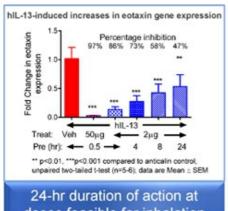
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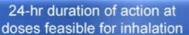
## PRS-060: First-in-Class Inhaled IL-4Ra **Antagonist For Uncontrolled Asthma**

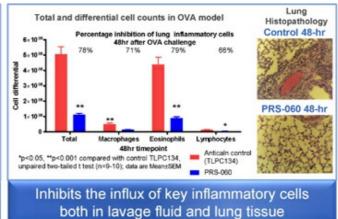


#### First inhaled biologic to potently engage the highly validated asthma target, IL-4Ra

- Localized target engagement in lung tissue supports a rationale for a convenient, low-dose, lowcost alternative to systemically administered antibodies
- Preclinical in vivo POC for pulmonary delivery







#### PRS-060: Phase 1 to Start Mid 2017



First-in-man study initiation planned for mid 2017



- Clear biomarker strategy and pathway to clinical PoC
- ~12 M moderate to severe uncontrolled asthma patients in US/EU

#### PRS-060 progressing through IND-enabling activities

- High affinity to human IL-4Ra: 20 pM
- Based on a protein found in lung epithelial cells (tear lipocalin)
- CMC / Manufacturing: microbial production with robust titers
- Ph I trial with a nebulized formulation
- Nebulization and spray drying feasibility demonstrated

Projected Timing

Non-Confidential

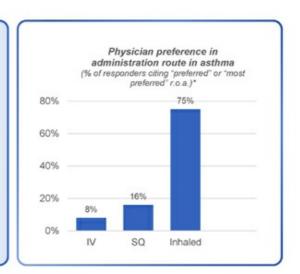
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# PRS-060: Transformational & Blockbuster Potential



#### 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 biologic is positioned to overcome these challenges
- An inhaled IL4Ra blocker has the potential to become market leader and create new markets

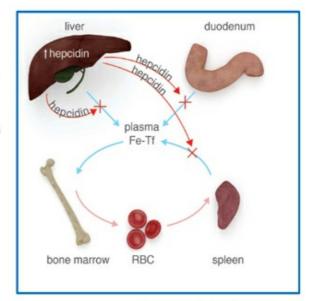


\* Primary market research with prescribing physicians by Artisan Healthcare Consulting (on behalf of Pieris) in 2016

# PRS-080 Offers Further Drug Class Validation & Niche Opportunity in Anemia



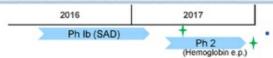
- PRS-080 is a PEGylated Anticalin that potently neutralizes Hepcidin
- Hepcidin is a peptide hormone that regulates iron entry into plasma from the three main sources of iron:
  - Dietary absorption in the duodenum
  - Release of recycled iron from macrophages
  - Release of stored iron from hepatocytes
- Chronic inflammation drives increased hepcidin production
  - Prevents transferrin-mediated transport to the bone marrow for erythropoiesis
  - Causes anemia of chronic disease
  - "functional" iron deficiency (FID), as opposed to absolute iron deficient anemia



Haematologica 2013 98:11

## **PRS-080 Drives Iron Mobilization in** Healthy Subjects; Ongoing Development - pierisin FID ESRD Patients







20

10

-0

40

-60

- Excellent Ph I results (ASH 2015)
  - Safe, well tolerated in HV (36 drug + 12 placebo)
  - Mode of action (iron mobilization) confirmed
    - Increase in serum iron mobilization (p = 0.005)
- First-in-patient trial (dialysis-dependent anemia)
  - ✓ Single Ascending Dosing completed
  - Drug well tolerated encouraging activity
  - Disclosing unblinded data in 2Q17
- Multi-dose trial initiation expected April 2017
  - Hemoglobin (Hb), reticulocyte concentration of Hb as endpoints
  - Planning to disclose data in 2H17

NEW: Regional partnership with ASKA Pharmaceutical in Japan

- First Anticalin projected to achieve clinical Proof of Concept (increased hemoglobin)
- · Will address FID anemia patients poorly responsive to ESAs and iron therapies

16.0 mg/kg

- . Within ESRD, among highest economic burden patient population
- . Est. 90k patients in the US and 80k patients in JP

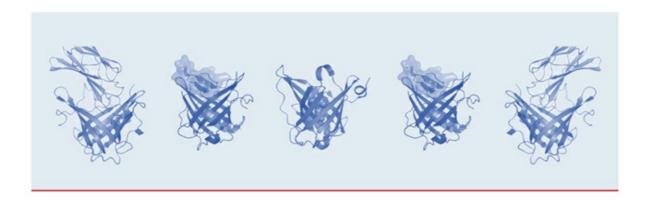
240

· Significant Commercial opportunity

140

Time after start of infusion [hours]

+ = report data



# Senior Management Financials & Milestones

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# **Management and Board Profile**



#### Senior Management Team



Stephen Yoder, J.D. President & CEO





SVP, Chief Development Officer



CGI Pharmaceuticals





Lance Thibault Interim CFO







Claude Knopf SVP, Chief Business Officer

Baxalta





#### **Board of Directors**

Partner, OrbiMed Advisors

Stephen Yoder

President & CEO

Chau Khuong (Chairman)

Amplimune, Chiron, MedImmune, Macrogenics Steven Prelack

Michael Richman

CEO, NextCure, Inc.

SVP, COO, VetCor Velquest Corp., Galectin Therapeutics, BioVex Group Jean-Pierre Bizzari, M.D.

Celgene, Servier, Rhone-Poulenc, Sanofi-Aventis

Julian Adams, PH.D.

Clal Biotechnology, Infinity, Millennium Pharm., LeukoSite Inc.

#### Christopher Kiritsy

CEO, Arisaph Pharmaceuticals Kos Pharmaceuticals

# Financial Highlights - As of 9/30/16



Cash & Cash Equivalents*	\$36.6M
Total Debt	\$0.0M
Revenue Since Inception (license & collaborations)	\$54.0M
Grant Revenue Since Inception	\$14.2M
9 Months 2016 Net Loss	(\$16.2M)
9 Months 2016 Cash Burn (less cash received from PIPE financing & Roche Up Front payment)	\$14.5M
Common Shares Outstanding	43.1M
Preferred Shares Outstanding (as converted)	4.9M
Options Outstanding	4.8M

<sup>\*</sup> Does not include upfront payment of ~\$ 31.3M from Servier collaboration or \$2.75M ASKA option fee

# 2016 Achievements and 2017 Expected Milestones



#### 2016: Significant Achievements

#### Immuno-Oncology

- ✓ Generated our first PD-1 based bispecific (PRS-332)
- ✓ In vivo POC for 4-1BB bispecific immune costimulatory (PRS-343)
- Progressing PRS-343 trough IND-enabling studies

#### Respiratory

 ✓ PRS-060 (asthma) through IND-enabling studies

#### Anemia

 Conducting first-in-patient study for PRS-080 in targeted patient population (FID in ESRD)

#### 2017: a Year of Transformation

#### Immuno-Oncology

- Cornerstone IO Servier Strategic Alliance incl. PRS-332. Runway into 2019 with PRS-343 unencumbered
- PRS 343: First-in-patient clinical trial initiation planned for 1H17
- Several preclinical-stage, highly differentiated multispecifics

#### Respiratory

PRS-060: Initiate First-in-human trial Mid-2017

#### Anemia

- > PRS-080
  - Regional partnership in Japan with ASKA
  - ✓ Phase 1b dosing completed early Q1 2017
  - Phase 1b results disclosure by end of Q2 2017
  - Phase 2a results 2H 2017





#### Pieris Pharmaceuticals, Inc.

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