
**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): January 9, 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

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))
-
-

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 January 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: January 9, 2017

PIERIS PHARMACEUTICALS, INC.

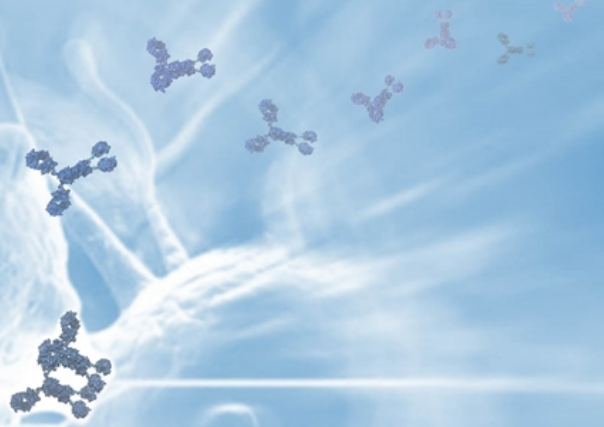
By: /s/ Darlene Deptula-Hicks

Name: Darlene Deptula-Hicks

Title: SVP and Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Corporate Presentation of Pieris Pharmaceuticals, Inc., dated January 2017.



Pieris Pharmaceuticals, Inc.

Nasdaq:PIRS

Corporate Presentation
January 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 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 (IO) multispecifics
 - TME-targeted T cell agonists / Multi-checkpoint blockade
- Inhalation – a topical approach to asthma may bring enormous benefits

Validation and Growth Capital

Partnerships and Capital to Pursue Clinical-based Inflection Points

- Transformative IO partnership with Servier brings significant upfront payment, fully retained US rights on several novel multispecific drug candidates
- \$2.5 B in biodollar potential across Large Pharma partnerships + royalties
- \$60+ million in cash on hand after Servier upfront provides runway into 2019 through key value inflection points on fully proprietary pipeline
 - **PRS-343** (IO): first-in-patient trial initiation 1H17; **PRS-060** (asthma): first-in-man trial initiation mid '17; **PRS-080** (anemia): multi-dose trial read-out (hemoglobin) 2H17



Servier Immuno-Oncology Partnership is a Transformative Strategic Alliance



Strategic Alliance Highlights

- IO co-development alliance with ~\$30M upfront, up to \$1.8B in potential milestones and low double-digit royalties
- 5 committed IO bispecifics, including PRS-332 (PD-1-based bispecific)
 - Potential to expand to 3 additional bispecific programs
 - Retained co-development and 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
- Strengthens cash position to fund development of proprietary product pipeline, while extending financial runway into 2019, through several clinical-stage value inflection points
- Fully retained rights on lead IO bispecific, PRS-343 (4-1BB/HER2), and ability to enter into additional partnerships

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



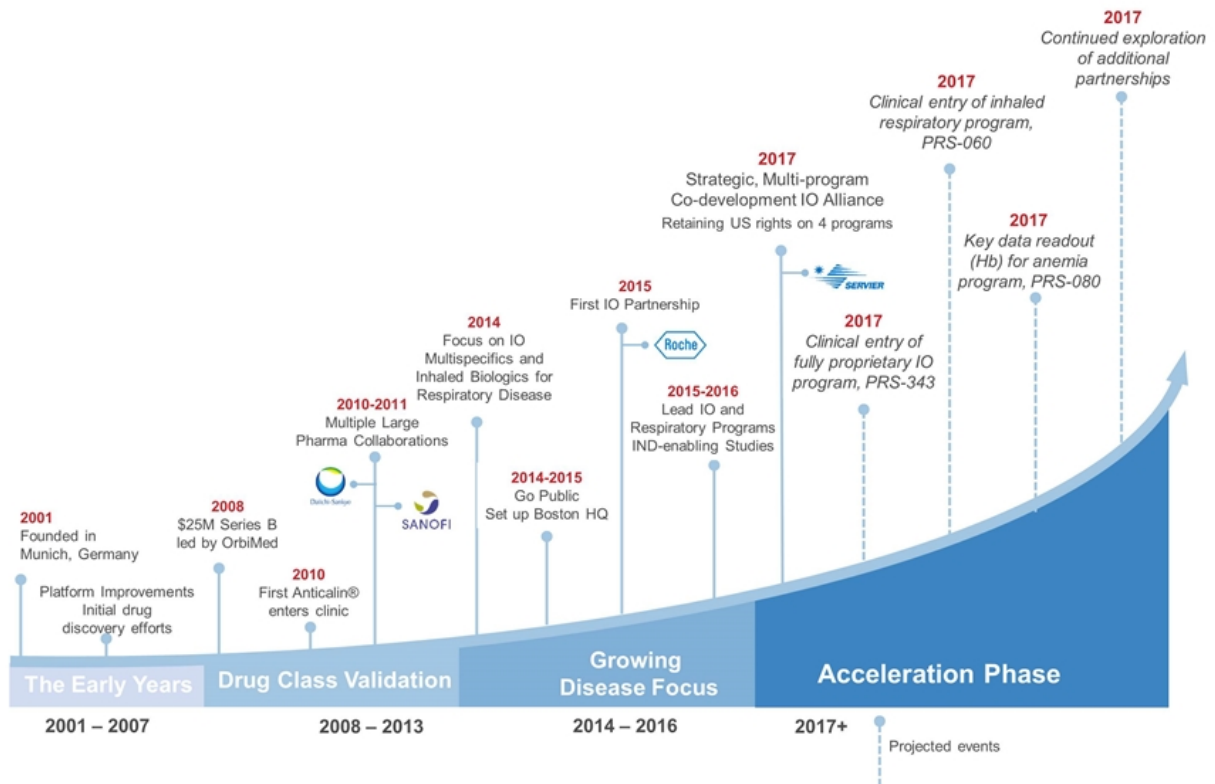
IMMUNO-ONCOLOGY PROGRAMS

Candidate	Target	Indication	Partner	Our Commercial Rights	Discovery	Preclinical	IND-enabling	Phase I	Phase Ib/IIa
PRS-343	4-1BB/HER2 Bispecific	IO		Worldwide	[Progress bar]				
PRS-342	4-1BB/GPC3 Bispecific	IO		Worldwide	[Progress bar]				
PRS-300s	n.d.	IO		Worldwide	[Progress bar]				
PRS-332	PD-1/n.d. Bispecific	IO		U.S.	[Progress bar]				
Servier 4 Programs	n.d./n.d. Bispecific	IO		U.S. / Milestones & Royalties	[Progress bar]				
Roche	n.d.	IO		Milestones & Royalties	[Progress bar]				

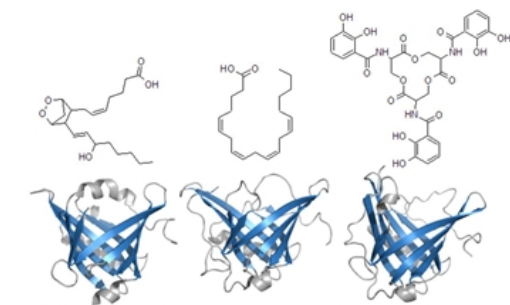
RESPIRATORY, ANEMIA AND OTHER DISEASE AREAS

Candidate	Target	Indication	Partner	Our Commercial Rights	Discovery	Preclinical	IND-enabling	Phase I	Phase Ib/IIa
PRS-080	Hepcidin	Anemia		Worldwide	[Progress bar]				
PRS-060	IL4Ra	Asthma		Worldwide	[Progress bar]				
DS-9001	PCSK9	Dyslipidemia		Milestones & Royalties	[Progress bar]				
Daiichi Sankyo	n.d.	n.d.		Milestones & Royalties	[Progress bar]				
Sanofi	<i>P. aeruginosa</i>	Infectious disease		Milestones & Royalties	[Progress bar]				
PRS-110	cMet	Oncology		Major Markets	[Progress bar]				

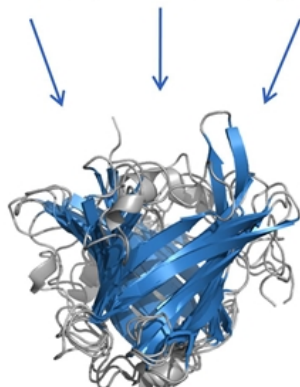
Entering an Acceleration Phase



Anticalin® Drug Class Origins



3 of 12 human lipocalins and endogenous ligands





Overlay of several lipocalin X-ray structures

- Anticalins® are recombinantly engineered human lipocalins
 - Lipocalins are non-immunogenic, extra-cellular binding proteins
 - Lipocalins have very low sequence identity, yet structural conservation among the 12 known human members is the foundation of the scaffold
- Monomeric, stable, low molecular weight (~18 kDa)
- Phage display-based drug discovery platform

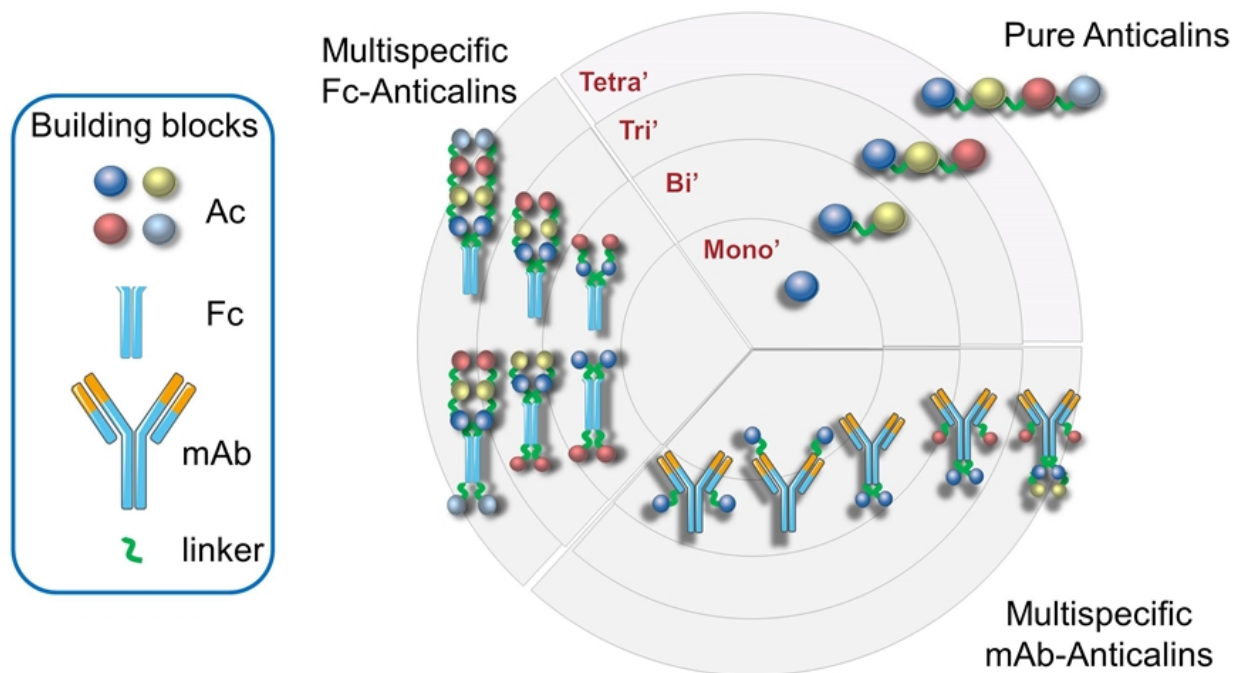
Anticalins® Share Several Features with mAbs yet are Highly Differentiated



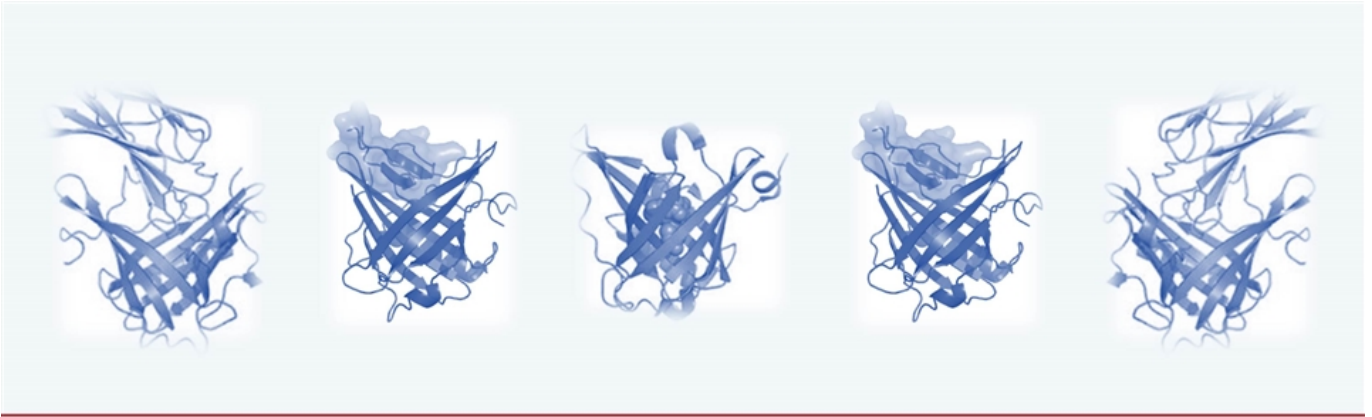
- Monoclonal Antibodies (mAbs) are highly successful drugs
- Anticalins share many of the beneficial properties of mAbs yet are highly differentiated

Differentiating Features	 Antibody	 Anticalin
Human-derived	√	√
Natural binding molecule	√	√
Non-immunogenic	√	√
High affinity and specificity	√	√
Systemic delivery	√	√
Tunable pharmacokinetics	(√)	√
Valent- and geometry-versatile multispecifics		√
Inhalable		√
Protein class exclusivity		√
Positive freedom to operate landscape		√
	Safety Related	Efficacy Related
		IP Related

Valent- and Geometry-Versatile Multi-specifics to Achieve Optimal Biology



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



Anticalins[®] in Immuno-Oncology

Differentiation Through Unique Multispecific Formats

- 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 (partnered with Servier)
 - Demonstrate superiority to existing PD-1 mAbs
 - Exploit independent and fully proprietary PD-1 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 studies¹

Next-Generation IO Therapies:
Novel multispecifics, novel combinations, wholly owned

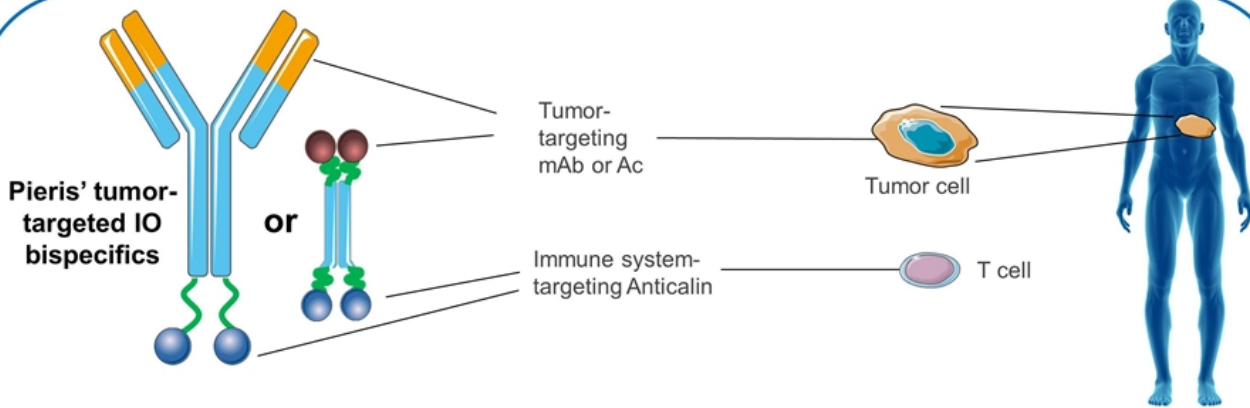
¹Shindo, Y et al., Anticancer Res. 2015 Jan;35(1):129-36

Lead IO Program (PRS-343) Addresses Biology Challenging for Antibodies Alone



The Challenges of Agonistic mAb Approaches

- Inconsistent agonistic activity (e.g. urelumab vs. utomilumab)
- Systemically agonizing mAbs have resulted in narrow therapeutic window due to cytokine storm (urelumab, TGN1412)



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

PRS-343 is a First-in-Class TME-activated Co-stim Agonist

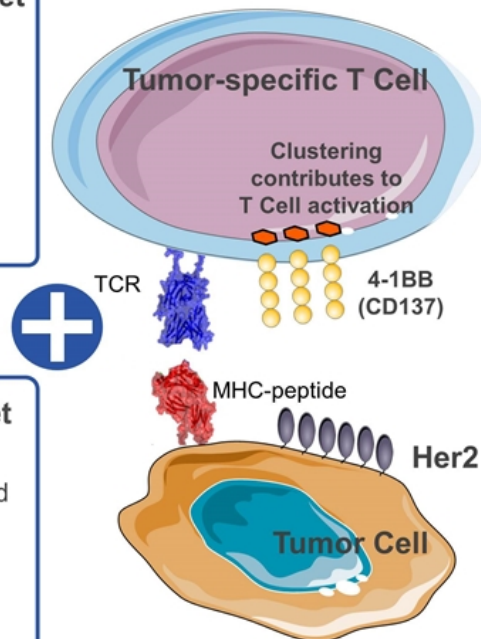


4-1BB (CD137) – Key Costimulatory Target

- 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, Esophageal, Colorectal, Biliary, Pancreas, Bladder, Ovarian, Endometrial, Lung (AdenoCa), Salivary Duct, Head/Neck
- Mediates drug mobilization and immune receptor activation within the tumor bed



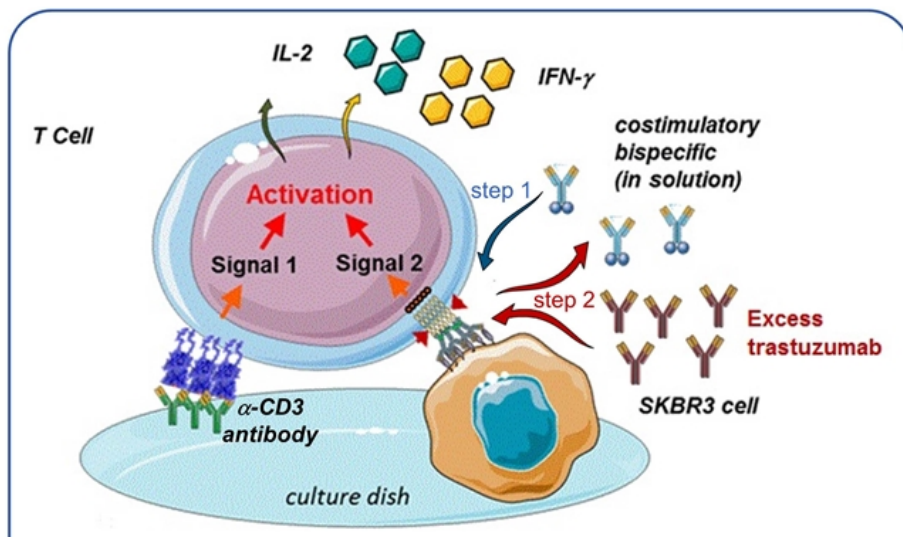
PRS-343

4-1BB-targeting Ac



HER2-targeting mAb

PRS-343 Demonstrates Targeted T Cell Activation Ex Vivo

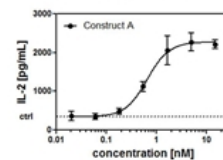


(Step 1) PRS-343 potently activates T cells mediated by 4-1BB cross-linking upon binding to HER2-positive tumor cells (SKBR3)

(Step 2) Addition of excess HER2-targeting trastuzumab prevents PRS-343 binding to HER2-positive cells and results in a loss of activity, as intended, confirming mode of action

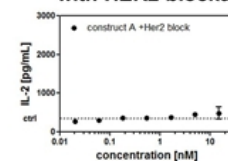
PRS-343 in presence of HER2-positive tumor cells (step 1)

Cell activation = IL-2 response

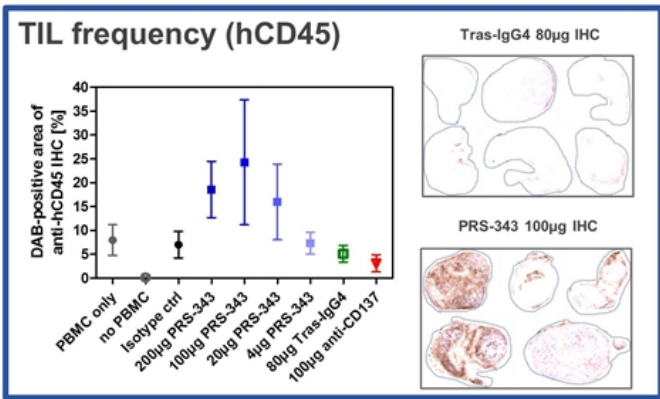
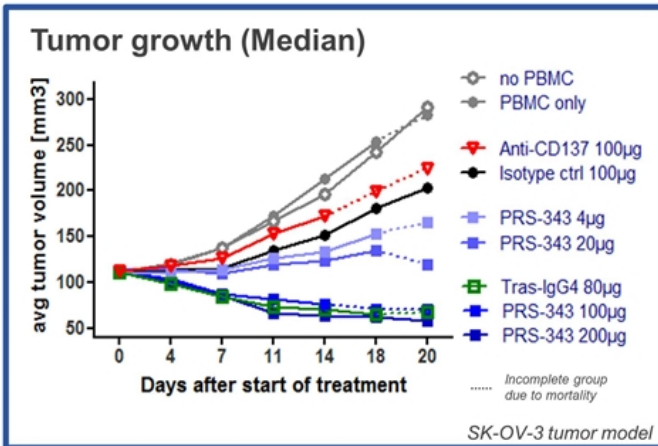


PRS-343 in solution, following addition of excess trastuzumab (step 2)

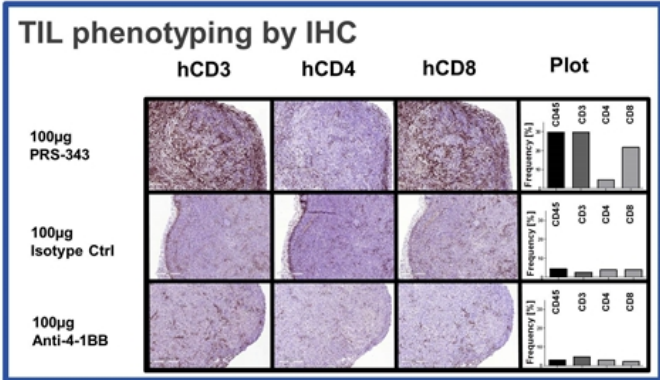
IL-2 response with HER2 blockade



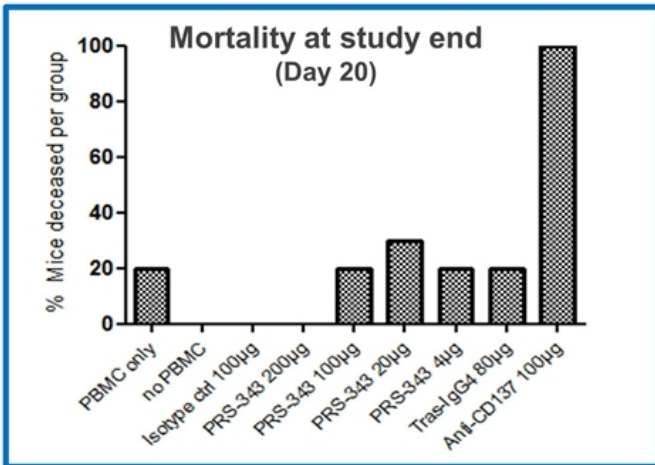
PRS-343 Shows Bifunctional Activity – Dose-dependent Tumor Growth Inhibition & CD8(+)TIL Expansion in SK-OV-3 Model



- 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



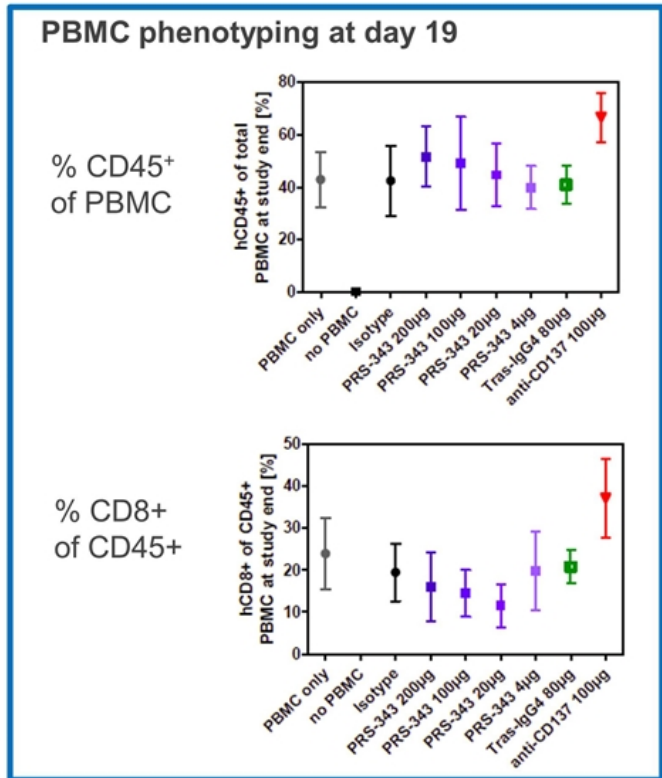
PRS-343 Repeatedly Demonstrates Differentiation Over anti-HER2 and 4-1BB mAbs



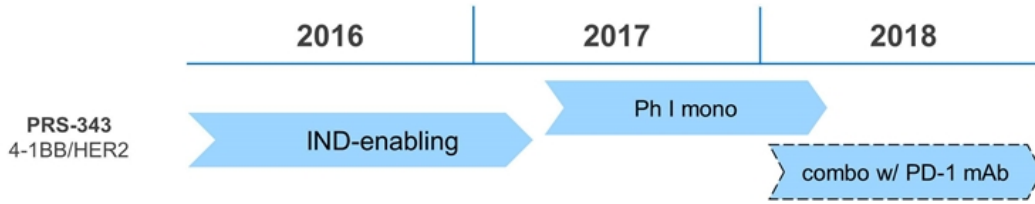
- Anti-CD137 benchmark mAb shows accelerated GvHD with significant mortality at day 20 in line with literature data²
- Toxicity corresponds with expansion of CD8-positive T cells in PBMC for this group

¹ GvHD = graft vs host disease

² Sanmamed et al., Cancer Res. 2015 Sep 1;75(17):3466-78.



PRS-343: IND Enabling Activities on Track to Support a FIM in H1 2017



Targeted Indication Characteristics

Known Immune Component

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

High Medical Need

- HER2 Patient Populations unresponsive to or relapsed from standard of care

Straightforward Registration Path

- Manageable trial size and duration with clear endpoints

Priority Patient Populations

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

❑ Differentiated profile vs HER2- and 4-1BB-directed benchmark mAbs

- PRS-343 has dual functionality based on monospecific HER2-targeting and bispecific, tumor-localized costimulation of 4-1BB.
 - Potential for synergistic anti-tumor activity
 - Anti-HER2 mediated tumor growth inhibition
 - 4-1BB-mediated anti-tumor T cell activation
 - Potential to avoid undesirable peripheral T cell activation (**reduced systemic side effects**)

❑ Excellent drug-like properties

- Antibody-like half-life in mice and cynomolgus monkey
- Low immunogenicity risk (ex vivo Lonza Epibase® test)
- High titers at GMP stage (1000L) and excellent stability

❑ Near-term clinical-stage milestones

- First-in-patient clinical trial initiation planned for 1H17
 - HER2+ solid tumor patients unresponsive to SOC
- Data-driven focus on high unmet need tumors, e.g. gastric, bladder and breast
- Combination trial with PD-1 mAb planned for 2018

PRS-332: Novel PD-1-based IO Bispecific Co-Developed by Pieris & Servier

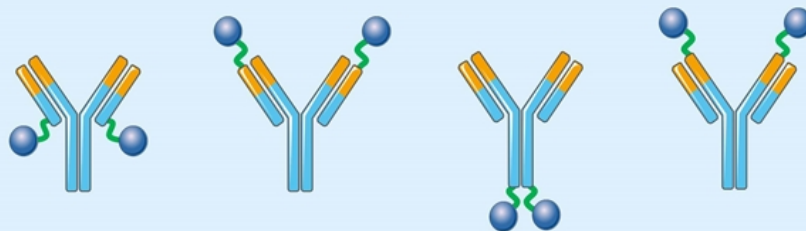


Undisclosed
anti-c.p. Ac

PD-1 mAb



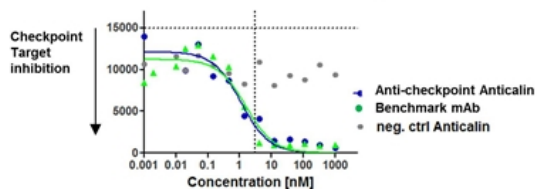
Peptide linker

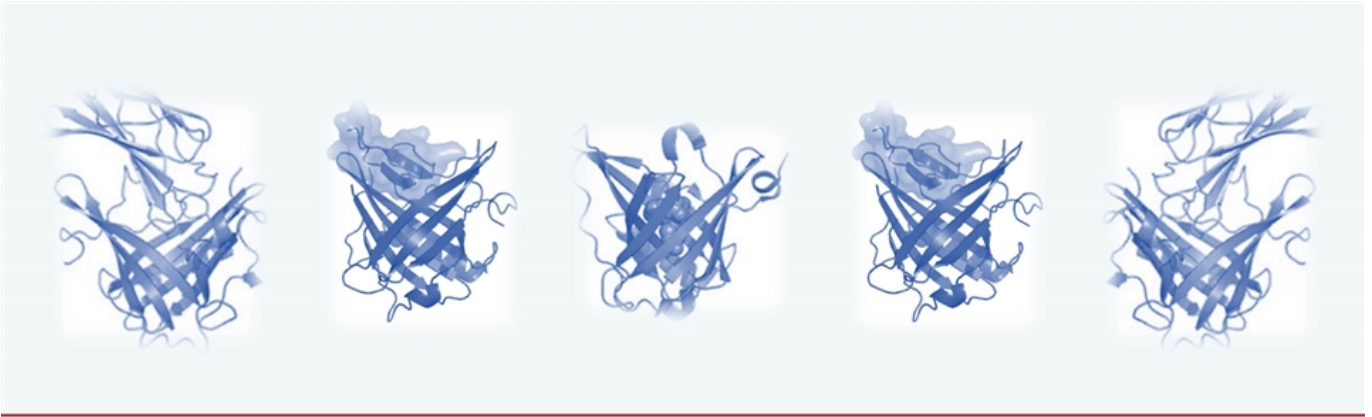


PRS-332: PD-1-based bispecifics

- Bispecific protein comprising proprietary Anticalin & novel in-licensed PD-1 mAb
- Several bispecific permutations under preclinical evaluation
- Future combination with PRS-343

Anti-checkpoint Anticalin is a potent, competitive antagonist



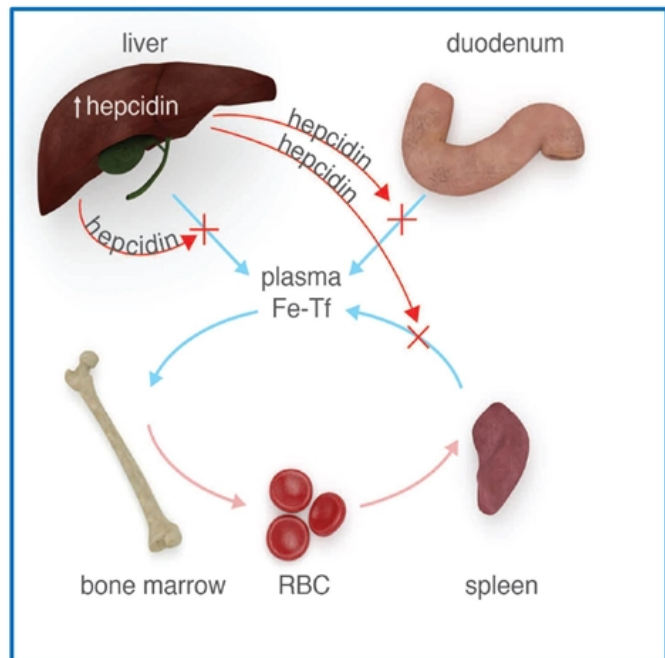


Anticalins in Anemia and Asthma

PRS-080 Potently Neutralizes Hepcidin, The Master Regulator of Iron Metabolism



- Hepcidin is a peptide hormone that serves as a key regulator of iron metabolism by **regulating 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) vs absolute iron deficient anemia
- PRS-080 is a pegylated Anticalin that binds with high affinity and neutralizes Hepcidin



Haematologica 2013 98:11

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

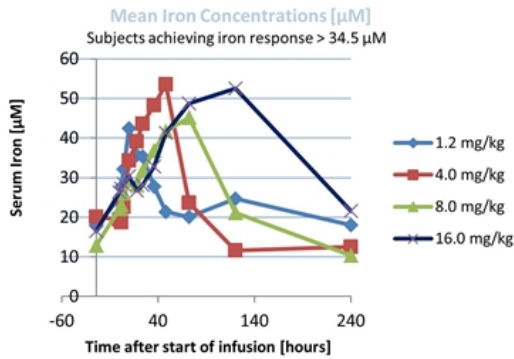


2016

2017

Ph Ib (SAD)

Ph 2
(Hemoglobin e.p.)

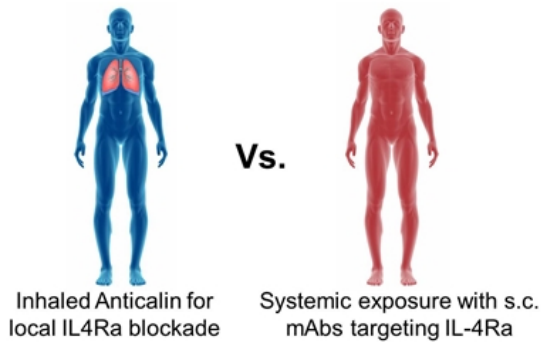


- Excellent Ph I results (ASH 2015)
 - Safe, well tolerated in HV (36 drug + 12 placebo)
 - Mode of action (iron mobilization) confirmed
 - Increase in serum iron mobilization ($p = 0.005$)
- First-in-patient trial (ESRD) ongoing
 - Single Ascending Dosing completion expected end of Jan 2017
 - Drug well tolerated – Encouraging activity
 - Disclosing unblinded data by end of Q2 17
- Multi-dose trial initiation expected April 2017
 - Hemoglobin (Hb), reticulocyte concentration of Hb as endpoints
 - Disclosing data in 2H 17

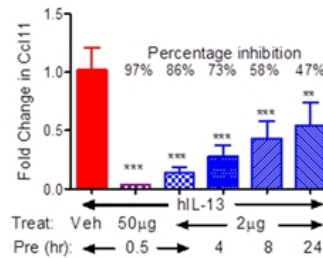
- **First Anticalin projected to achieve clinical Proof of Concept (increased hemoglobin)**
- Will address FID anemia patients poorly responsive to ESAs and iron therapies
 - Within ESRD, among highest economic burden patient population
 - Est. 90k patients in the US and 80k patients in JP
 - Significant Commercial opportunity

✦ = report data

PRS-060: First-in-Class Inhaled IL4Ra Antagonist For Uncontrolled Asthma



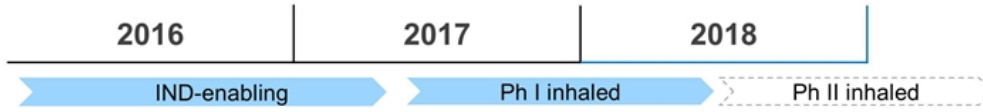
PRS-060 inhibits IL4Ra-mediated inflammation *in vivo*



- First **inhaled biologic** to potentially engage highly validated asthma target (IL4Ra)
 - IL4Ra is a critical target in uncontrolled asthma
 - Target engagement on lung tissue is a key differentiator over SQ injected mAbs
 - Potential low-dose, low-COGs alternative to mAbs
- Preclinical *In-vivo* POC for pulmonary delivery
- Formulability for pulmonary delivery

PRS-060: Phase 1 to start mid 2017

Convenient Formulation, Large Addressable Market



- First-in-man study initiation planned for mid 2017
- Targeted uncontrolled asthma population of ~20M patients world-wide

RATIONALE AND ADVANTAGES:

Clear Biology Rationale with Manageable Development Path

- Validated target in inflammation associated with uncontrolled asthma
- Clear biomarker strategy and pathway to clinical PoC & Registration

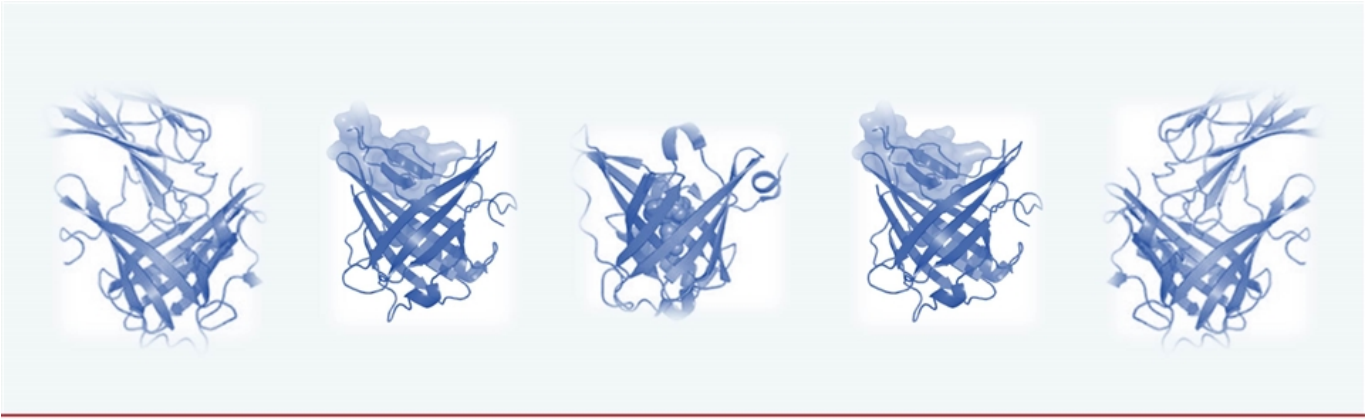
Potential Manufacturing advantages:

- Low manufacturing cost
- Highly potent drug requiring reduced drug concentration

Patient- and Physician-friendly

- Locally inhaled to increase patient convenience
- Primary care physicians not as comfortable with IV and SQ injections

Antibodies	Anticalins
✓	✓
	✓
	✓



Corporate – Financials – Goals – Accomplishments

Expanding the Playing Field for Therapeutic Proteins



Novel Drug Class

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

Novel Modes of Action

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Management and Board Profile



Senior Management Team



Stephen Yoder, J.D.
President & CEO



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



Darlene Deptula-Hicks
SVP, Chief Financial Officer



Claude Knopf
SVP, Chief Business Officer



Board of Directors

Stephen Yoder
President & CEO

Chau Khuong (Chairman)
Partner, OrbiMed Advisors

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

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

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

Julian Adams, PH.D.
Director
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

* Does not include upfront payment of ~\$ 31.3M from Servier collaboration

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 through 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** including PRS-332. Financial runway into 2019 and leaves PRS-343 unencumbered
- **PRS 343: First-in-patient** clinical trial initiation planned for 1H17
- Several preclinical-stage, highly differentiated multispecifics

Respiratory

- **PRS-060: Initiation of First-in-patient** trial Mid-2017

Anemia

- **PRS-080**
 - **Phase 1b results** disclosure by end of Q2 2017
 - **Phase 2a results** 2H 2017



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