
**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): December 8, 2015

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.)

Lise-Meitner-Strasse 30
85354 Freising-Weihenstephan, Germany
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: +49 81 6114 11400

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 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 Corporate Presentation of Pieris Pharmaceuticals, Inc., dated December 8, 2015.

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: December 8, 2015

PIERIS PHARMACEUTICALS, INC.

By: /s/ Darlene Deptula-Hicks

Name: Darlene Deptula-Hicks

Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No. Description

99.1 Corporate Presentation of Pieris Pharmaceuticals, Inc., dated December 8, 2015.



Pieris Pharmaceuticals, Inc.

Nasdaq:PIRS

Corporate Presentation – December 2015

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 preliminary prospectus filed with the SEC on June 17, 2015. 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 Pharmaceuticals

Corporate Profile



- We are a clinical-stage biotechnology company developing **Anticalin[®]**-based therapeutic proteins
 - We target validated disease pathways in a unique and transformative way
 - Unique potential in IO with several high-value opportunities
- Proprietary to us, Anticalins are a novel class of drugs validated in the clinic and by partnerships with leading pharmaceutical companies
- Our pipeline includes three fully proprietary Anticalin-based programs
 - First-in-class immuno-oncology bispecific tailored for the tumor micro-environment
 - First-in-class inhaled Anticalin to treat uncontrolled asthma
 - Best-in-class half-life-optimized Anticalin to treat anemia
- We have additional partnered programs generating milestone income
- Headquartered in Boston, MA

NEWS: First IO Partnership Roche – The Global Oncology Leader



Scope:

- One-target but potentially multi-program
- Roche solely responsible starting from IND-enabling studies

Financial:

- Pieris receives upfront payment of ~US\$6.4 million
- Roche fully funds collaborative research phase
- Total potential deal could exceed US\$400 million
 - Majority of agreed payments for development milestones
 - Not including royalties, which are up to low double-digit

Strategic Implications:

- Validation of Anticalins[®] in IO by industry leader
- Ability to sign additional partnerships
- Free cash flow to advance proprietary programs





Anticalins

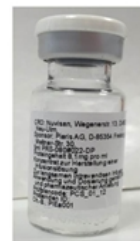
Proprietary Next-generation Therapeutic Proteins With Several Degrees of Validation

- **Human data demonstrating desired drug-like properties**
 - 26 solid tumor patients with VEGF-A antagonist
 - 36 healthy volunteers with hepcidin antagonist
- **Several Big Pharma R&D partnerships generating >\$45 M in revenue**
 - Several milestone payments in 2015
 - First partnered program entered clinical stage in 4Q15 (Daiichi)



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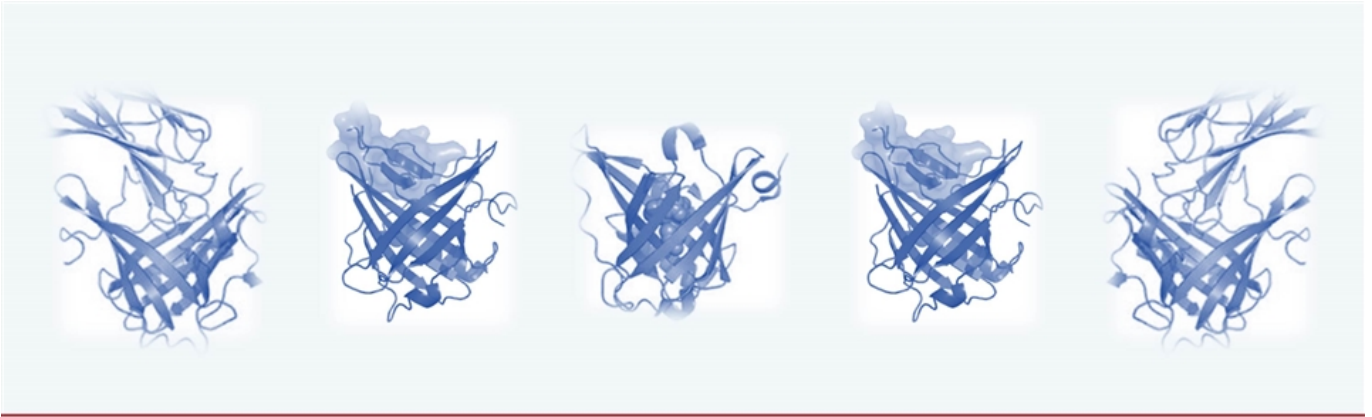
- **High-caliber Investors**
 - OrbiMed Advisors (18%), Tekla Capital Management (10%), Omega Funds (7%), Lombard Odier (6%); Auriga, Emerald Mutual Fund, Gilde, Novo Nordisk, Sphera Funds, Zydus

Anticalin Product Pipeline



	Product	Target(s)	Indication	Partner	Discovery	Preclinical	Phase 1	Phase 2
1. Validated Targets	PRS-080	Hepcidin	Anemia		PEGylated Anticalin			
	PRS-060	IL4Ra	Asthma		inhalable Anticalin			
2. IO	PRS-343	CD137/HER2			mAb-Anticalin fusion			
	PRS-300s	n.d.	Immuno-Oncology		bi-/multispecifics			
	Roche	n.d.						
3. Non-IO Partnered Programs	Daiichi Sankyo	n.d.	n.d.					
	Sankyo	n.d.	n.d.					
	Sanofi	<i>P. auruginosa</i>	inf. Dis.					
	Zydus	cMet	oncology					
	Stelis	n.d.	ophtha					

n.d. = not disclosed

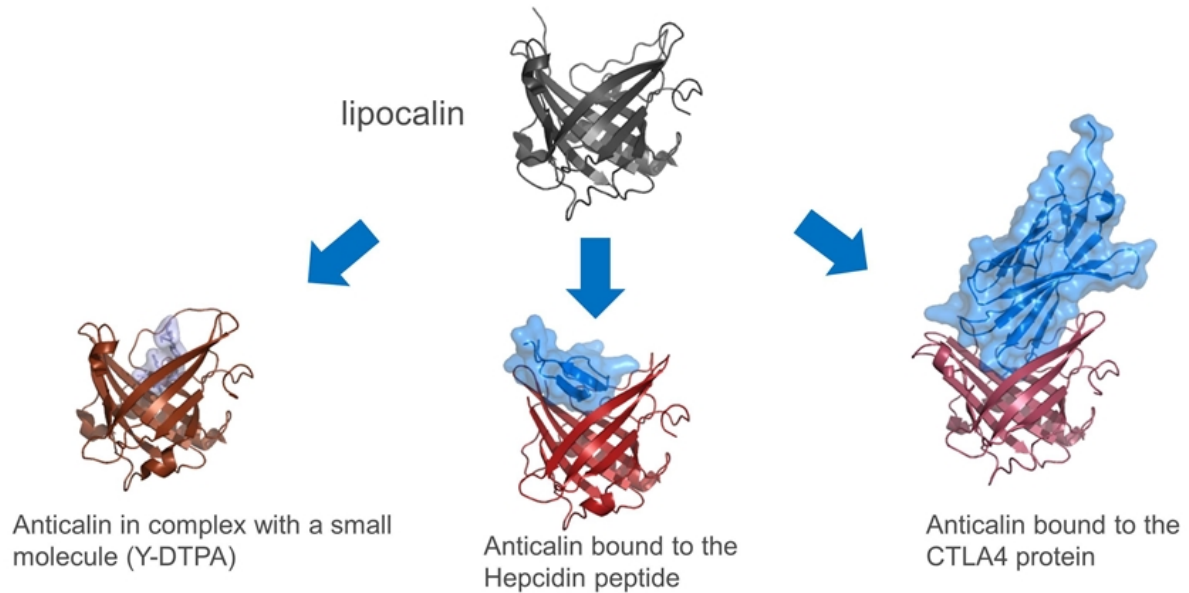


Anticalins Platform Basics

Anticalins are a Novel Class of Therapeutic Proteins





- Anticalins® are derived from lipocalins – human extracellular binding proteins
 - Small and simple make-up
 - Individual derivatives can be generated that bind to a broad range of targets

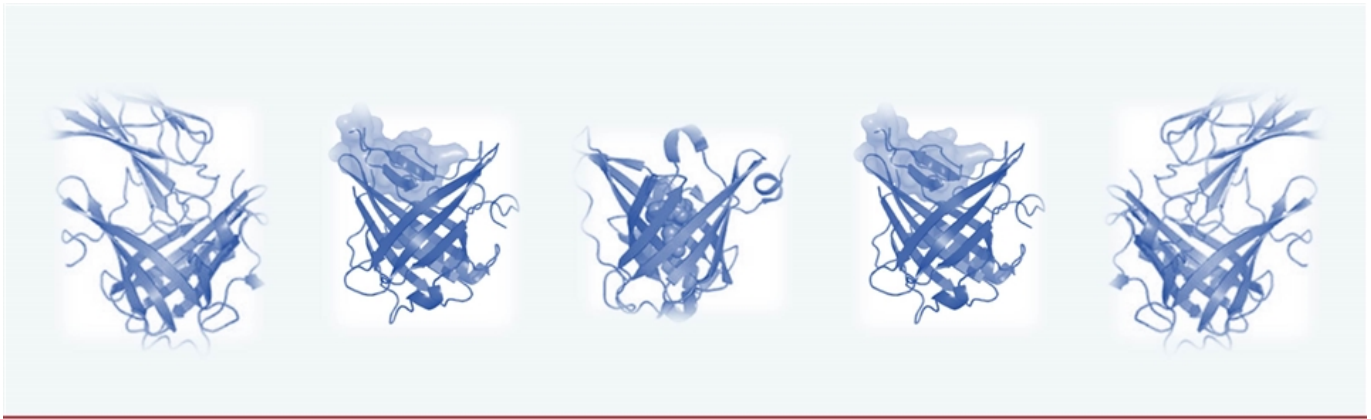


Anticalins Share Several Features with mAbs yet are Highly Differentiated



- 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		√
Local delivery (e.g., inhalation)		√
Versatile bispecifics & multispecifics		√
Protein class exclusivity		√
Positive freedom to operate landscape		√
Safety Related	Efficacy Related	IP Related



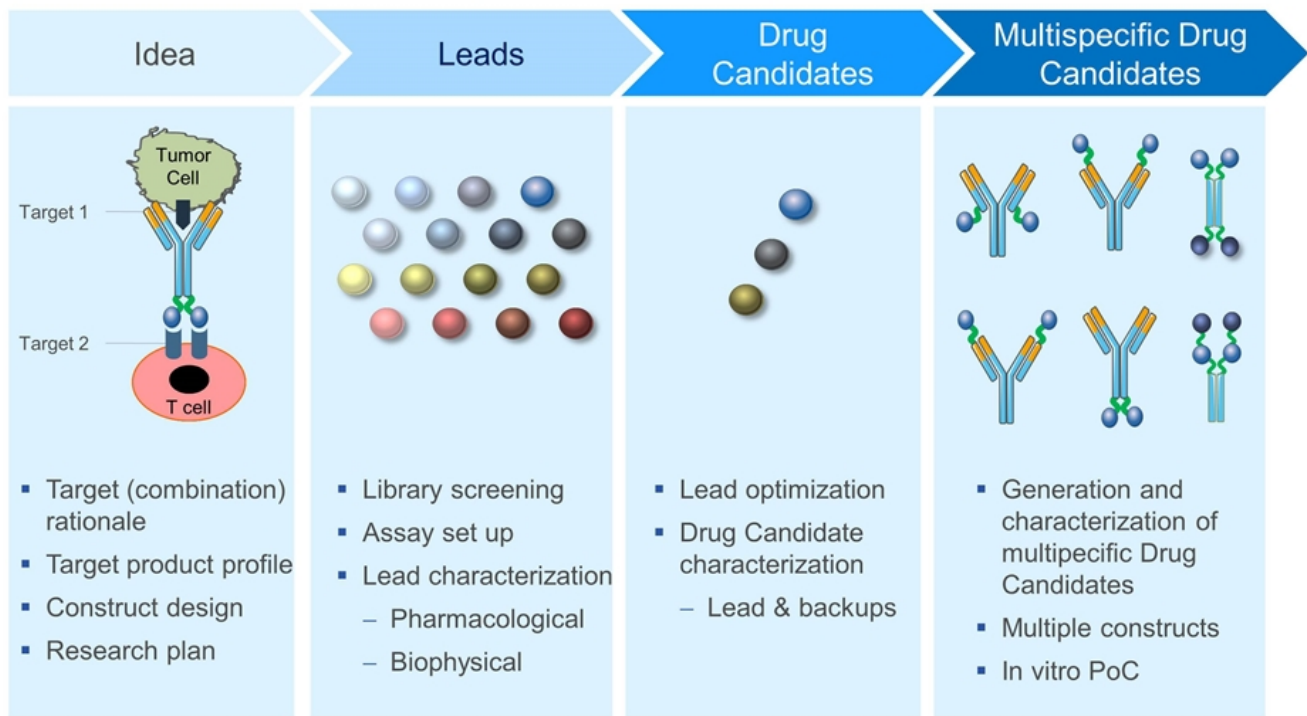
Anticalins in Immuno-Oncology

Unique opportunity due to format richness, potential for safer and more effective drugs tailored to tumor-microenvironment

From Idea to Drug Candidate – Efficient Platformed Process

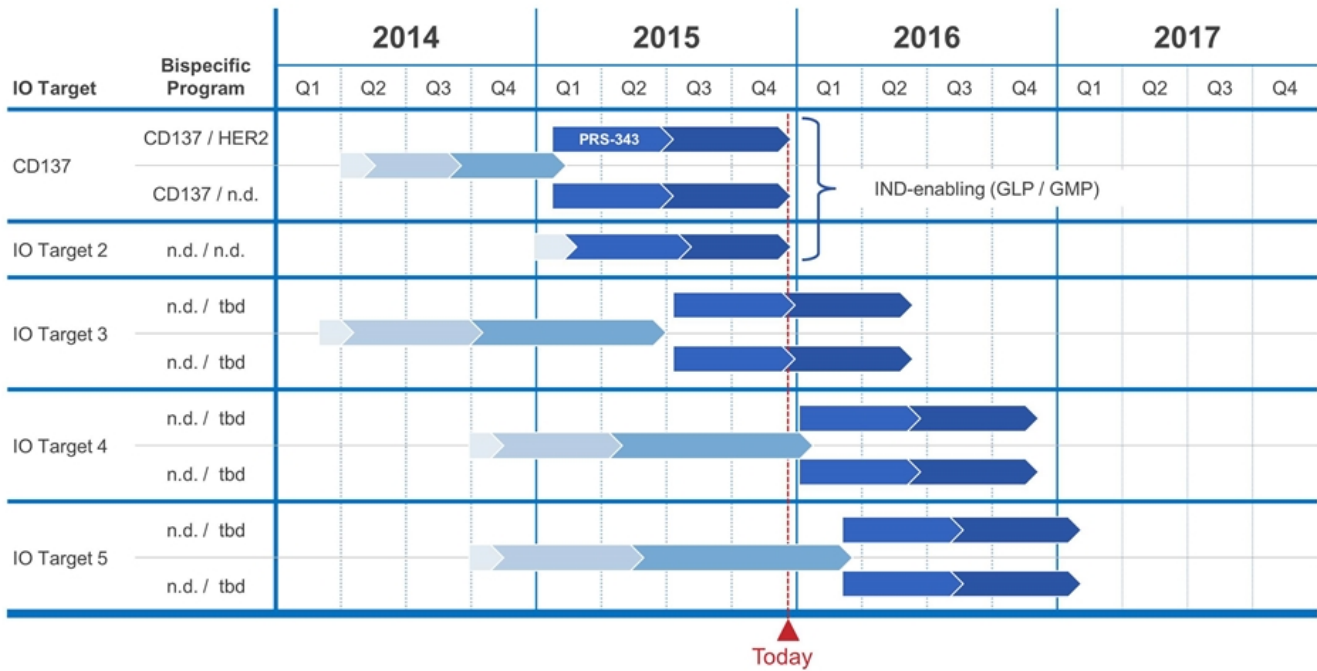


12 – 18 months

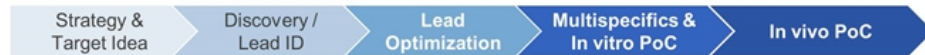


Pieris Proprietary IO Pipeline

Several Options & Partnering Opportunities



n.d.: not disclosed
tbd: 2nd target to be defined

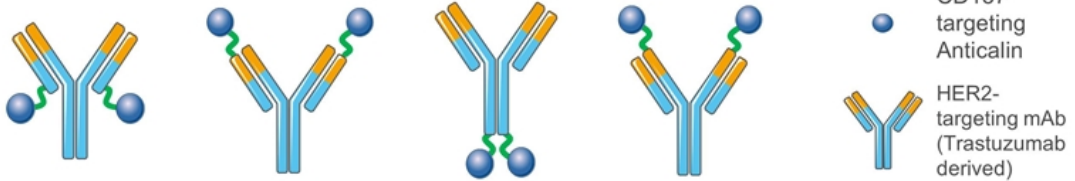


PRS-343: HER2-CD137 Bispecifics

Multiple Formats Under Preclinical Evaluation



PRS-343:
HER2-CD137
Bispecifics



CD137 – a TNFR Costimulatory Target

- **Preclinically and clinically validated**
 - Marker for tumor-reactive T cells
 - Activation leads to tumor elimination in vivo
 - Signaling included in clinical CAR-T cells
- **mAbs struggle to find therapeutic window**
 - Activity depends on Fc receptor interaction
 - Doses required for T cell activation have led to toxicity
 - Current approaches focus on NK activation



HER2 – Validated but not fully exploited

- **Upregulated on several solid tumors with significant unmet medical need**
- **Restricted expression on normal tissue favors immunotherapy approach**
- **Bispecific immunotherapy approach may expand responding population**
 - HER2+ tumors with lower expression levels not adequately addressed with current therapy

CD137-Targeting Anticalin® Has Demonstrated Agonistic Properties



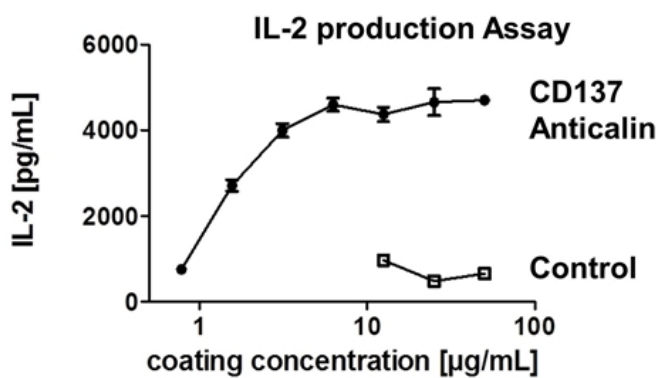
Binding to CD137

- Affinity: $KD_{hCD137} = 2nM$
- “Non-competitive” CD137 engagement preserves ligand-binding capability to CD137L

Biophysical properties

- 100% monomeric expression
- $TM = 74^{\circ}C$ (DSC)
- Fully stable after 1 week at $37^{\circ}C$ in PBS, hu or mu plasma

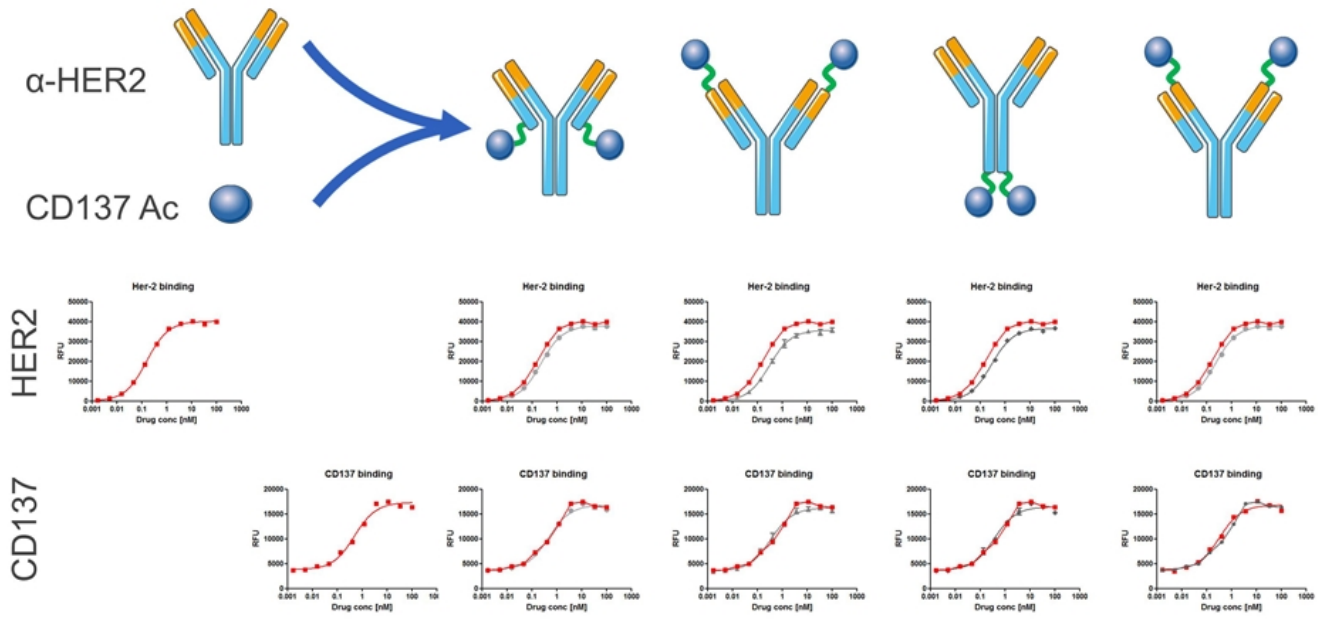
In vitro functional testing



Dose-dependent T-cell activation in ex vivo human donor cell assay by CD137 cross linking

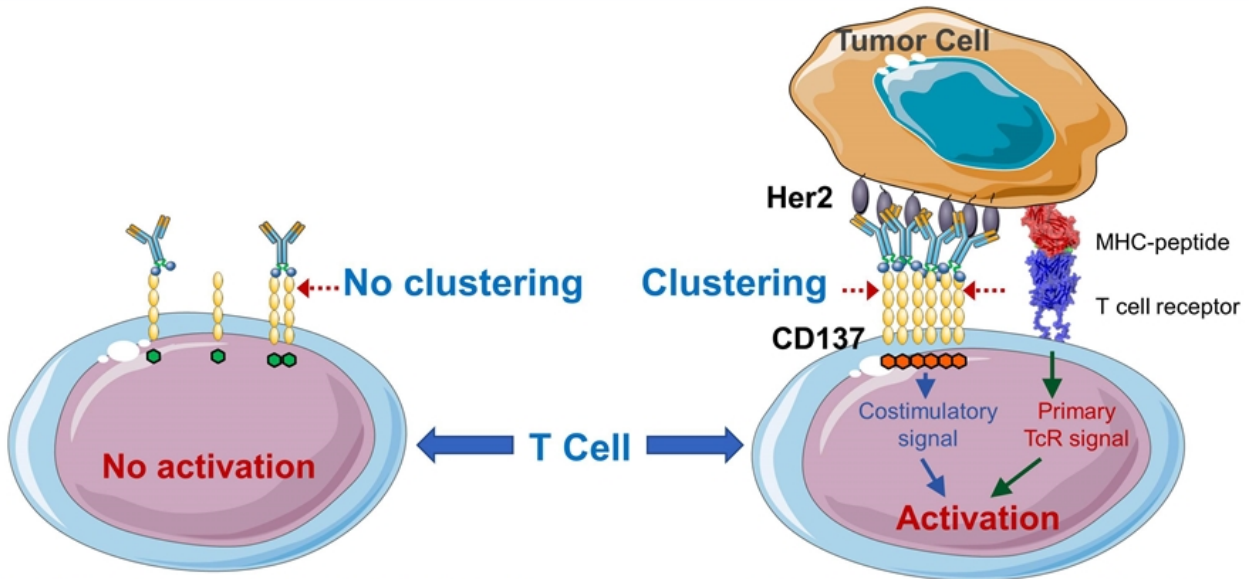
- CD137-specific Anticalin coated together with subthreshold concentration of aCD3 antibody on ELISA plate

HER2-CD137 Bispecific Formats Retain Target Binding Capacity



Bispecific formats show similar binding to CD137 and HER2 as building blocks

PRS-343: First-in-Class Bispecific for Tumor-localized Activation of T cells

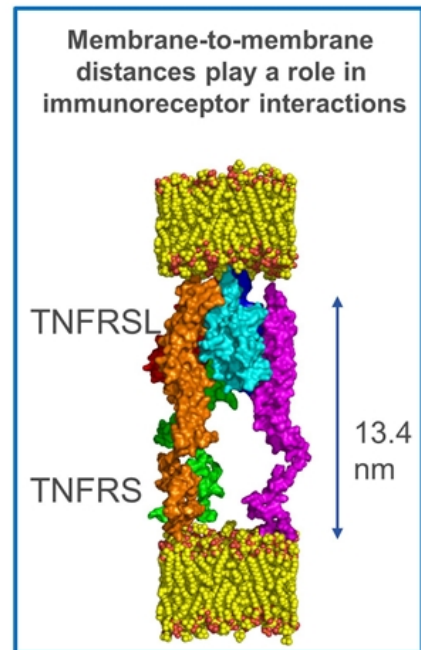
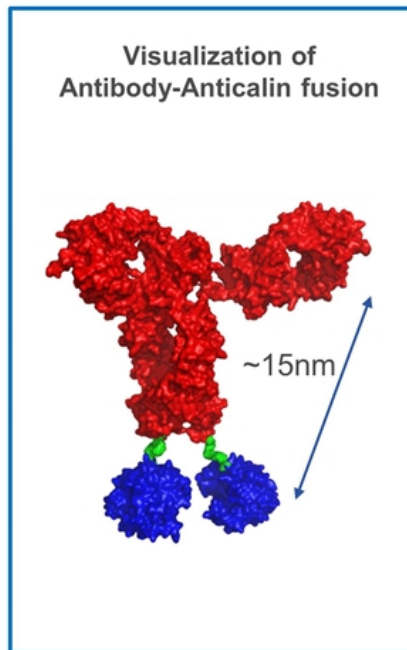
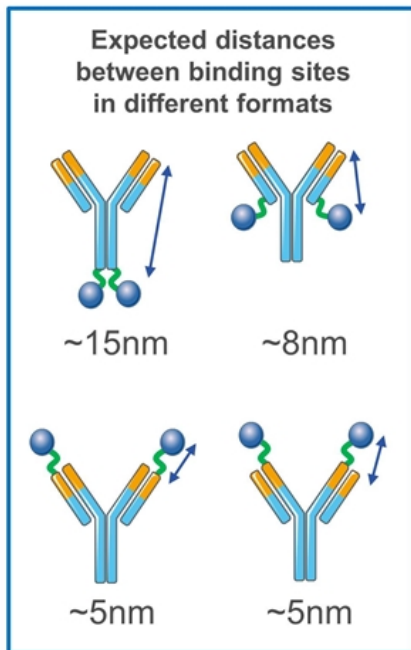


No T cell costimulation in periphery

T cell costimulation in tumor

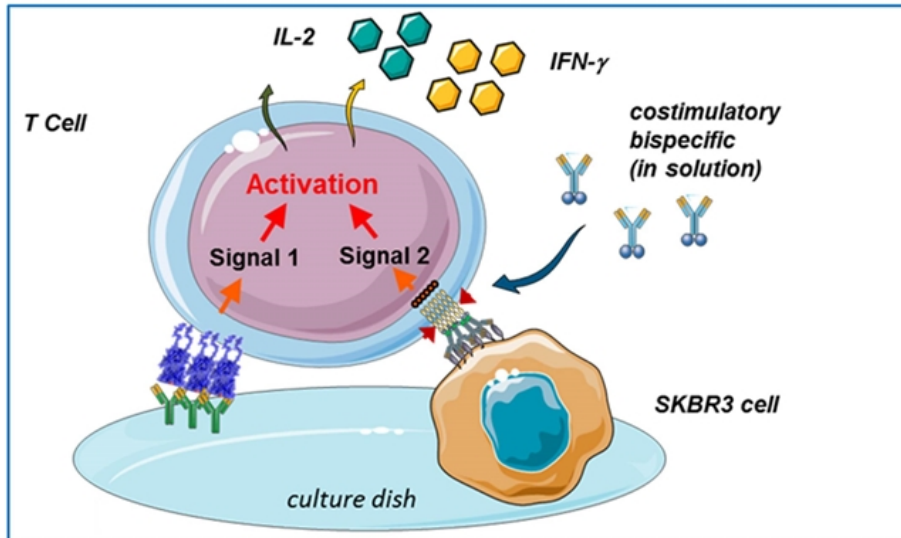
- CD137 is activated via clustering (trimerization)
- HER2-mediated clustering of bispecific drives CD137-mediated T cell activation
- Activating via a co-stimulatory signal (instead of a primary signal) is expected to maintain tumor antigen specificity by T cell receptor

Bispecific Geometry Impacts Immune Synapse



- Straightforward access to a range of distances between target binding sites
- Several formats to interrogate optimal target synapse for tumor cell killing

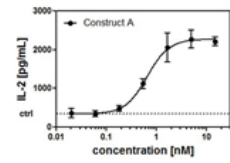
PRS-343 Bispecific Geometry Impacts T Cell Activation



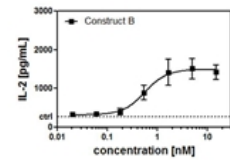
- Despite having identical building blocks, constructs A to D exhibit different potency *ex vivo*, demonstrating the importance of bispecific geometry

IL-2 response

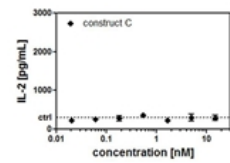
Construct A



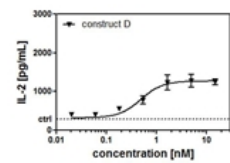
Construct B



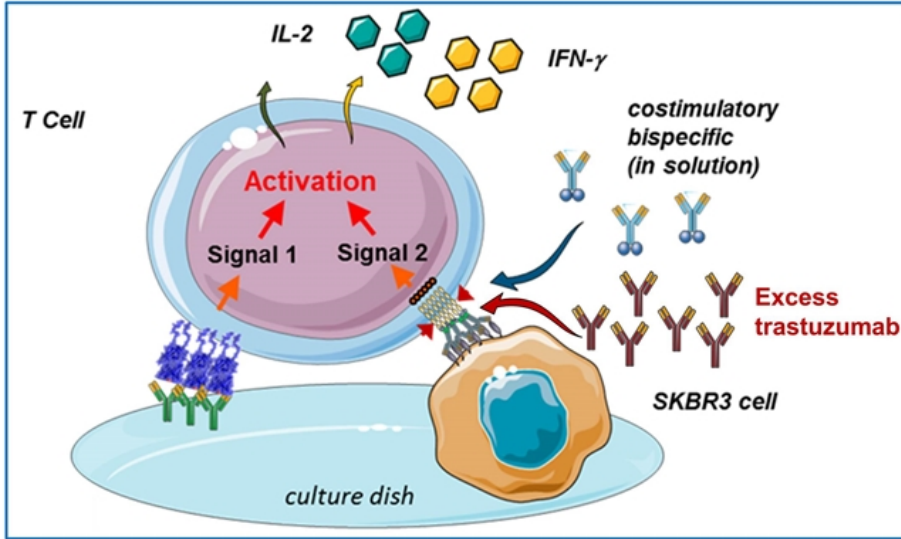
Construct C



Construct D



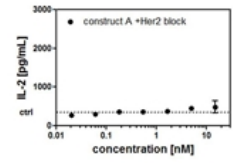
PRS-343 T Cell Activation is HER2 Target-Dependent



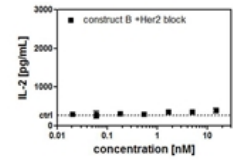
▪ Addition of excess HER2-targeting trastuzumab prevents PRS-343 binding to HER2-positive cells and results in a loss of activity, as intended, confirming mode of action

IL-2 response with Her2 blockade

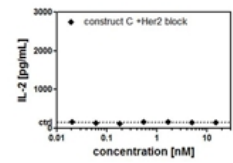
Construct A



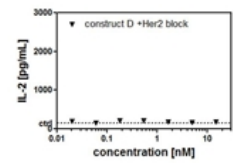
Construct B



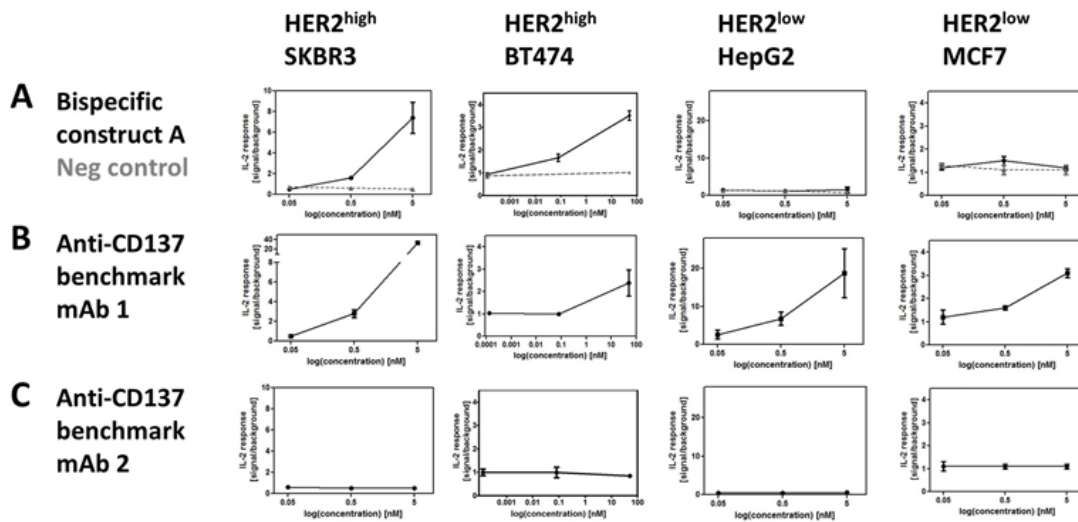
Construct C



Construct D

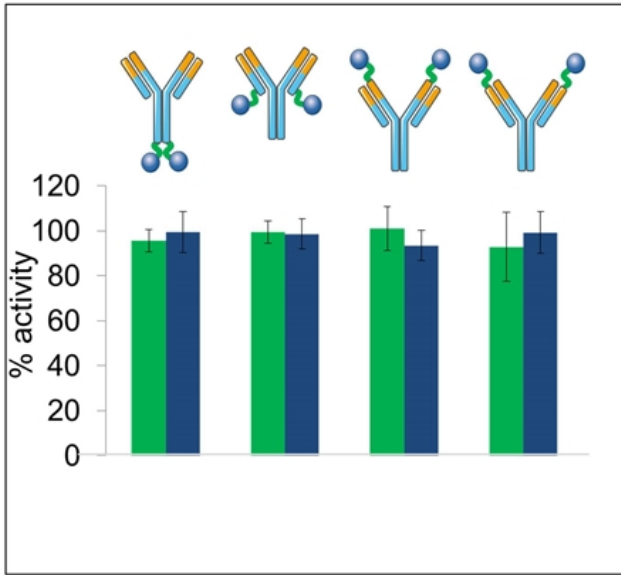


PRS-343 Has a Mode of Action Distinct From Benchmark Antibodies



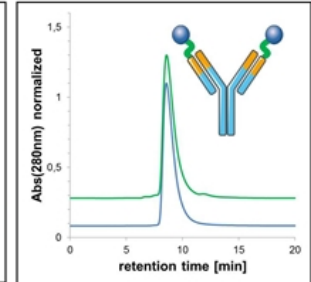
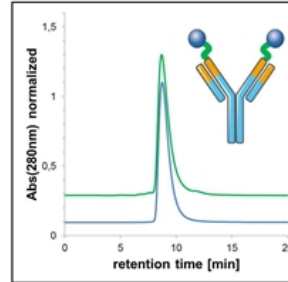
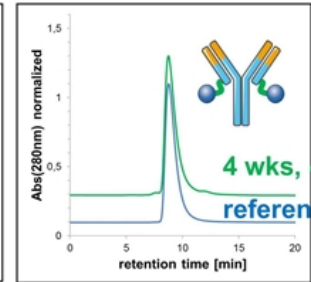
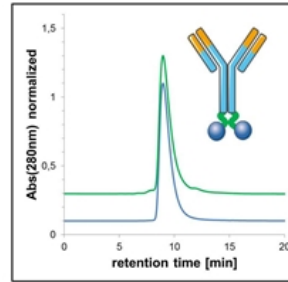
- IL-2 production was determined as a measure of T cell activation
- CD137/HER2 bispecific construct A selectively leads to activation of T cells on HER2-High tumor cells, but not on HER2-Low cells, distinct from benchmark antibodies

Plasma and Storage Stability Confirmed



Plasma stability confirmed

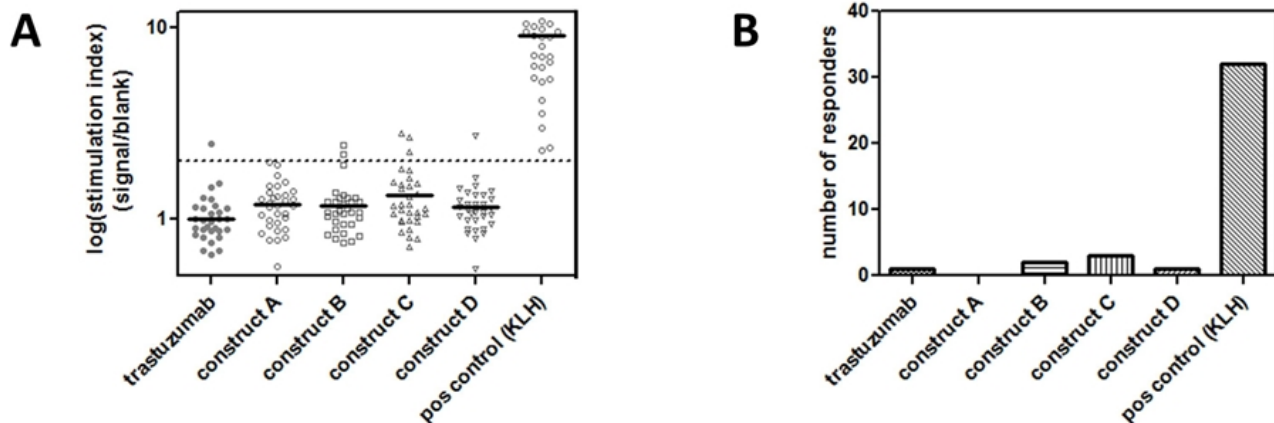
- Fully active after 1 week in human (green) and mouse plasma (blue) at 37°C (0.5mg/ml; dual binding qELISA)



Storage stability confirmed

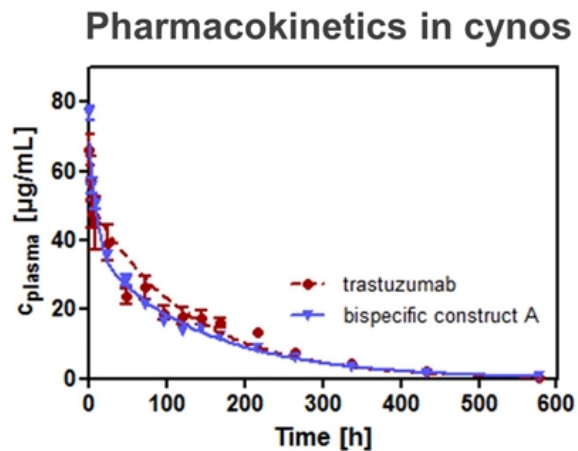
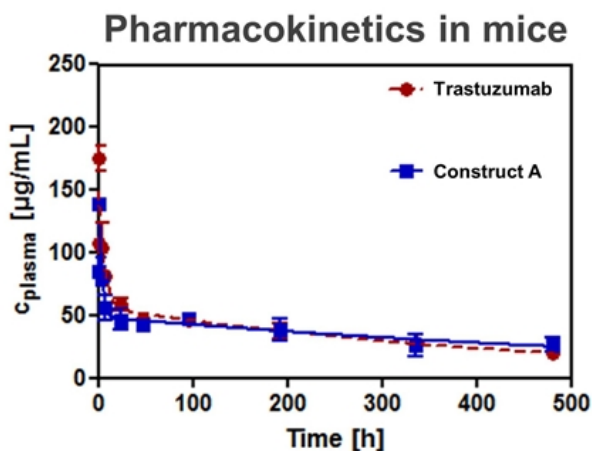
- Fully stable and active after 4 weeks at 40°C in PBS (20mg/mL, aSEC and dual binding ELISA)

CD137/HER2 Bispecifics Exhibit a Low Immunogenicity Risk

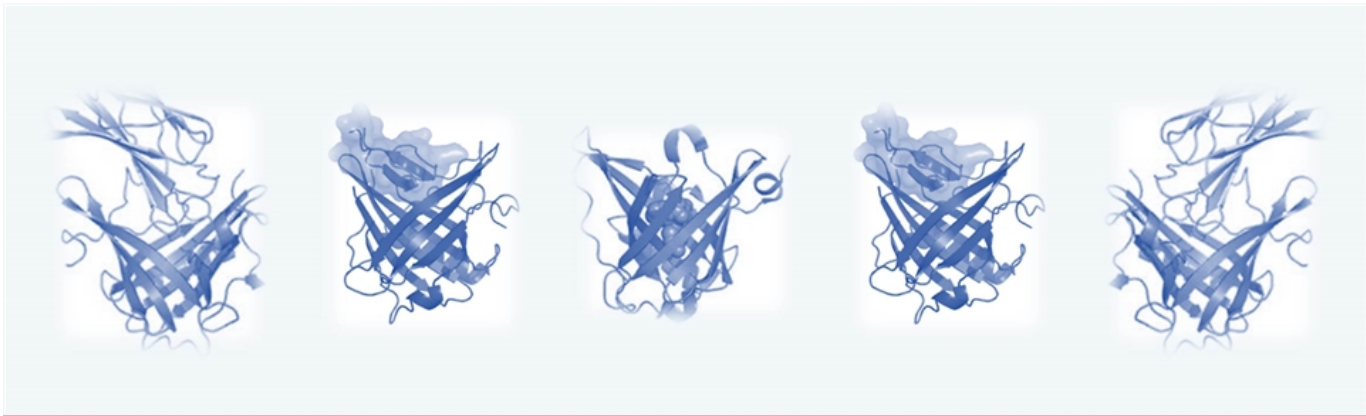


- An in vitro T cell immunogenicity assessment was performed (Epibase, Lonza) using a PBMC-based format with 32 donors and HLA allotypes reflective of the distribution in a global population
- The number of responding donors is low and comparable to trastuzumab for all CD137/HER2 bispecifics
- This indicates that the clinically demonstrated low immunogenicity of trastuzumab may be retained in CD137/HER2 bispecifics

Antibody-like Half-life For PRS-343 Confirmed in Mice and Cyno



- In mice, terminal half-lives of bispecifics range from 15-21 days compared to 13 days for trastuzumab
- In cynos, terminal half-life of tested bispecific 99 hours compared to 86 hours for trastuzumab
- As desired, long half-life of parental antibody is preserved



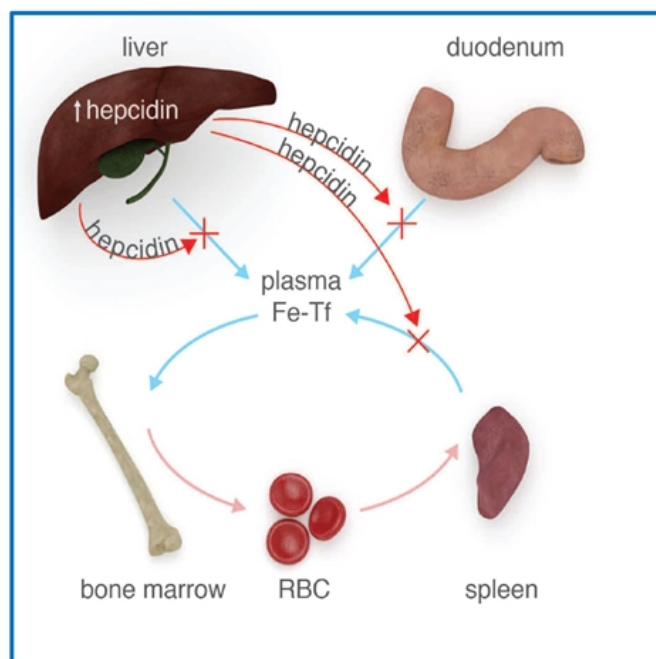
Anticalins in Other Disease Areas

Addressing validated targets in a novel way

Hepcidin Plays a Central Role in Iron Metabolism

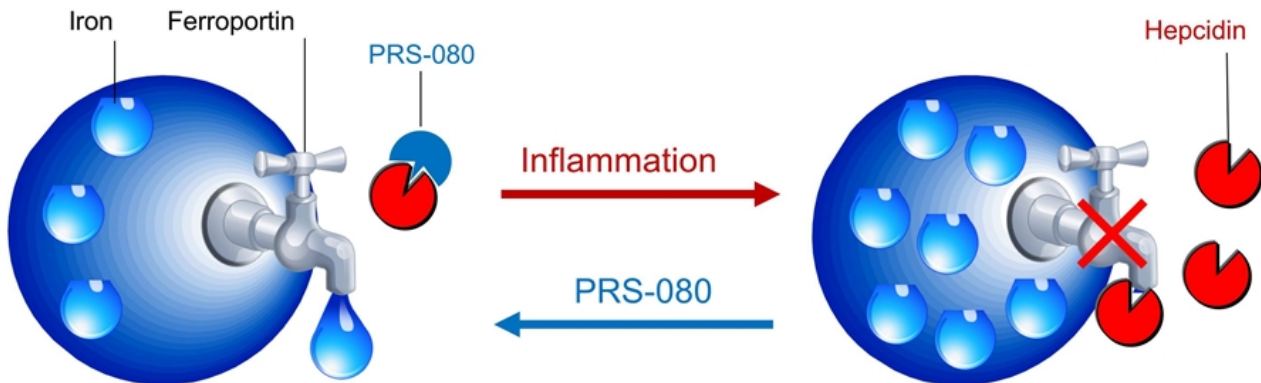
Hepcidin is a 25 amino acid peptide hormone that serves as a **key regulator of iron metabolism** by inhibiting iron entry into plasma from the three main sources of iron:

- Dietary absorption in the duodenum
- Release of recycled iron from macrophages
- Release of stored iron from hepatocytes



Haematologica 2013 98:11

PRS-080: Best-in-Class Hepcidin Antagonist For Functional Iron Deficient Anemia



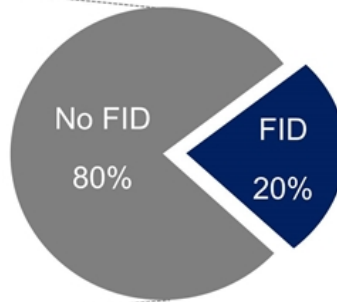
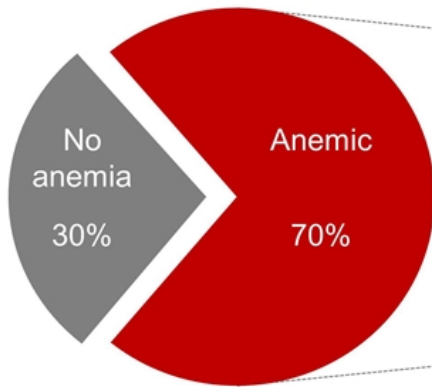
- Hepcidin is a clinically validated anemia target
- PRS-080 designed to reverse hepcidin-mediated anemia by potently antagonizing hepcidin and mobilizing iron trapped in iron storage cells
- Biomarkers (e.g. ferritin, TSAT, hepcidin) used to find & monitor patients
- Addresses patients unresponsive to ESA and iron therapies
- PK profile (half-life) of PRS-080 for a best-in-class approach

PRS-080: US Market Opportunity in Chronic Kidney Disease (Stage 5)



CKD Stage 5 Patients
(Total 640K in U.S.)

CKD Stage 5 Patients with Anemia
(Total 450K in U.S.)

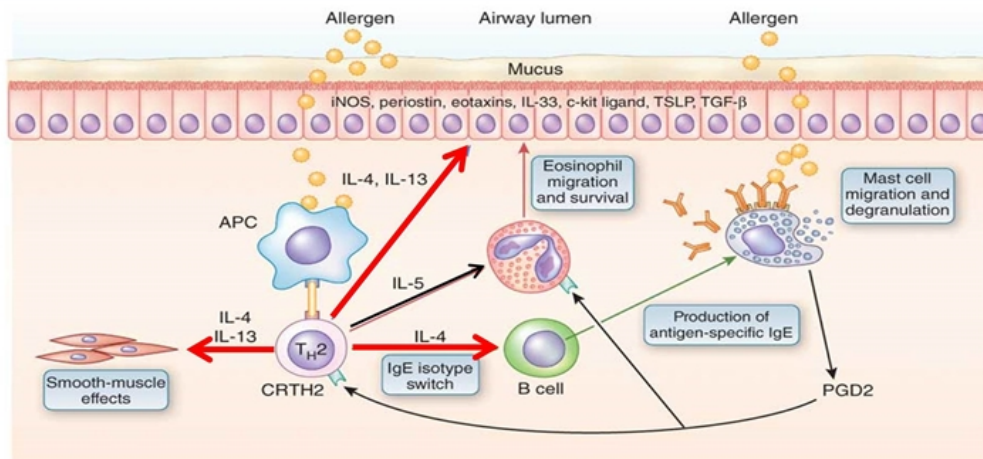


Target Functional Iron-Deficient (FID) population in U.S. is ~ 90,000 patients

We believe treating FID anemic patients has large commercial potential

Sources:
USRDS 2014 Annual Data Report (2012 numbers); Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the U.S
Competitive Landscape Report, Tech Atlas Group, September 2013; Artisan Healthcare Consulting market research study 2013

PRS-060: First-in-Class Inhaled Biologic For Uncontrolled Asthma



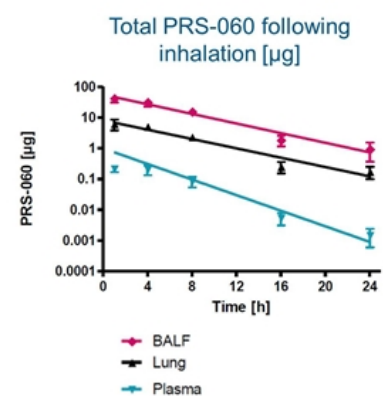
Adapted from Wenzel, Nature Medicine 18, 716–725 (2012)

- IL4Ra is a clinically validated asthma target, mediating IL4 & IL13 signaling
- PRS-060 designed to antagonize IL4Ra specifically in the lung, bypassing on-target-off-tissue engagement → inhaled delivery and short plasma half-life
- Biomarkers (e.g., exhaled nitric oxide) used to find & monitor patients
- Addresses patients uncontrolled on standard of care (inhaled ICS/LABA)
- Local delivery (inhalation) of PRS-060 for a first-in-class approach

PRS-060: Positive Preclinical Data and Advancing Toward the Clinic



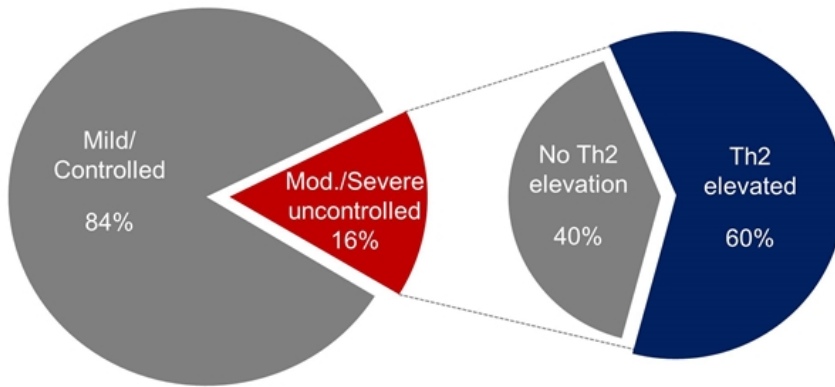
- Preclinical data highlights
 - In vivo proof of concept in transgenic mouse model
 - PRS-060 significantly reduced inflammation marker (IL13-induced eotaxin expression) up to 24 hrs after single dose via pulmonary administration
 - Early onset of inhibition (< 0.5 hr)
 - Low systemic exposure and short plasma half-life (2.7 hr) following pulmonary administration in mice
 - Feasibility of local delivery (nebulization and spray drying) demonstrated
 - Appropriate particle size with no aggregation
 - High yield with full functional activity
- Clear differentiation from injected mAbs
- First-in-man study (nebulized formulation) planned for 1H 2017



PRS-060: Market Opportunity in Asthma in Major Markets



Asthma Patients (Total ~195M in Major Markets¹) Moderate/Severe Uncontrolled Patients (Total ~32M in Major Markets)



Target Th2 elevated Asthma population:
19M in Major Markets

Treating Th2-elevated uncontrolled Asthma patients with PRS-060 is a blockbuster opportunity

¹ Major Markets: U.S., EU, Japan, Brazil, Russia, India, China
Source:
Artisan Healthcare Consulting market research study

Broad Patent Portfolio

- Drug class protected through 2020s
- Controlled patent filings and prior art enable broad follow-on protection
- Unique IP for each program

Freedom to Operate

- No third party IP identified to date for FTO on platform or therapeutic programs

Program (Target)	CoM Patent Term
080 Hepcidin	2031
060 IL4Ra	2031
343 HER2/CD137	2036

Financial Highlights & Capitalization – at September 30, 2015

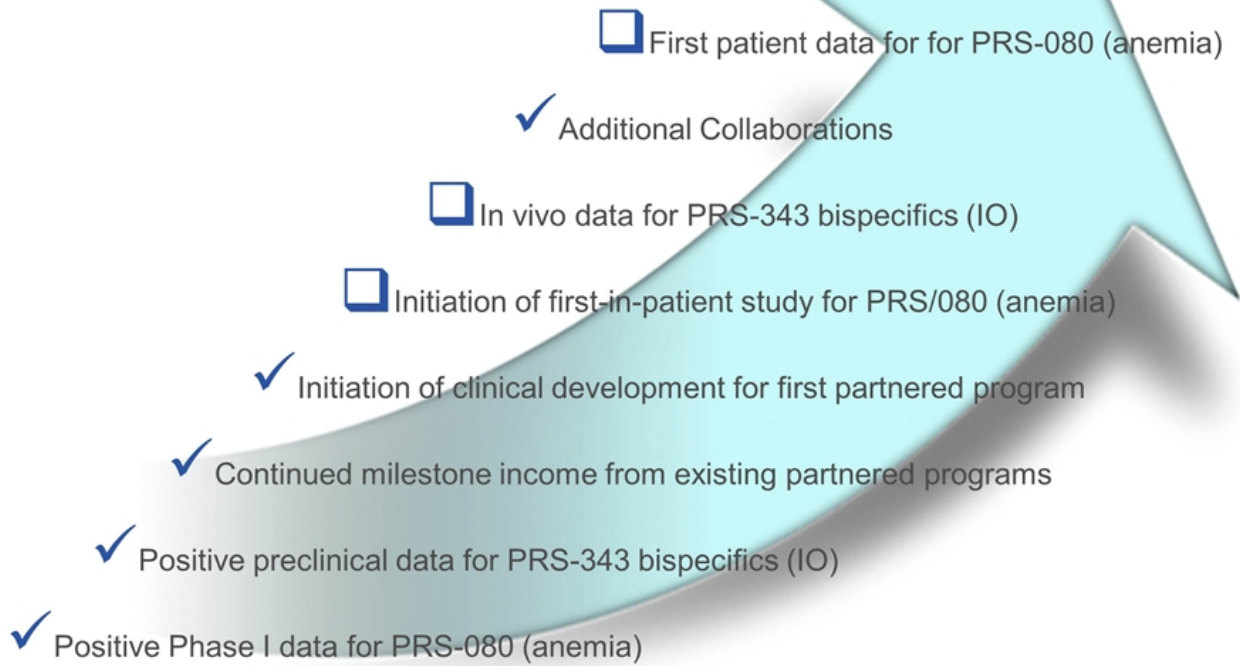


Cash & Cash Equivalents	\$32.3M
Total Debt	\$ 0.0M
Revenue Since Inception *	~ \$44.0M
Grant Revenue Since Inception	\$14.1M
9 Months 2015 Cash Burn (includes \$1.2M in debt repayment)	\$12.0M
Market Cap – at November 30, 2015	\$100.0M
52 Week Range	\$1.54 - \$3.70
Common Shares Outstanding	39,732,258

** Includes Revenue from Licensing, Collaborations & R&D Services; excludes 4Q15 Daiichi & Sanofi milestone payments and Roche upfront payment*

Potential Future Milestones



- 
- A large, light blue arrow pointing upwards and to the right, containing a list of milestones. The arrow has a subtle gradient and a shadow effect.
- First patient data for for PRS-080 (anemia)
 - ✓ Additional Collaborations
 - In vivo data for PRS-343 bispecifics (IO)
 - Initiation of first-in-patient study for PRS/080 (anemia)
 - ✓ Initiation of clinical development for first partnered program
 - ✓ Continued milestone income from existing partnered programs
 - ✓ Positive preclinical data for PRS-343 bispecifics (IO)
 - ✓ Positive Phase I data for PRS-080 (anemia)

December 2015 through 2016



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