
**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 11, 2016

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
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: 603-553-5803

Lise-Meitner-Strasse 30
85354 Freising-Weihenstephan, Germany
(Former name or former address, if changed since last report)

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))
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Item 7.01 Regulation FD Disclosure.

Attached hereto as Exhibits 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 January 11, 2016.

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 11, 2016

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 January 11, 2016.



Pieris Pharmaceuticals, Inc.

Nasdaq:PIRS

January 2016 Corporate Presentation

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



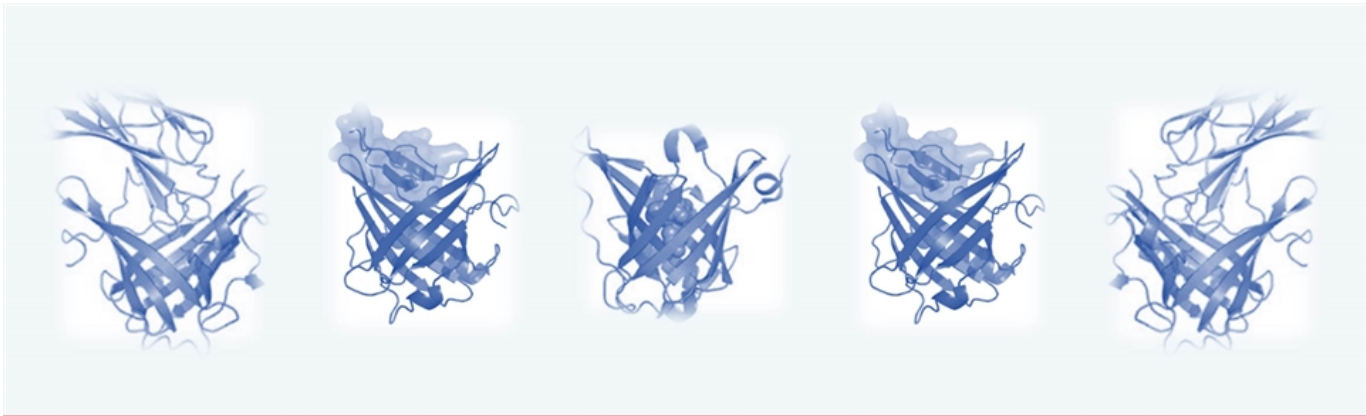
- We own a next generation therapeutic protein drug class, **Anticalins**[®]
 - Addressing validated targets in a unique and transformative way
 - Clinical validation demonstrates excellent drug-like properties
- Our rapidly advancing proprietary pipeline addresses large markets
 - Immuno-oncology bispecific tailored for the tumor micro-environment
 - Inhaled Anticalin to treat uncontrolled asthma
 - Half-life-optimized Anticalin to treat anemia
- We have an excellent cadre of investors and R&D partners
 - OrbiMed Advisors (18%), Tekla Capital Management (10%), Lombard Odier (7%), Omega Funds (6%)
 - Roche, Sanofi, Daiichi, etc: >\$50 million in non-dilutive funding to date and combined milestone potential of \$>700 million
- Our unique multispecifics platform provides broad potential for attractive partnerships in immuno-oncology and other areas

Anticalin Product Pipeline



	Product	Target(s)	Indication	Partner	Discovery	Preclinical	IND-enabling	Ph 1 - 1b/2a
1. Validated Targets	PRS-080	Hepcidin	Anemia		PEGylated Anticalin			
	PRS-060	IL4Ra	Asthma		inhalable Anticalin			
2. IO	PRS-343	CD137/HER2	Immuno-Oncology		mAb-Anticalin fusion			
	PRS-342	CD137/GPC3			Ac/Ac Fc fusion			
	PRS300s	n.d/n.d.			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



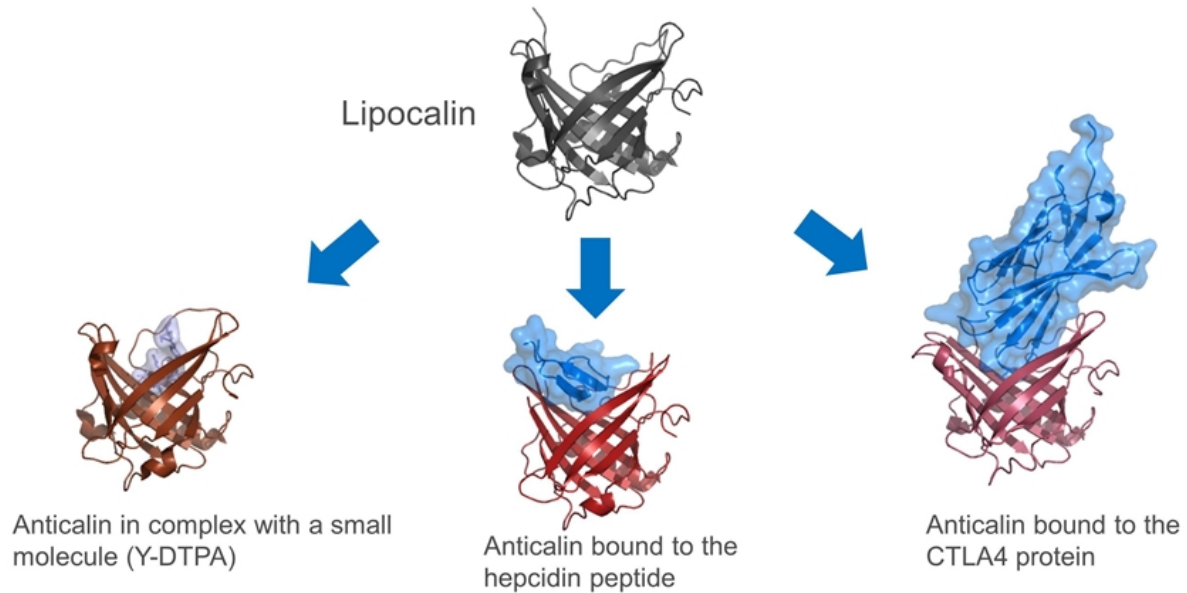
Anticalins Platform Basics

Anticalins are a Novel Class of Therapeutic Binding Proteins



- Anticalins® are derived from lipocalins – human extracellular binding proteins
- Small (18 kDa vs 150 kDa mAbs), high selectivity and potency



Anticalins Have Been Generated Against a Broad Range of Targets



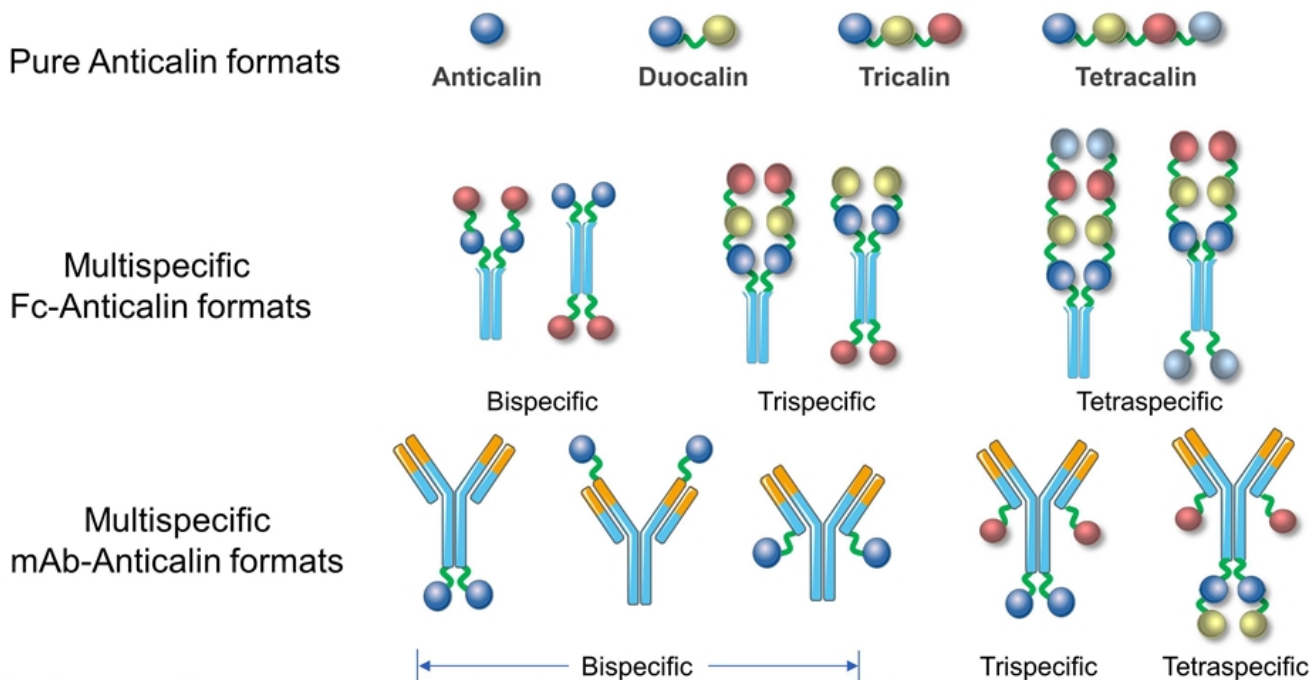
Anticalins Share Several Features with mAbs yet are Highly Differentiated



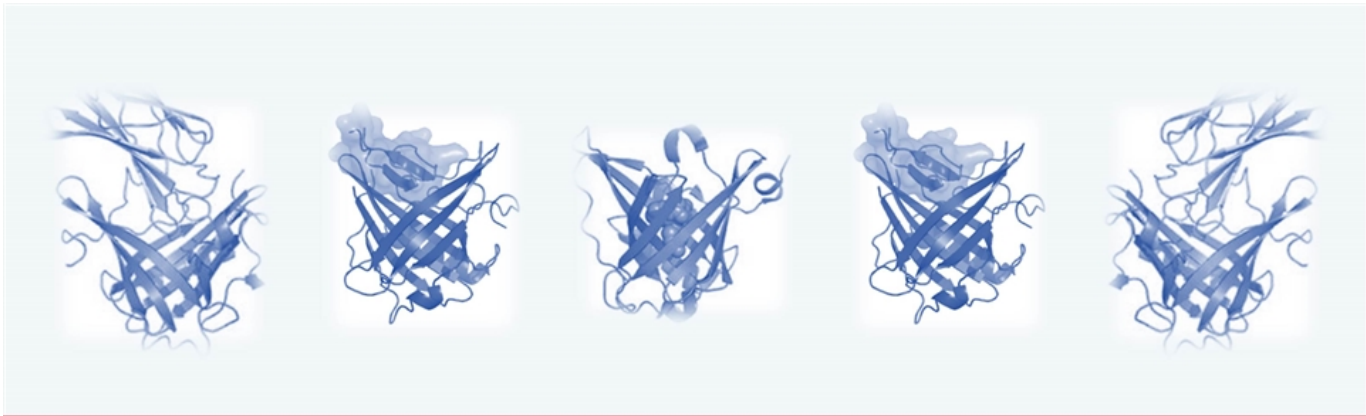
- Monoclonal Antibodies (mAbs) are highly successful drugs
- Anticalins share many of the beneficial properties of mAbs yet are highly differentiated

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 multispecifics		√
Protein class exclusivity		√
Positive freedom to operate landscape		√
	Safety Related	Efficacy Related
		IP Related

Anticalin-Based Drug Candidates Have Been Tailored to Multiple Formats



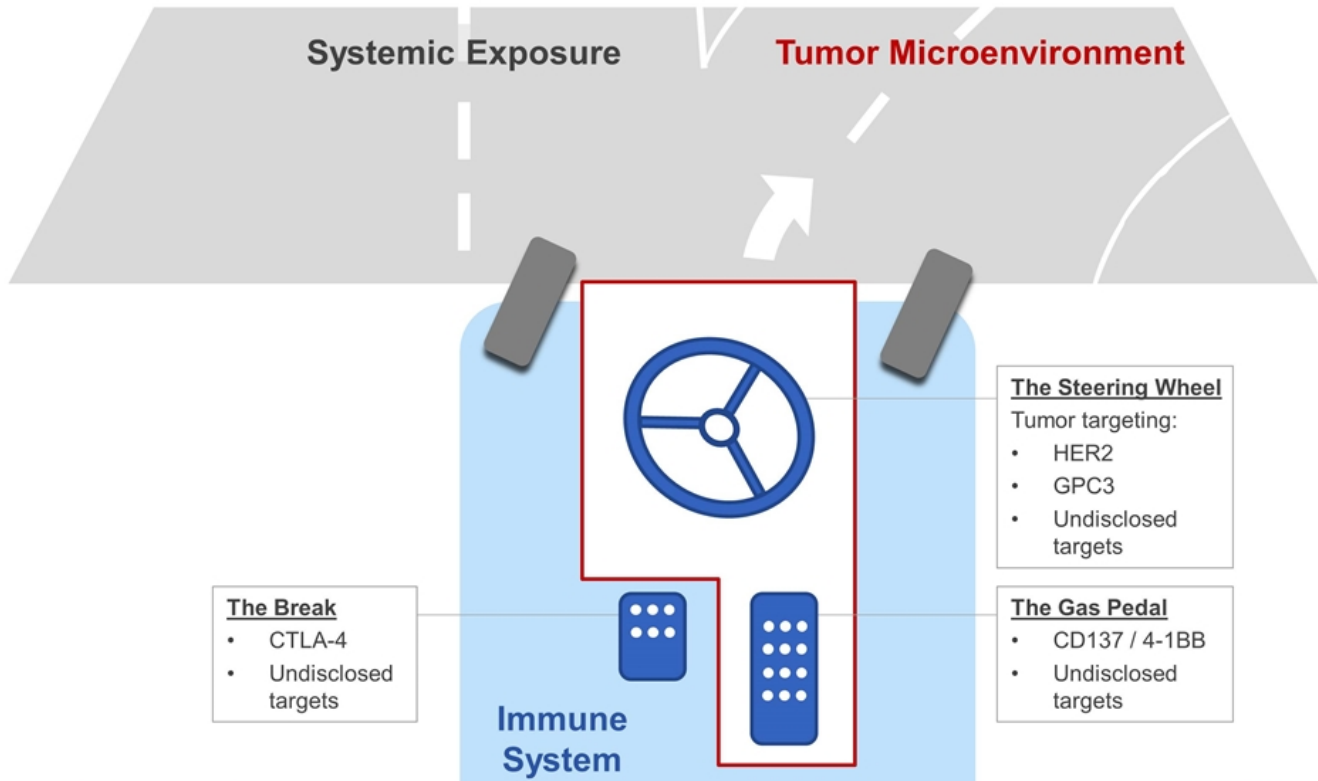
- Drug candidates with potent multi-target engagement & excellent drug-like properties
- Binding site geometry and valency designed to address biological and clinical needs



Anticalins in Immuno-Oncology

Differentiation Through Unique Multispecific Formats

Pieris' Unique Costimulatory Approach – Steering Immune Activation to the TME



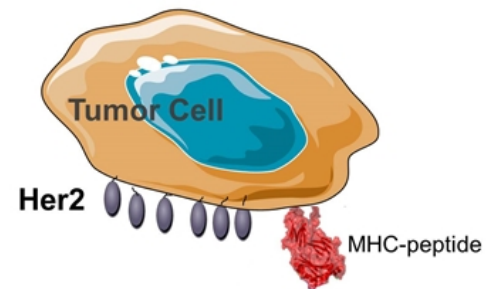
PRS-343: HER2-CD137 Bispecifics

Target Rationale for Lead IO Program



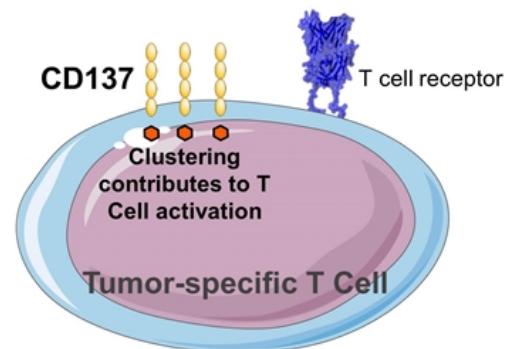
HER2 – Validated but not fully exploited

- Restricted expression on normal tissue favors immunotherapy approach
- Several HER2+ tumors nonresponsive to approved anti-HER2 therapies
 - Bladder, Gastric, Endometrial, Breast, etc.
 - Several nonresponders have CD137+ TILs (T cells in tumor microenvironment)

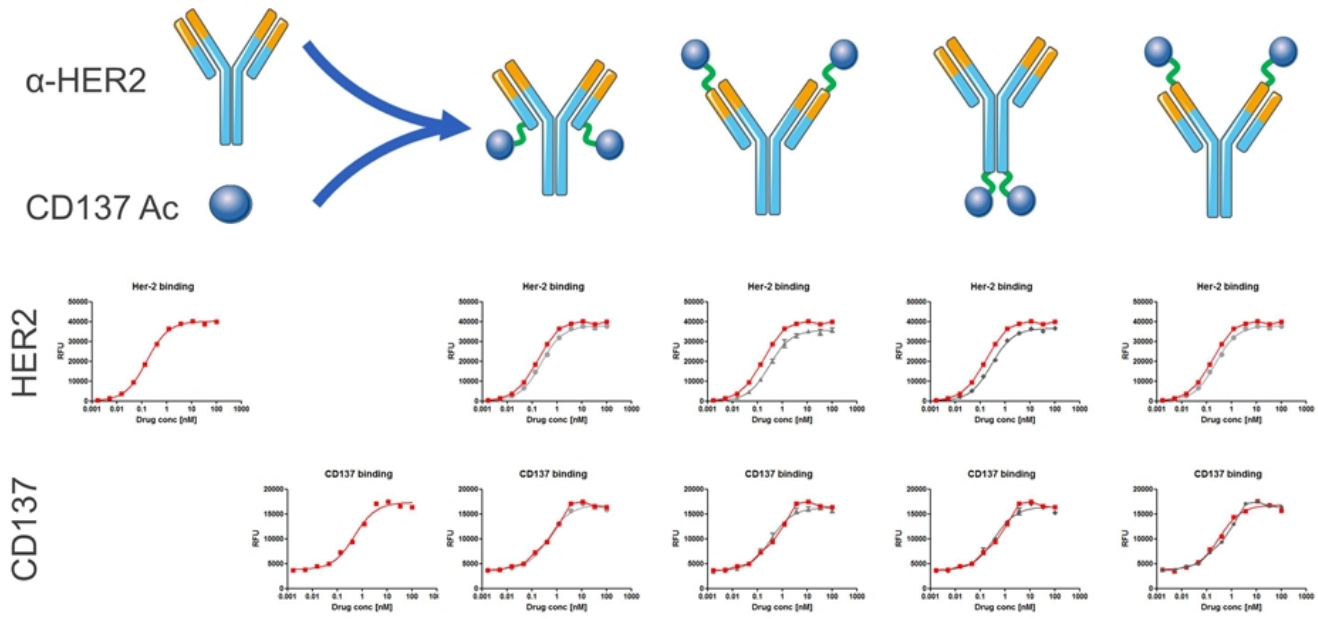


CD137 – a TNFR Costimulatory Target

- Preclinically and clinically validated
 - Marker for tumor-reactive T cells
 - Activation leads to tumor elimination in vivo
- Pure mAb approaches are sub-optimal
 - Systemic immune system engagement
 - Doses required for T cell activation have led to severe toxicity

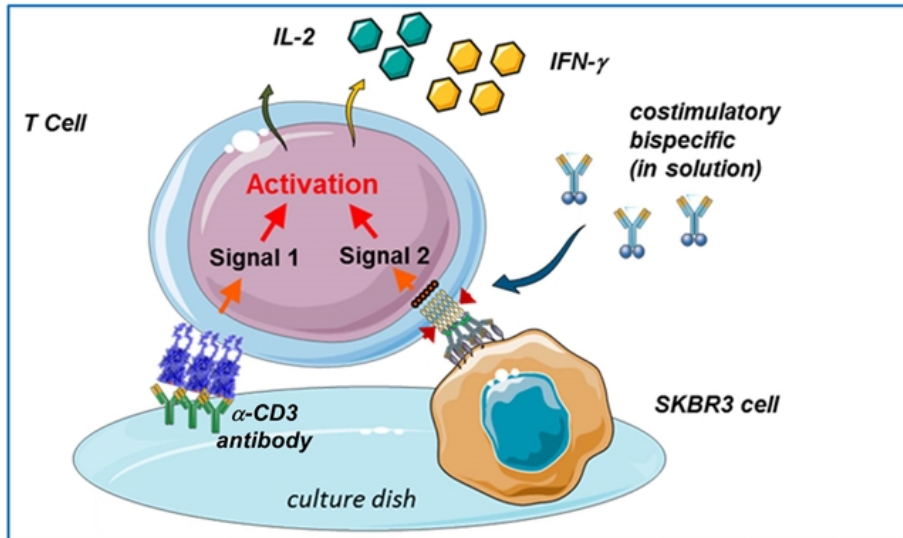


Several HER2-CD137 Bispecific Formats Capable of Robust Target Engagement...

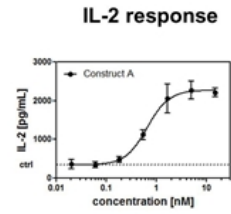


Bispecific formats show similar binding to CD137 and HER2 as building blocks

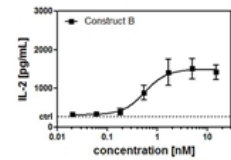
Bispecific Geometry Impacts Activation of Human T Cells



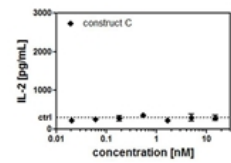
Construct A



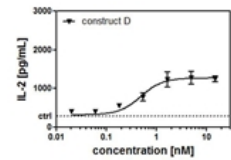
Construct B



Construct C

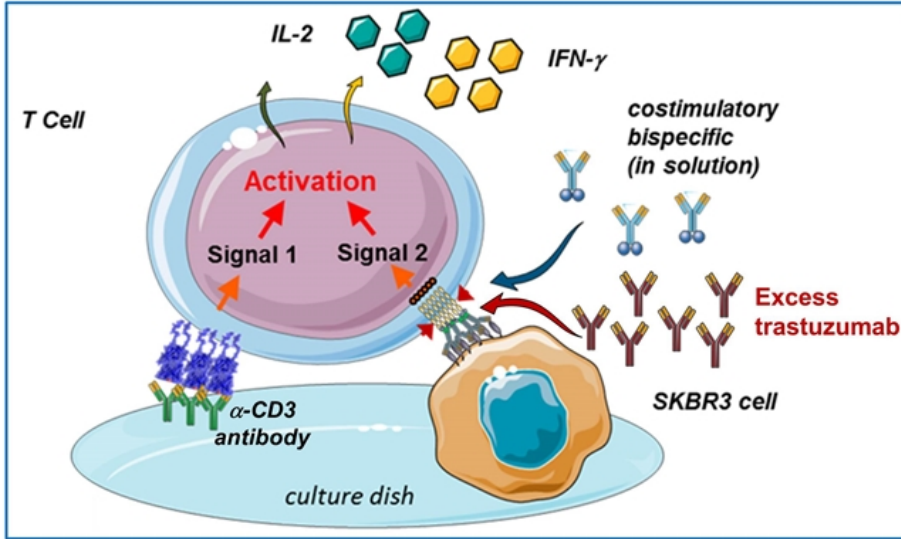


Construct D



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

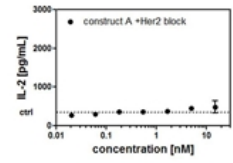
T Cell Activation is HER2 Target-Dependent



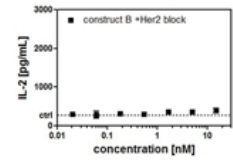
▪ Addition of excess HER2-targeting trastuzumab prevents PRS-343 binding to HER2-positive cells and results in a loss of activity, as intended, confirming mode of action

IL-2 response with Her2 blockade

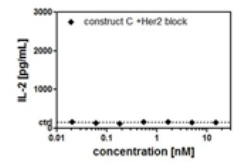
Construct A



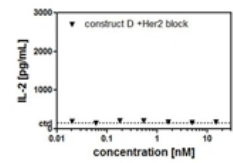
Construct B



Construct C



Construct D

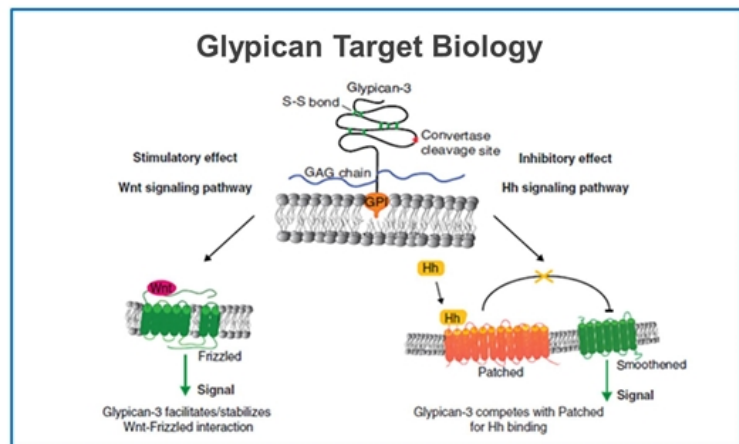


- Development candidate nominated
 - Demonstrated ability to activate human T cells consistent with desired mode of action
 - Potent, tumor-dependent activation
 - Differentiation over anti-CD137 mAbs
 - Desired drug-like properties
 - CMC: Robust titers and long-term stability
 - Low risk of immunogenicity
 - Antibody-like half-life in mouse and cynomolgus monkey
- IND-enabling activities underway
- First-in-Patient Study planned for 1H17
 - HER2+ solid tumor patients

PRS-342: GPC3-CD137 Bispecific Target Rationale for GPC3 as Tumor Target

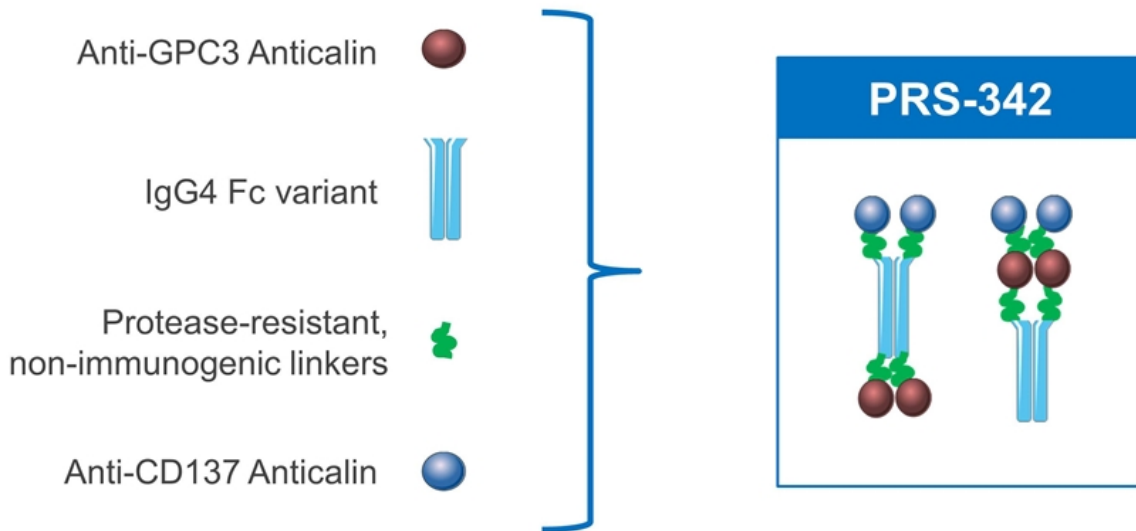


- **Glypican 3 (GPC3)** is an oncofetal antigen with almost no expression in normal adult tissue, therefore **favoring a tumor-targeted immunotherapy approach**
- Thought to be involved in modulation of growth in the predominantly mesodermal tissues and organs during development

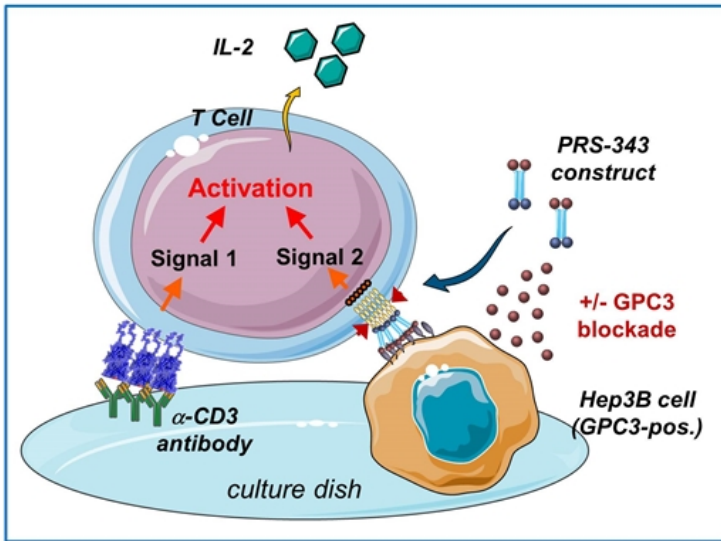


- **Expression is pronounced in multiple cancers that are known to have CD137+ TILs**
 - **Hepatocellular Carcinoma (HCC):** Overexpressed in 60-80% of lesions with no expression in healthy liver tissue; correlated with poor prognosis
 - **Merkel Cell Carcinoma:** Overexpressed in 80% of tumors
 - **Melanoma:** Overexpressed in 40-80% of melanoma lesions

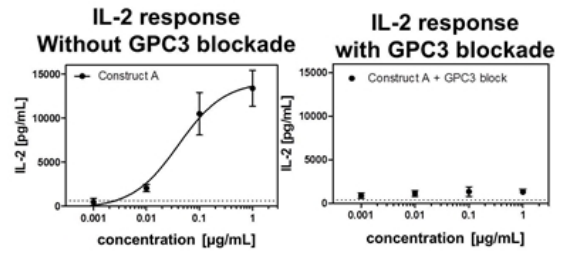
PRS-342: GPC3-CD137 Bispecific Different Formats Under Preclinical Evaluation



PRS-342 Bispecific Tumor-dependent T Cell Activation



Representative PRS-343 bispecific construct



PRS-342 is a first-in-class bispecific that targets highly unmet patient populations and demonstrates that our Anticalin-based co-stimulatory approach is repeatable

NEWS: First IO Partnership Roche – The Global Oncology Leader



Scope:

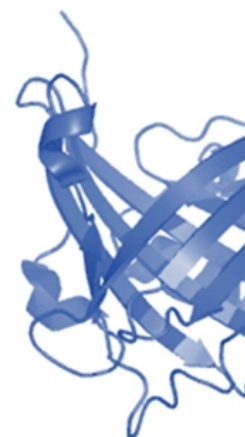
- One-target but potentially multi-program
- Roche solely responsible starting from IND-enabling studies

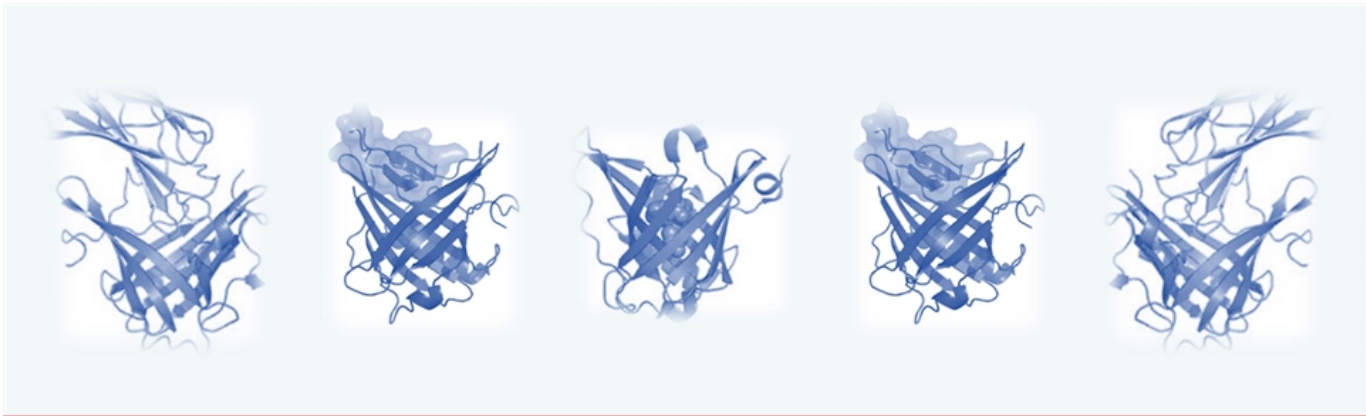
Financial:

- Pieris receives upfront payment of ~US\$6.5 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





Anticalin Programs in Other Disease Areas

Novel approaches to validated disease targets

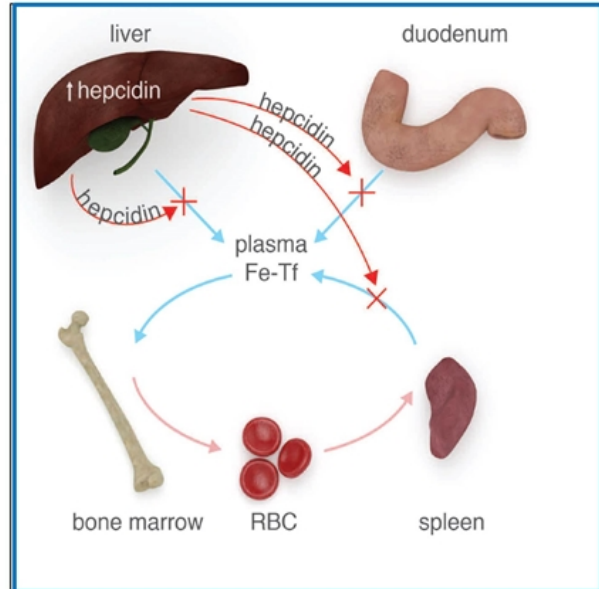
PRS-080: Best-in-Class Hepcidin Antagonist For Functional Iron Deficient Anemia (FID)



Hepcidin elevation a hallmark of anemias of chronic disease

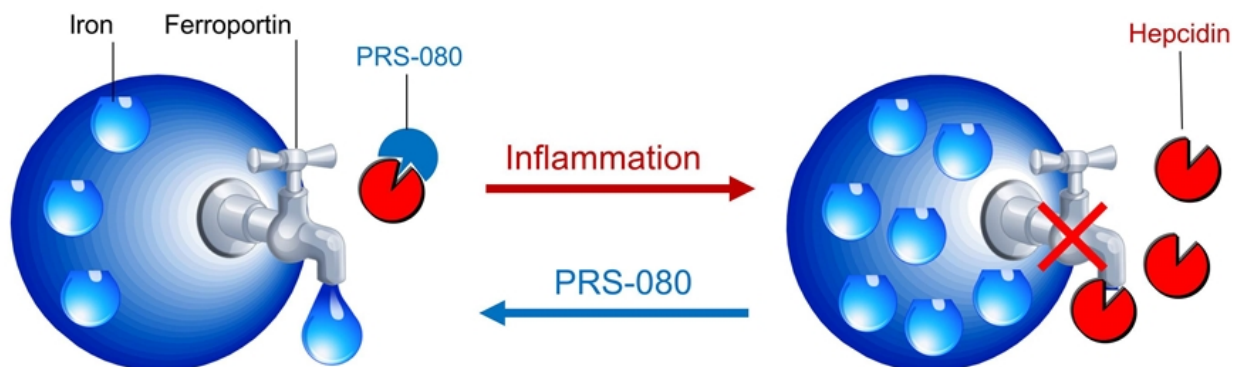
Hepcidin is a 25 amino acid peptide hormone that serves as a **key regulator of iron metabolism** by inhibiting iron entry into plasma from the three main sources of iron:

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



Haematologica 2013 98:11

PRS-080-mediated Heparidin Inhibition Mobilizes Iron for Red Blood Cell Production



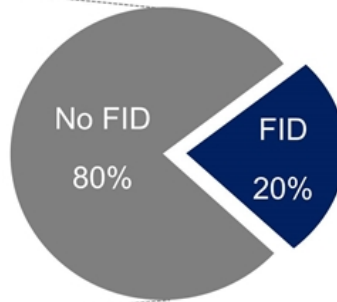
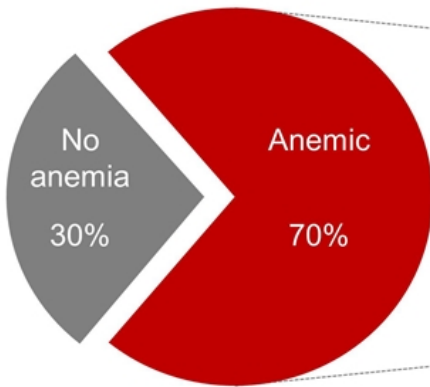
- Heparidin is a clinically validated anemia target
- The pegylated Anticalin PRS-080 is a potent heparidin antagonist designed to reverse heparidin-mediated anemia by mobilizing iron trapped in iron storage cells
- Established biomarkers (e.g. ferritin, TSAT, heparidin) used to find & monitor patients
- Addresses patients poorly responsive to ESA and iron therapies
- PK profile (half-life) of PRS-080 designed 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

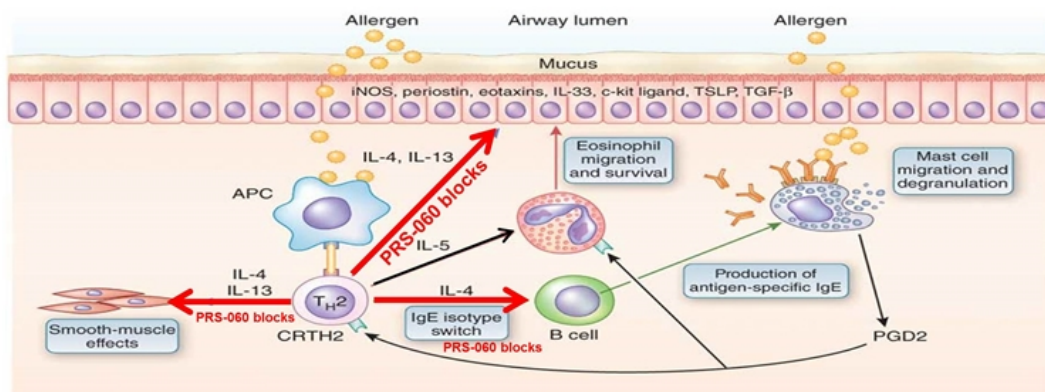
We believe treating FID anemic patients has large commercial potential

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 Anticalin Targeting IL-4Ra For Uncontrolled Asthma



T_H2 immune processes in the airways of people with asthma



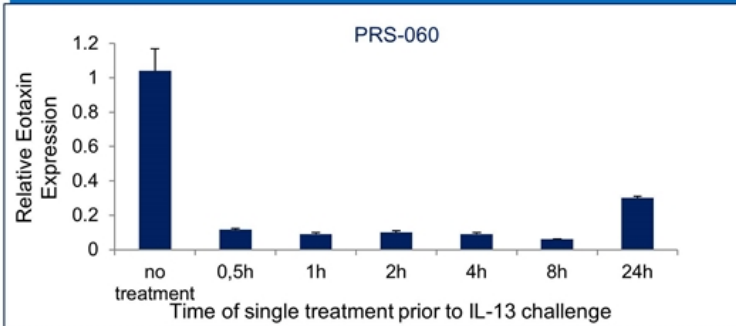
Adapted from Wenzel, Nature Medicine 18, 716–725 (2012)

- IL4Ra is a clinically validated asthma target, mediating IL4 & IL13 T_H2 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) can be 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

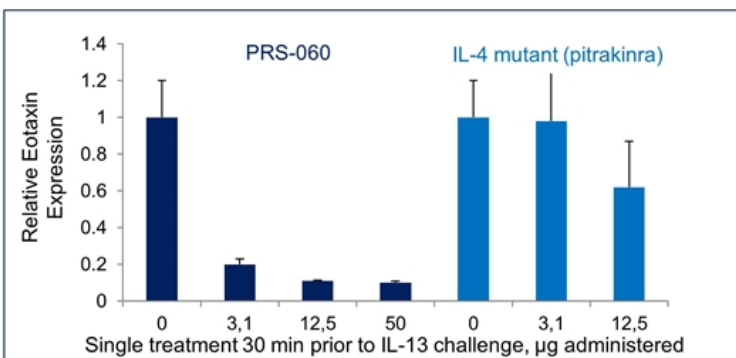
PRS-060: Potent *in vivo* Target Inhibition Following Pulmonary Delivery in TG Mice Expressing Human IL-4R α /IL-13R



Inhibition of IL-13-induced eotaxin expression in the lung by pulmonary administration of PRS-060



- Early onset of inhibition and durability of effect up to 24h post pulmonary administration

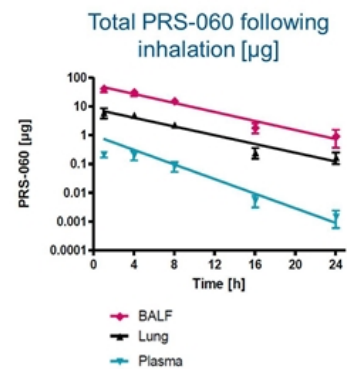


- Low pulmonary dose of PRS-060 (3.1 µg) is effective
- Superior inhibition by PRS-060 compared to pitrakinra (discontinued competitor product)

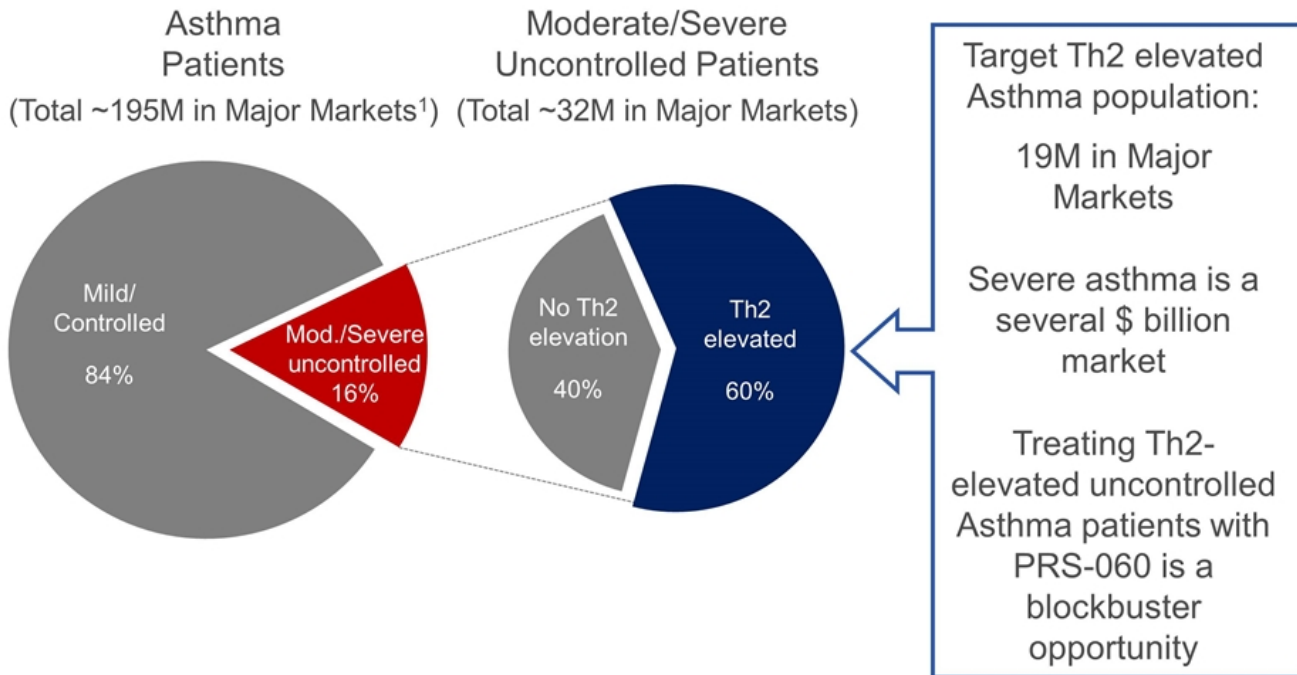
PRS-060: Positive Preclinical Data and Advancing Toward the Clinic



- 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
- IND-enabling studies underway
- First-in-man study (nebulized formulation) planned for 1H 2017



PRS-060: Market Opportunity in Asthma in Major Markets



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

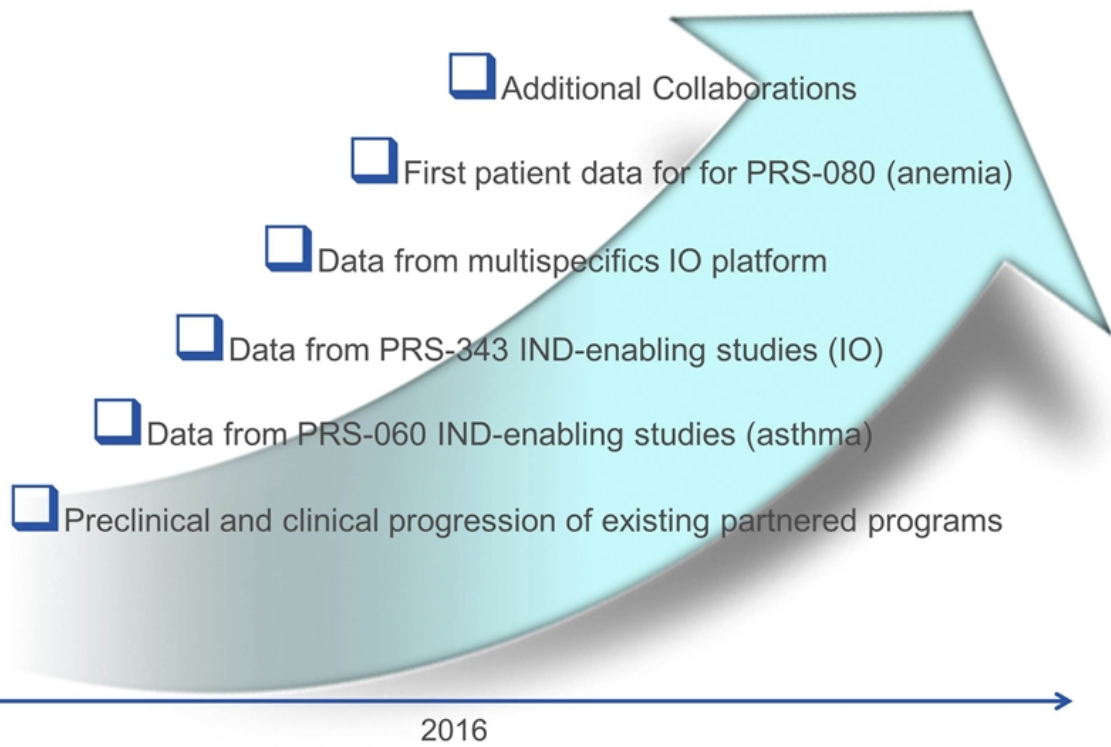
Financial Highlights & Capitalization – at September 30, 2015



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 December 31, 2015	\$91.2M
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 2016 Milestones





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