
**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): November 5, 2015

PIERIS PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Nevada
(State of Incorporation)

333-190728
(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))
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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 November 5, 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: November 5, 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, dated November 5, 2015.



Pieris Pharmaceuticals, Inc.

Nasdaq:PIRS

Corporate Presentation

November 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

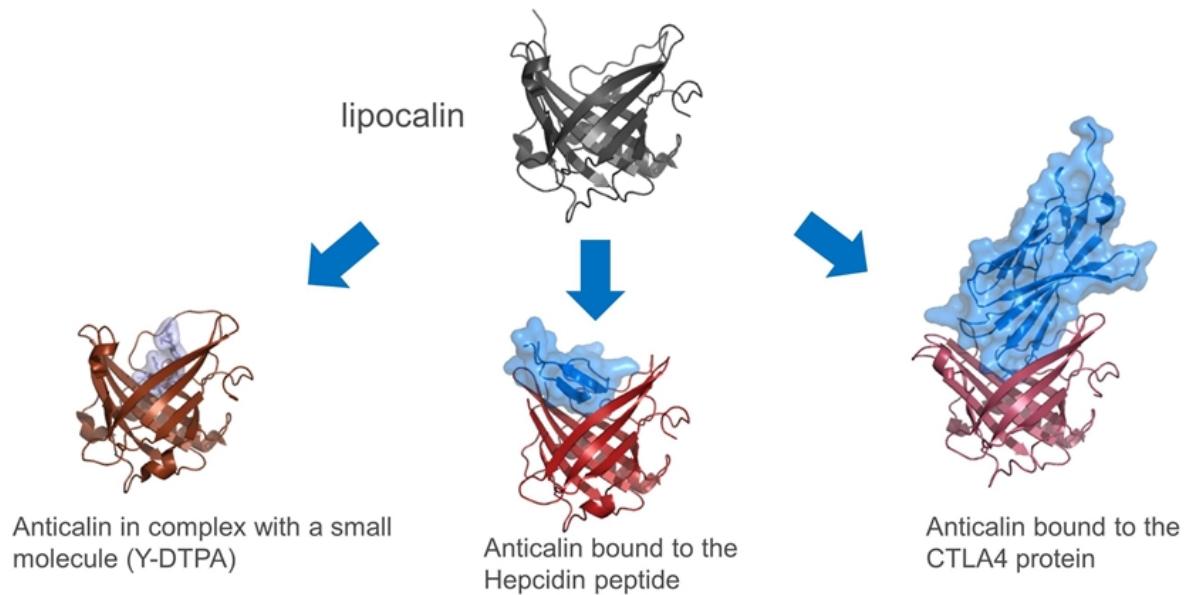


- We are a clinical-stage biotechnology company developing **Anticalin®**-based therapeutic proteins
 - We target validated disease pathways in a unique and transformative way
- Proprietary to us, Anticalins are a novel class of drugs validated in the clinic and by partnerships with leading pharmaceutical 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 are headquartered in Boston, MA, and have operations in the US and Germany.

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

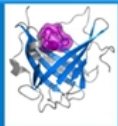


Anticalins Share Several Features with mAbs yet are Highly Differentiated



- 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

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 R&D partnerships generating ~\$44 M in revenue**
 - Potential for future milestone and royalties
 - Retained commercial rights in major markets

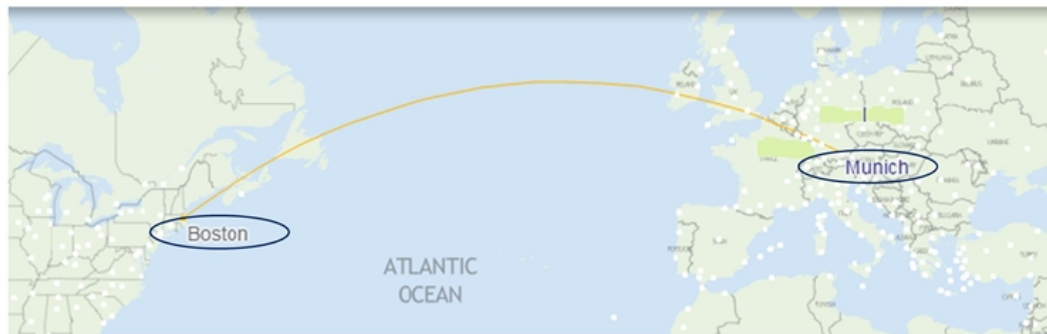


SANOFI



- **High-caliber Investors**
 - OrbiMed Advisors (~19%), Tekla Capital Management (~10%), Lombard Odier (~6.5%); Ally Bridge Group, Auriga, Emerald Mutual Fund, Forbion, Gilde, GLSV, Novo Nordisk, Sphera Funds, Zydus

Management and Operations Trans-Atlantic Synergies



© Lufthansa

Munich











- Proven team in place
- Great drug discovery and protein engineering expertise ~33 FTEs

Boston

- Corporate HQ September 2015 - CEO, CFO, CDO
- Becoming translational pharmacology and drug development hub

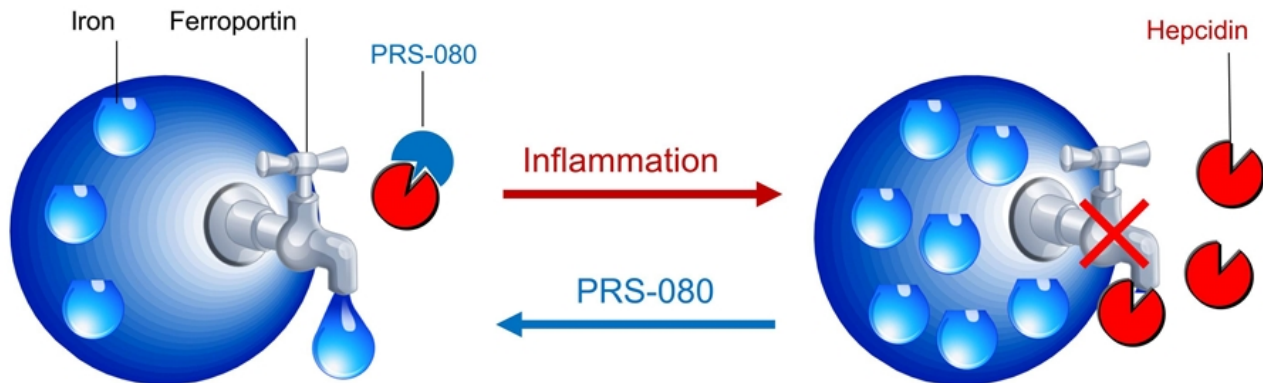
Anticalin Product Pipeline



	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 multi-specifics	PRS-343	CD137/HER2	Immuno-Oncology		mAb-Anticalin fusion			
	PRS-300s	n.d.			bi-/multispecifics			
3. Partnered Programs	PRS-110	cMet	Oncology					
	PRS-NN	n.d.	n.d.					Retained commercial rights in maj. mkts
	PRS-NN	n.d.	Ophthalmology					
	PRS-NN	n.d.						
	Daiichi Sankyo	n.d.	n.d.					Milestones & Royalties
		n.d.	n.d.					
	Sanofi	n.d.	n.d.					

n.d. = not disclosed

PRS-080: Best-in-Class Drug Candidate For Functional Iron Deficient Anemia

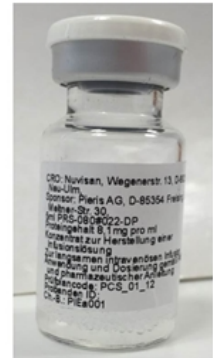


- Hepcidin is a clinically validated anemia target
- PRS-080 designed to reverse hepcidin-mediated anemia by mobilizing iron trapped in the body's iron storage cells
- Addresses patients unresponsive to ESA and iron therapies
- PK profile (half-life) of PRS-080 designed for a best-in-class approach

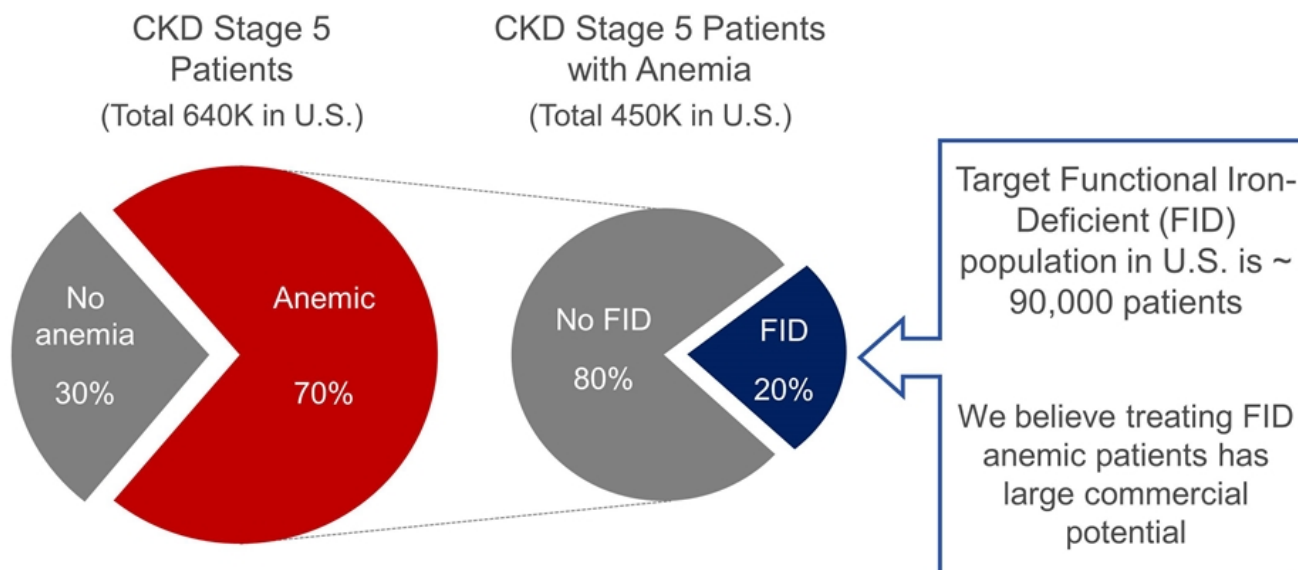
PRS-080: Successfully Completed Ph I and Advancing Into Patients



- Ph I study highlights
 - Safe and well tolerated in 48 healthy volunteers across six dose levels (0.08 to 16.0 mg/kg, i.v.), with no reported severe adverse events (SAE)
 - Confirmation of desired 3-day half-life, as predicted from animal studies
 - Confirmation of mode of action: a marked decrease in plasma hepcidin within one hour, followed by elevation of serum iron concentration and transferrin saturation
 - Duration of serum iron elevation and transferrin saturation increased in a dose-dependent manner
- Detailed results to be presented at ASH Annual Conference in December 2015
- First-in-patient trial in end-stage renal disease (ESRD) patients expected to begin by end of 2015



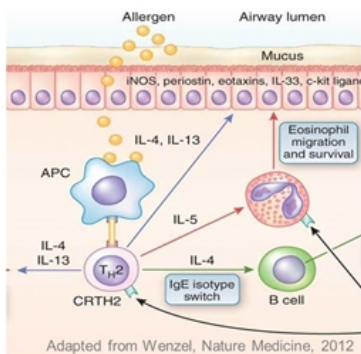
PRS-080: US Market Opportunity in Chronic Kidney Disease (Stage 5)



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 Targeting IL4Ra



Strong target validation & biomarker availability

- ✓ IL4Ra mAb (dupilumab) with strong efficacy in Phase 2b
- ✓ Biomarker-based patient selection is straight-forward
- ✓ Validated biomarkers (e.g. FeNo) allow for early clin. read-out

Clear differentiation from injected mAbs

- ✓ PRS-060 optimized for reduced on-target, off-tissue targeting
 - ✓ PRS-060 is administered directly to the lung and has a short half-life (several hours predicted in man, leading to predicted low systemic exposure)
 - ✓ In contrast, ~1% of systemically administered mAb has been shown to reach the lung compartment, leading to high systemic exposure*
- ✓ More convenient: standard of care is inhaled ICS/LABA
- ✓ Predicted Lower COGS may enable reach to broader patient populations, where pharmaco-economic burden is not as pronounced

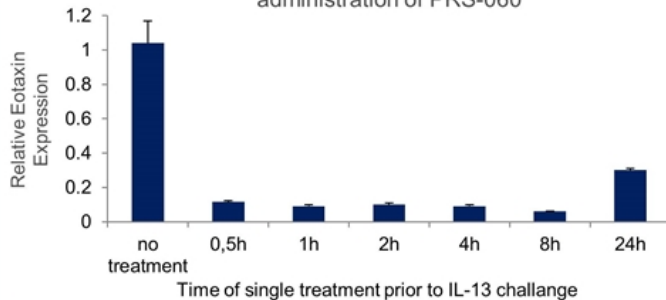


*(Hart et al. (2001) JACI. 108:250)

PRS-060: Pulmonary Delivery Effective in vivo & Feasible Formulation



Inhibition of IL13-induced eotaxin expression following pulmonary administration of PRS-060

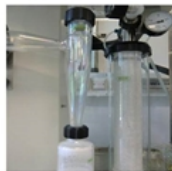


Early onset of inhibition and durability of effect up to 24h post pulmonary administration

Nebulizer

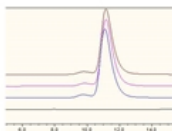
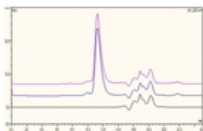


Spray Dryer



Device

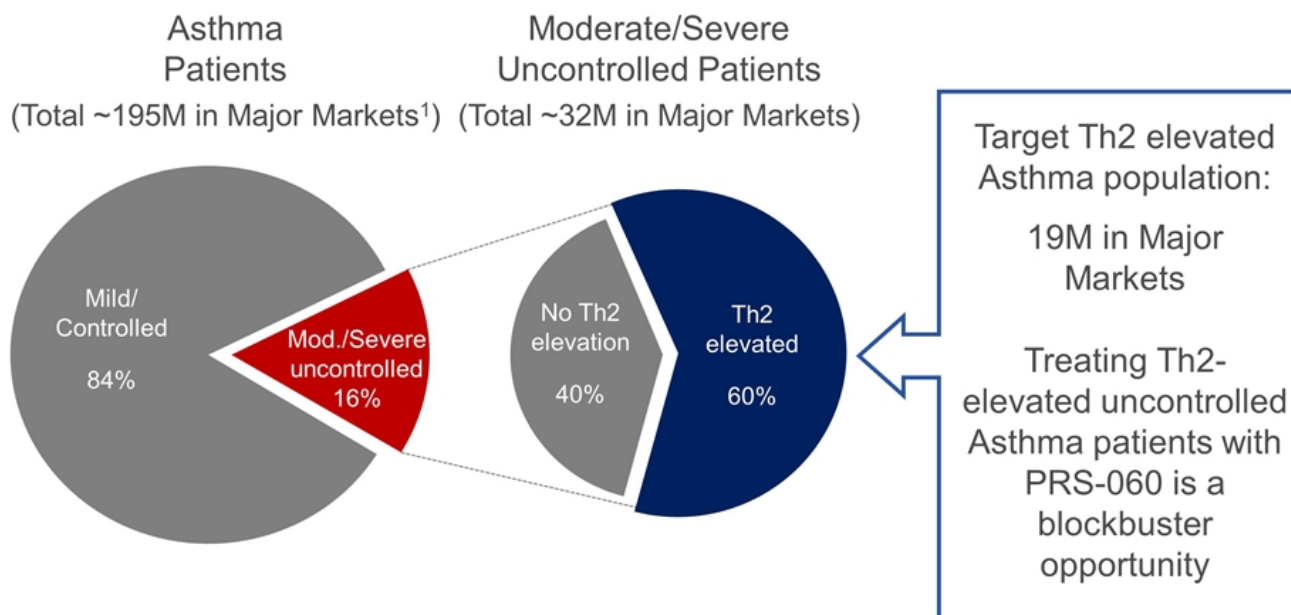
SEC Diagrams



Nebulization and spray drying feasibility demonstrated

- ✓ Appropriate particle size
- ✓ No aggregation
- ✓ Full functional activity
- ✓ High yield

PRS-060: Market Opportunity in Asthma



¹ Major Markets: U.S., EU, Japan, Brazil, Russia, India, China

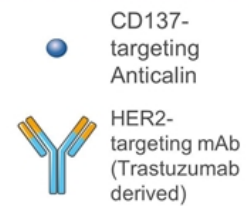
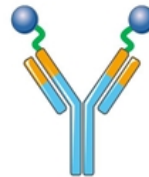
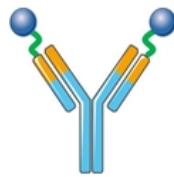
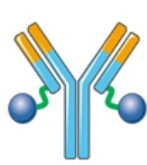
Source:
Artisan Healthcare Consulting market research study

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



HER 2 – 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 Lead Anticalin® Has Demonstrated Agonistic Properties



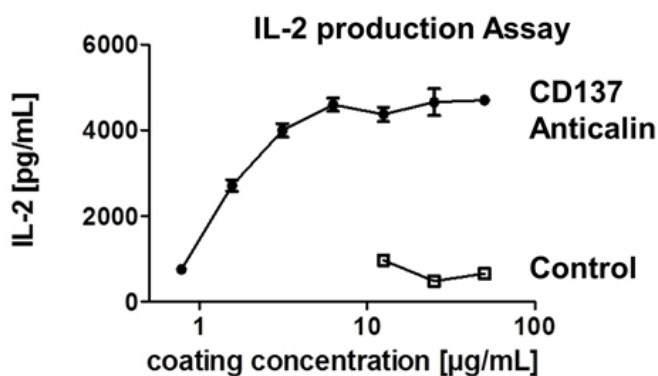
Binding to CD137

- 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

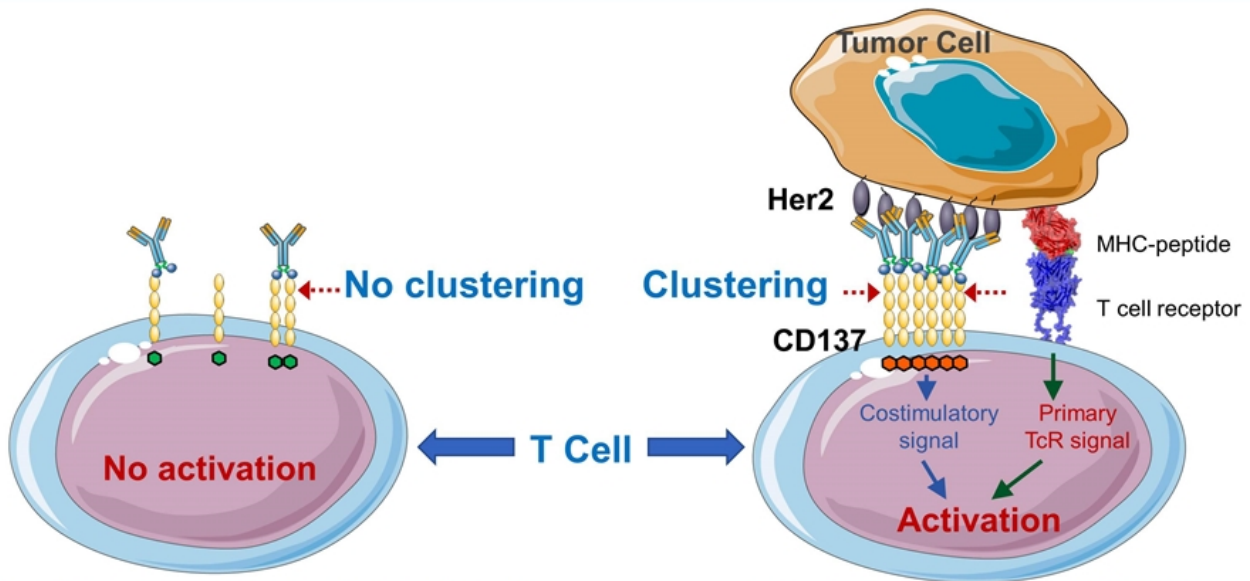
In vitro functional testing



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

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



No T cell costimulation in periphery

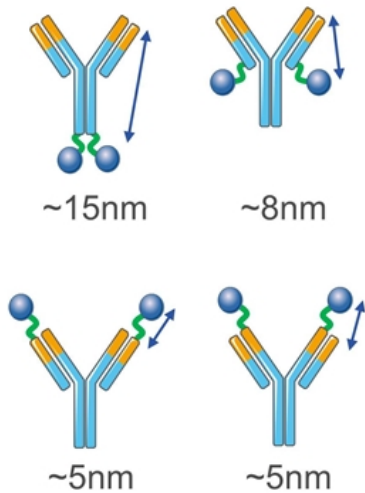
T cell costimulation in tumor

- 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

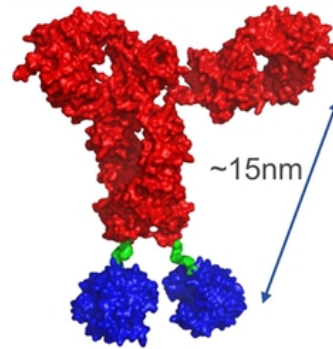
Bispecific Geometry Impacts Immune Synapse



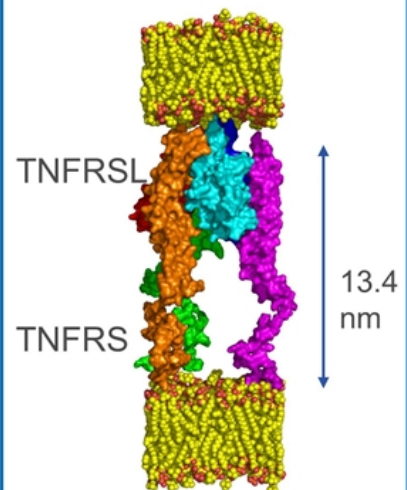
Expected distances
between binding sites
in different formats



Visualization of
Antibody-Anticalin fusion

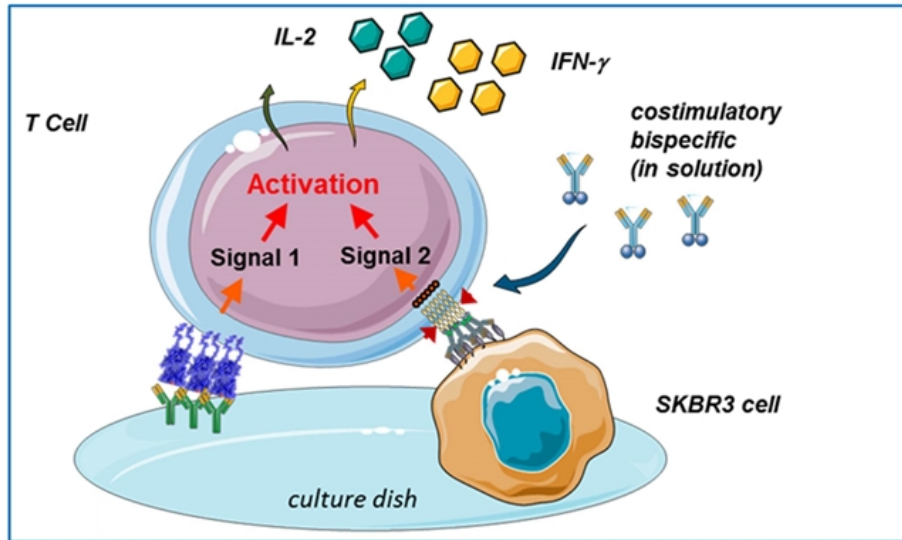


Membrane-to-membrane
distances play a role in
immunoreceptor interactions



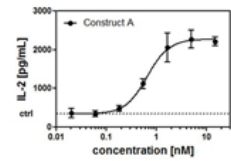
- Straightforward access to a range of distances between target binding sites
- Several formats to interrogate optimal target synapse for tumor cell killing

PRS-343 Bispecific Geometry Impacts T Cell Activation

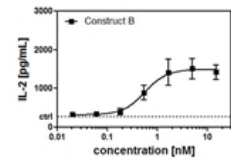


IL-2 response

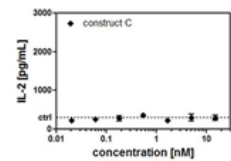
Construct A



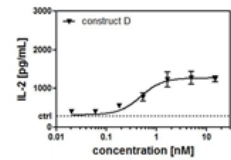
Construct B



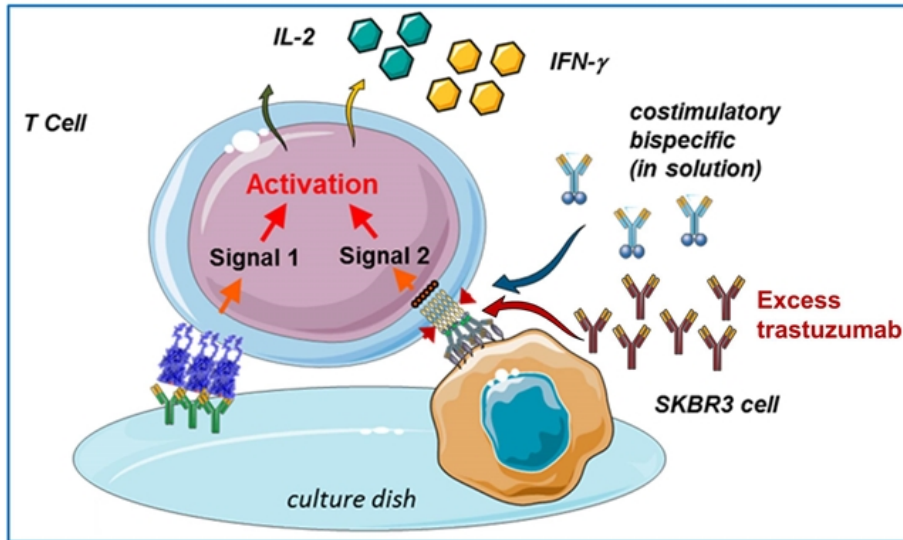
Construct C



Construct D



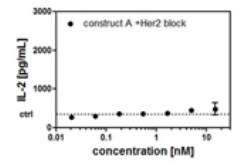
PRS-343 T Cell Activation is HER2 Target-Dependent



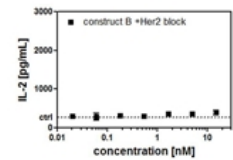
- Addition of excess HER2-targeting trastuzumab prevents PRS-343 binding to HER2-positive cells and results in a loss of activity, as intended, confirming mode of action

IL-2 response with Her2 blockade

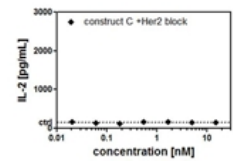
Construct A



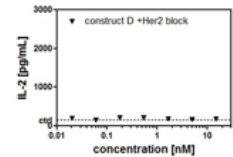
Construct B



Construct C



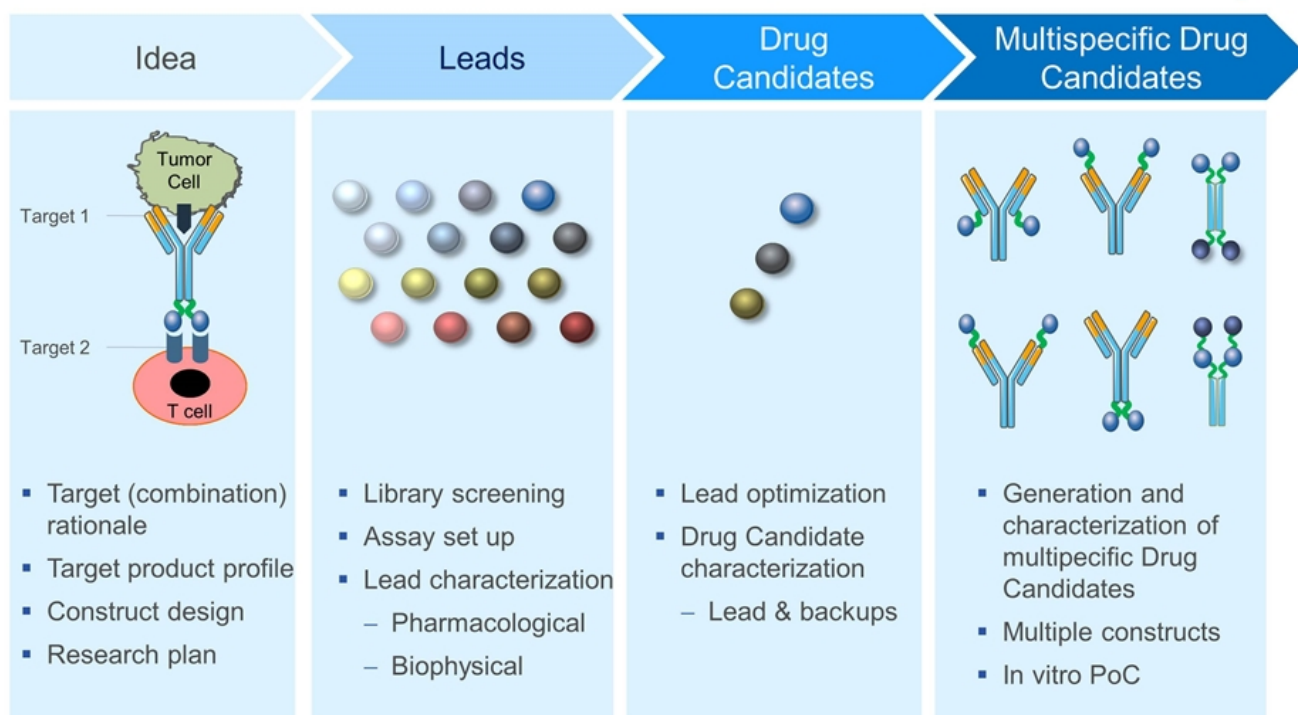
Construct D



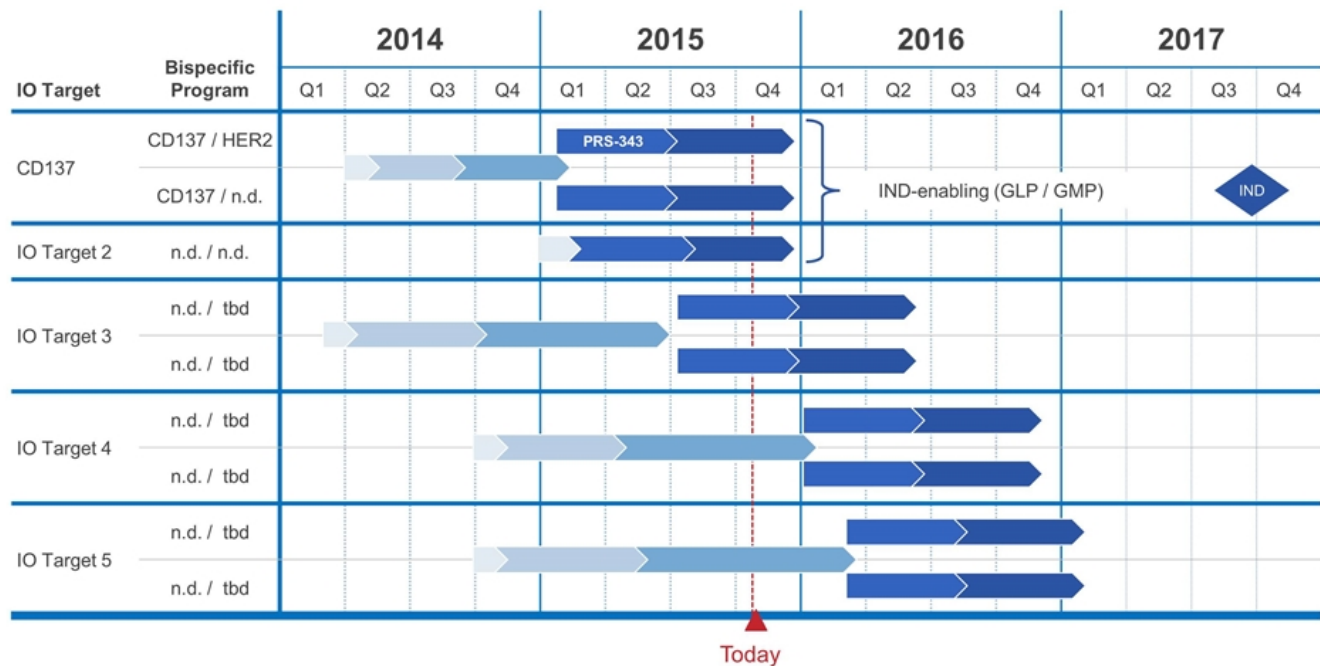
From Idea to Drug Candidate – Efficient Platformed Process



12 – 18 months

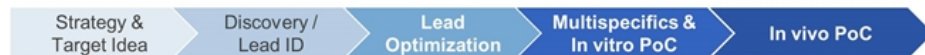


Pieris IO Pipeline Progressing Multiple Options & Partnering Opportunities



n.d.: not disclosed

tbd: 2nd target to be defined



Anticalin Intellectual Property – Safe & Sound



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



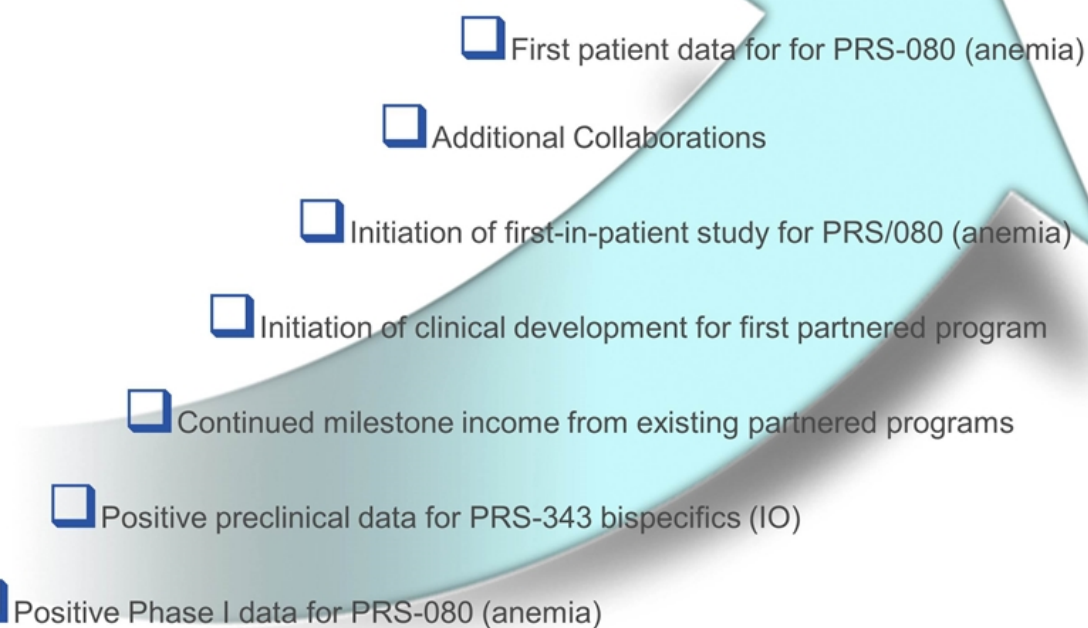
Cash & Cash Equivalents*	\$34.3M
Total Debt	\$ 0.0M
Revenue Since Inception **	~ \$44.0M
Grant Revenue Since Inception	\$14.1M
H1 2015 Cash Burn (includes \$1.2M in debt repayment)	\$ 8.4M
Market Cap – at November 3, 2015	\$ 76.7M
52 Week Range	\$1.54 - \$3.70
Common Shares Outstanding*	39,732,258

• At July 31, 2015

** Includes Revenue from Licensing, Collaborations & R&D Services

Potential Future Milestones



- 
- A large, light blue arrow pointing upwards and to the right, serving as a background for the milestones.
- First patient data for for PRS-080 (anemia)
 - Additional Collaborations
 - 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)

November 2015 through 2016



Pieris Pharmaceuticals, Inc.

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USA
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