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 15, 2018

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

Nevada	**001-37471**	**EIN 30-0784346**
(State of Incorporation)	**(Commission File Number)**	**(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging Growth Company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01: Regulation FD Disclosure.

Attached hereto as Exhibit 99.1 and incorporated by reference herein is the November 15, 2018 Jefferies London Healthcare Conference 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 Jefferies London Healthcare Conference Presentation, dated November 15, 2018.

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.

PIERIS PHARMACEUTICALS, INC.

Dated: November 15, 2018

/s/ Allan Reine

Allan Reine
Chief Financial Officer

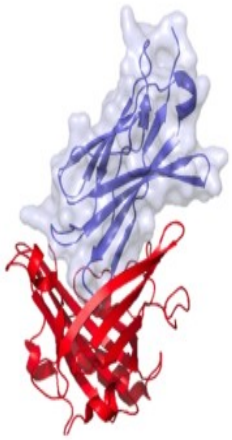

pieris
PHARMACEUTICALS
Jefferies London
Healthcare Conference
November 2018
(Nasdaq: PIRS)

Forward Looking Statements

This presentation contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to novel technologies and methods and our business and product development plans, including the advancement of our proprietary and co-development programs into and through the clinic. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, our ability to raise the additional funding we will need to continue to pursue our business and product development plans; the inherent uncertainties associated with developing new products or technologies and operating as a development stage company; our ability to develop, complete clinical trials for, obtain approvals for and commercialize any of our product candidates, including our ability to recruit and enroll patients in our studies; our ability to address the requests of the FDA; competition in the industry in which we operate and market conditions. These forward-looking statements are made as of the date of this press release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents we file with the SEC available at www.sec.gov, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and the Company's Quarterly Reports on Form 10-Q.

Anticalin Proteins – A Novel Therapeutic Class with Favorable Drug Properties

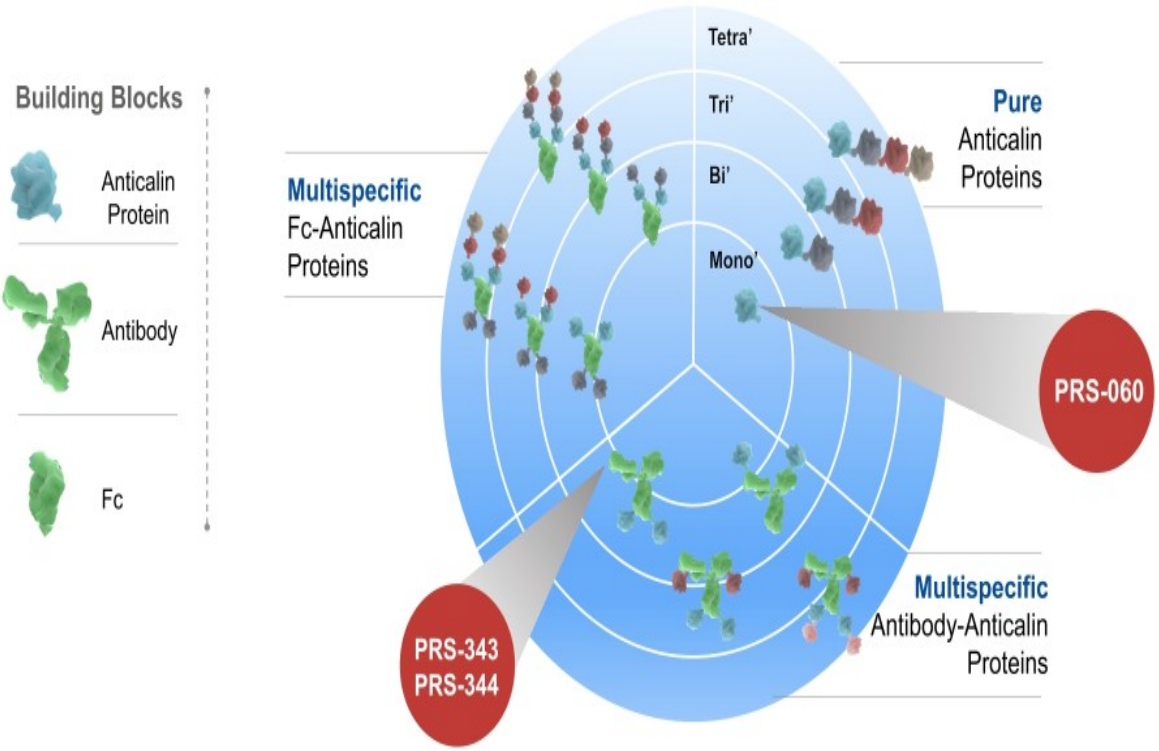
- Derived from lipocalins (human extracellular binding proteins)
  - multifunctional, non-immunogenic polypeptides
- Engineerable binding pocket for robust target engagement
- Small size (18 kDa vs 150 kDa in the case of antibodies)
- Can be formulated for inhalable delivery
- Can be formatted into novel bi- and multi-specific constructs



Underpinned by a Powerful Drug Discovery Platform

- Highly diverse libraries (>10^{11}) of potential drug candidates
- Automated high-throughput drug screening technology (phage display)
  - High hit rates, quick to development candidates, versatile use
- Extensive protein engineering know-how

Anticalin Protein-based Drug Candidates can be Tailored to Multiple Formats



Potent Multi-target Engagement • Novel Inhaled and Multispecific MoA • Favorable Drug-like Properties

Pieris Investment Opportunity

- Validation through three anchor partnerships
  - $120M+ in upfront payments and milestones since January 2017
  - Each partnership includes co-development & US-focused commercialization rights
- Upcoming clinical-based inflection points
  - Respiratory: co-developed (AstraZeneca) inhaled IL-4Ra antagonist (PRS-060)
  - IO: wholly owned bispecific 4-1BB agonist (PRS-343)
- Strong balance sheet to bridge through clinical inflection points
- Partnerships and pipeline supported by IND engine yielding several drug candidates with excellent drug-like properties

Financial Update (9/30/18)

(in millions)

Cash & Cash Equivalents	$137.3
Debt	$0.0
YTD OPEX (9/30)	$35.7
CSO	54.0

Recent and Upcoming Milestones

Core Clinical	✓ PRS-060: First-in-human SAD data in 2H18 ❑ PRS-060: MAD PK/PD biomarker (FeNO) data ❑ PRS-343: Initial safety and PD data
Next-Gen Pipeline	✓ PRS-344 data at SITC 2018 ✓ Advance multiple programs in immuno-oncology and respiratory
Non-Core Clinical	✓ PRS-080: Phase IIa data in 2H18 (safety, PK, hemoglobin change post 5QW dosing)

Pipeline Highlights

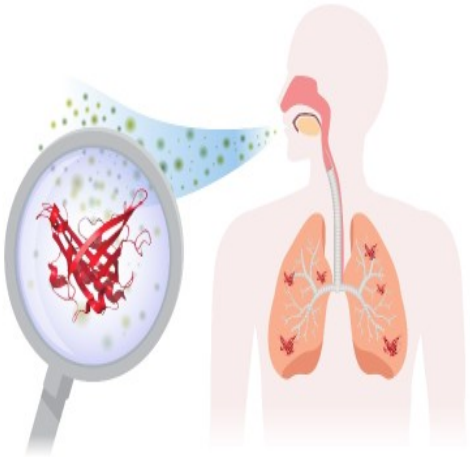
	DISCOVERY	PRECLINICAL	PHASE I	PHASE II
PRS-080				✓
PRS-343			✓	
PRS-060 (AZ)			✓	
PRS-344 (Servier)		✓		
Servier	✓	✓		
PRS-300s	✓	✓		
AstraZeneca	✓			
PRS Respiratory	✓			
Seattle Genetics	✓			

-pieris-

Two IO INDs planned in 2019

Respiratory Franchise

Addressing validated targets through inhalation



AstraZeneca Collaboration AstraZeneca

- PRS-060: IL-4 receptor alpha antagonist in clinical development for the treatment of moderate-to-severe uncontrolled asthma
- 4 additional committed novel inhaled Anticalin protein programs
- Retained co-development and co-commercialization (US) options on PRS-060 and up to two additional programs
- Attractive economics
  - Received $57.5M: $45M upfront & $12.5M Phase I milestone
  - ~$2.1B in milestone potential, plus up to double-digit royalties
  - AZ funds all PRS-060 development costs through post-Phase IIa co-development opt-in decision
- Access to complementary formulation and device know-how for inhaled delivery
- Initiated a discovery program in 2H18

Proprietary Clinical (worldwide rights)

- Initiated two proprietary respiratory programs for undisclosed targets in 2H18

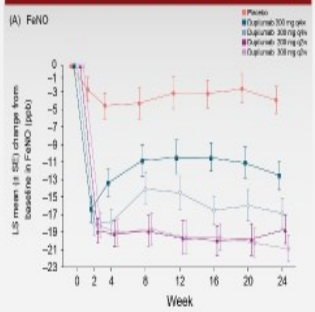
PRS-060 is an Inhaled Drug Candidate for Uncontrolled Asthma

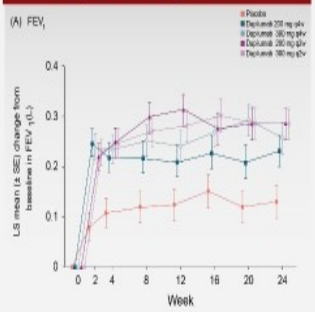
Why did we design this?

What We Know

Regeneron/Sanofi's dupilumab (systemically administered anti-IL-4Ra antibody) has demonstrated the following:

Reduction in biomarker (FeNO*) → **Improved lung function** → **Exacerbation Reduction** & **Steroid Sparing**





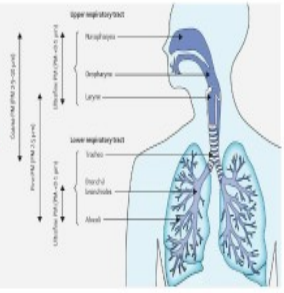
67% reduction in high-eosinophil patients

80% avg. reduction in corticosteroid use

*Fractional exhaled nitric oxide

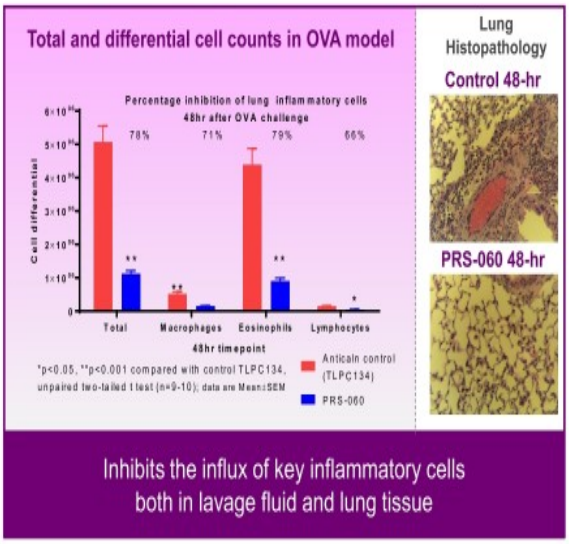
What We Are Testing

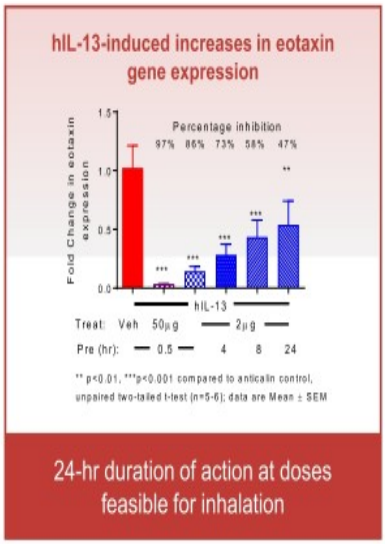
- Is this a local phenomenon?
- First-in-man study underway via inhaled delivery



Preclinical *In Vivo* PoC Supports Clinical Development

- First inhaled Anticalin protein to potently engage the highly validated asthma target, IL-4Ra
- Localized target engagement in lung tissue supports a rationale for a convenient, low-dose, low-cost alternative to systemically administered antibodies
- Preclinical in vivo PoC for pulmonary delivery at doses supportive of daily administration



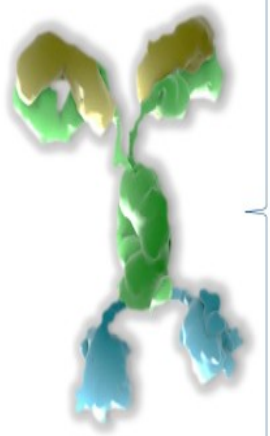


PRS-060 Phase I Trial

Single Ascending Dose	Multiple Ascending Dose
Healthy volunteers	Dosing patients with mild asthma, elevated FeNO at baseline
Initiated in December 2017	Initiated in July 2018
Oral inhalation phase completed IV infusion arm (to study PK) ongoing	Evaluating safety, tolerability, PK, PD and will also evaluate FeNO reduction vs. placebo
Safe and well-tolerated in 48 subjects at dose levels ranging from 0.25 mg to 400 mg	Pieris is sponsoring the trial, AstraZeneca is reimbursing Pieris for all associated costs

Immuno-oncology Franchise

Prioritizing PRS-343, "fast-followers" and diversified costim agonism beyond 4-1BB



Proprietary Clinical (worldwide rights)

- PRS-343: First-in-class bispecific to preferentially activate T cells in the tumor microenvironment (TME)
- Committed to advancing several additional tumor-localized costimulatory bispecific fusion proteins

Servier Collaboration SERVIER

- PRS-344: PD-L1/4-1BB antibody/anticalin bispecific
- 5-program deal (all bispecific fusion proteins)
- Pieris retains **full U.S. rights** for 3 out of 5 programs
- $31M upfront payment, $1.8B milestone potential
- Up to low double-digit royalties on non-codev products

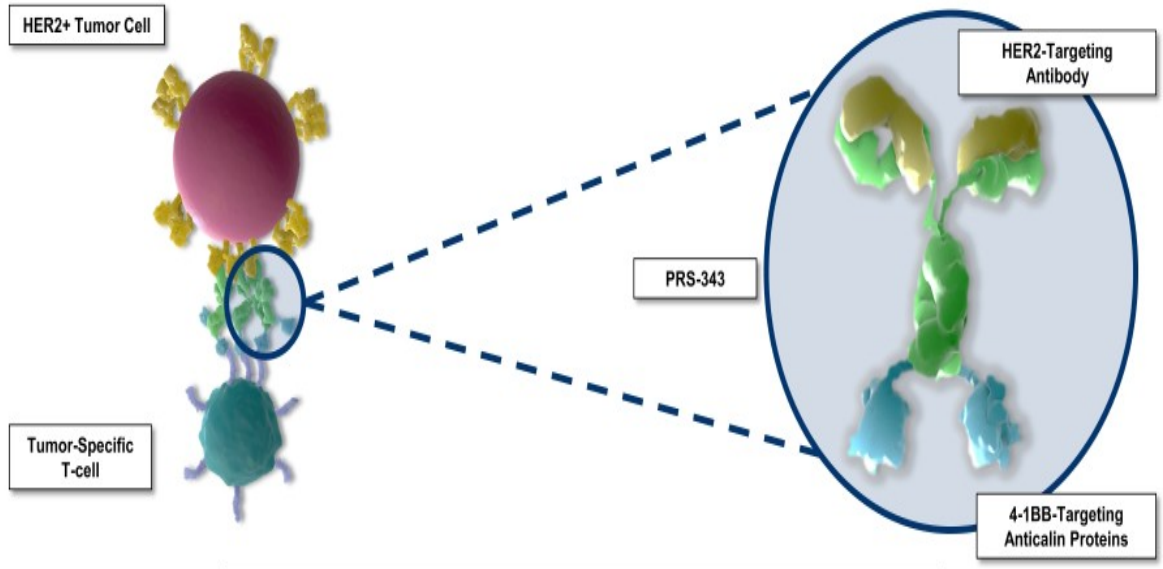
Seattle Genetics Collaboration SeattleGenetics

- 3-program partnership based on tumor-localized costimulatory bispecific fusion proteins
- Pieris retains opt-in rights for **50/50 global profit split and U.S. commercialization rights** on one of the programs
- $30M upfront payment, $1.2B milestone potential
- Up to double-digit royalties on non-codev products

4-1BB (CD137): Validated Target in Need of Appropriate Drug

- Marker for tumor-specific T cells in TME
- Ameliorates T cell exhaustion & critical for T cell expansion
- Drives anti-tumor cytolytic activity
- Drives central memory T cell phenotype

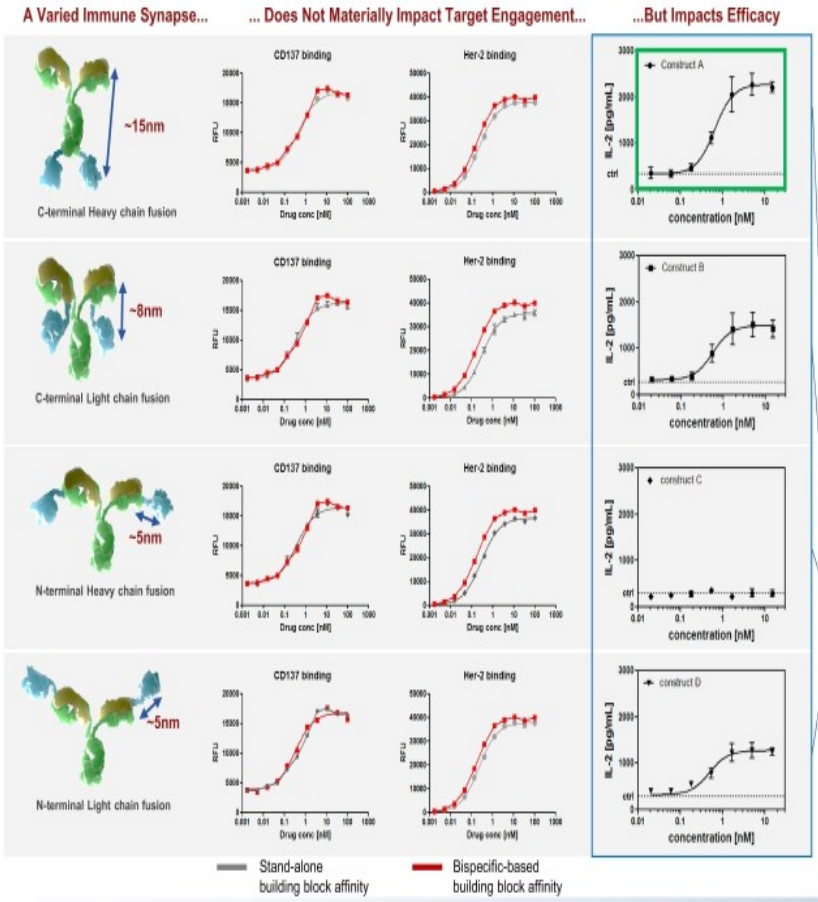
Systemically agonizing 4-1BB mAb (urelumab) has shown clinical activity yet caused significant toxicity

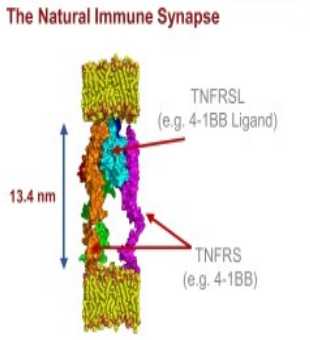


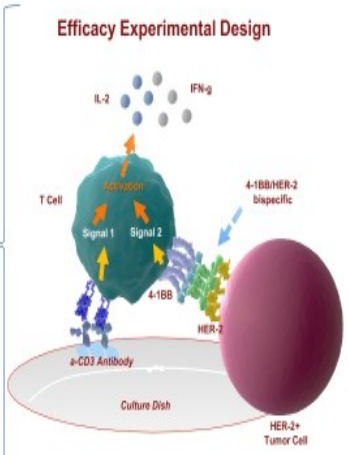
PRS-343 was designed for TME-specific 4-1BB activation*

*4-1BB *trimerization* required for activation

Anticalin Platform: Well-Equipped for Targeted IO Agonism



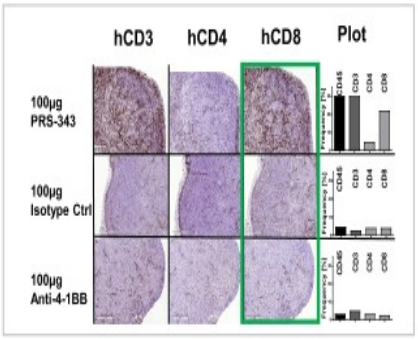




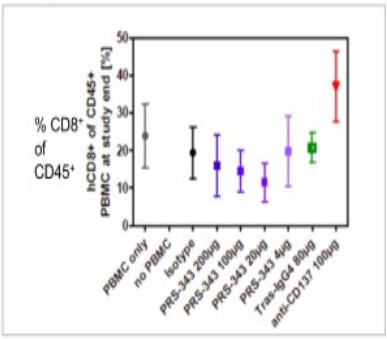
PRS-343 Shows Localized Activity in Humanized Mouse Model

	CD8⁺ Proliferation in TME	Peripheral CD8⁺ Proliferation	Systemic Toxicity
PRS-343	Yes	No	No
4-1BB mAb	No	Yes	Yes
Isotype Control	No	No	No

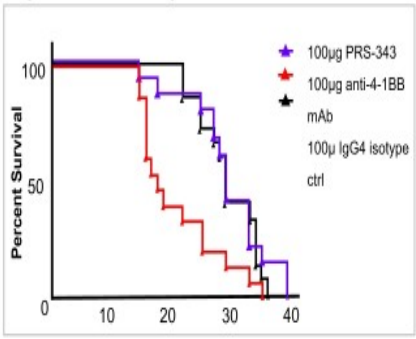
CD8⁺ Proliferation in TME



Peripheral CD8⁺ Proliferation



Systemic Toxicity



Experimental Design:

- SKOV-3 tumor cells grafted onto immune-deficient mice and grown to predetermined volume
- Human PBLs + control or PBLs + PRS-343 administered

PRS-343 Phase I Escalation and Expansion Trials

ESCALATION

HER2+ all-comers to efficiently interrogate therapeutic window during escalation

First patient dosed September 2017

Treating patients with HER2+ solid tumors

Dose-escalation trial

Initial PK, safety, tolerability and biomarker data in 1H19

First patient dosed in combination with atezolizumab (Tecentriq®) in August 2018 (drug supply agreement with Roche)

EXPANSION

- Bladder
- Gastric
- Other(s)

START Center for Cancer Care · SARAH CANNON Fighting Cancer Together · next · JOHNS HOPKINS MEDICINE · Georgetown University · MD Anderson Cancer Center · Memorial Sloan Kettering Cancer Center · UCLA · UPMC HILLMAN CANCER CENTER

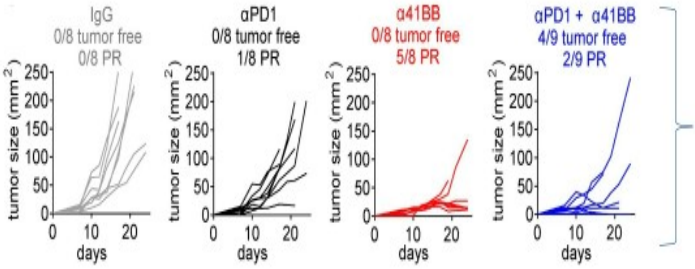
PRS-344: PD-L1/4-1BB Antibody-Anticalin Bispecific

- Combining the benefits of tumor-localized 4-1BB agonism with PD-L1 blockade
- Pan-tumor opportunity
- Partnered with Servier
- Publications support preclinical rationale of the combination as evidenced below:

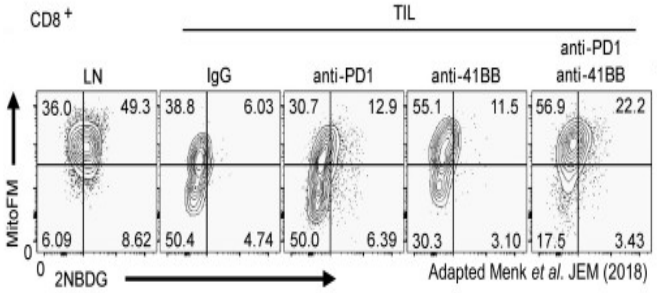
Synergistic Response of PD-1+4-1BB Combination Demonstrated In Preclinical Models

PD-L1 Targeted Antibody

4-1BB-Targeting Anticalin Proteins

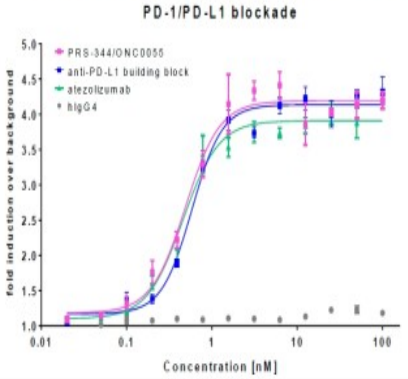


PD-1+4-1BB combo demonstrates robust preclinical anti-tumor activity



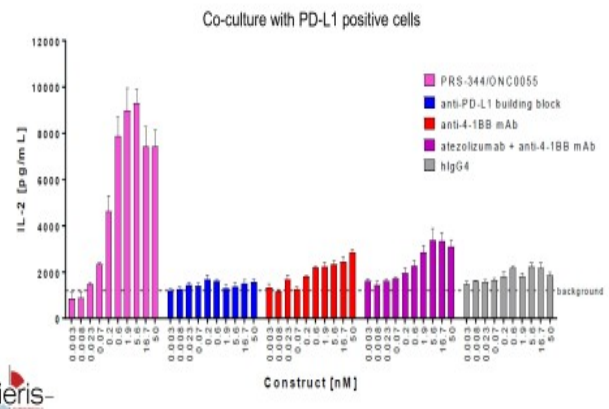
4-1BB agonism enhances mitochondrial function in T cells

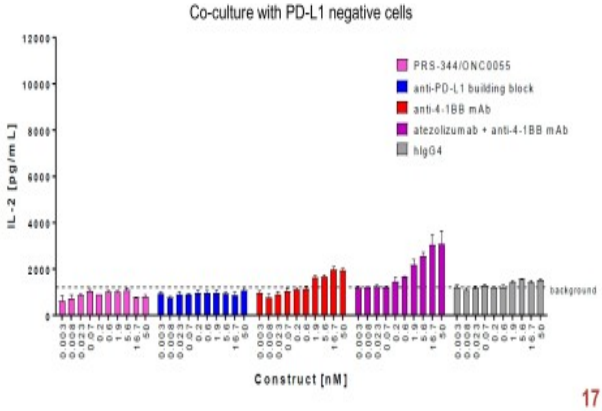
PRS-344: Localized, Simultaneous Costimulatory T-cell Engagement and Checkpoint Inhibition to Provide Synergistic Efficacy With Favorable Therapeutic Window



PRS-344 drives checkpoint blockade activity similar to anti-PD-L1 antibody building block and benchmark

PRS-344-mediated costimulation is strictly PD-L1 dependent, reducing the risk of peripheral toxicity





Pieris Investment Opportunity

- Validation through three anchor partnerships
  - $120M+ in upfront payments and milestones since January 2017
  - Each partnership includes co-development & US-focused commercialization rights
- Upcoming clinical-based inflection points
  - Respiratory: co-developed (AstraZeneca) inhaled IL-4Ra antagonist (PRS-060)
  - IO: wholly owned bispecific 4-1BB agonist (PRS-343)
- Strong balance sheet to bridge through clinical inflection points
- Partnerships and pipeline supported by IND engine yielding several drug candidates with excellent drug-like properties

Respiratory

Immuno-oncology

Scientific and Clinical Advisory Boards

SCIENTIFIC ADVISORY BOARD: ONCOLOGY

- Michael Curran, PhD
  MD Anderson Cancer Center
- Vijay Kuchroo DVM, PhD
  Harvard Medical School
- Padmanee Sharma, PhD
  MD Anderson Cancer Center
- E. John Werry, PhD
  University of Pennsylvania
- Dario Vignali, PhD
  University of Pittsburgh

SCIENTIFIC ADVISORY BOARD: RESPIRATORY

- Ian Adcock, PhD
  Imperial College
- Gary Anderson, PhD
  University of Melbourne
- Peter Barnes, FRS
  Imperial College
- Fan Chung, MD, DSc
  Imperial College
- Oliver Eickelberg, MD
  University of Denver
- Bruce Levy, MD
  Harvard University, Brigham and Women's Hospital
- David Schwartz, MD
  University of Colorado, Denver
- Sally Wenzel, MD
  University of Pittsburgh Medical Center

CLINICAL ADVISORY BOARD: ONCOLOGY

- Funda Eric-Bernstam, MD, PhD
  Institute for Personalized Cancer Therapy, MD Anderson Cancer Center
- Noah Hahnm, MD
  Johns Hopkins University School of Medicine
- David Ilson, MD, PhD
  Memorial Sloan-Kettering Cancer Center, Weill Cornell Medical College
- Sandra Swain, MD
  Georgetown University Cancer Center
- Mario Sznol, MD
  Yale University


Pieris Pharmaceuticals, Inc.
Corporate HQ: 255 State Street, 9th Floor, Boston, MA 02109, USA
R&D Hub: Freising, Germany (Munich)
info@pieris.com
www.pieris.com