
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 14, 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))

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 an investor 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 [Investor Presentation of Pieris Pharmaceuticals, Inc., dated November 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: November 14, 2017

PIERIS PHARMACEUTICALS, INC.

By: /s/ Allan Reine
Name: Allan Reine
Title: Chief Financial Officer



Investor Presentation

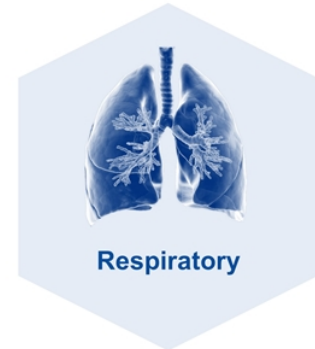
November 2017

Forward Looking Statements

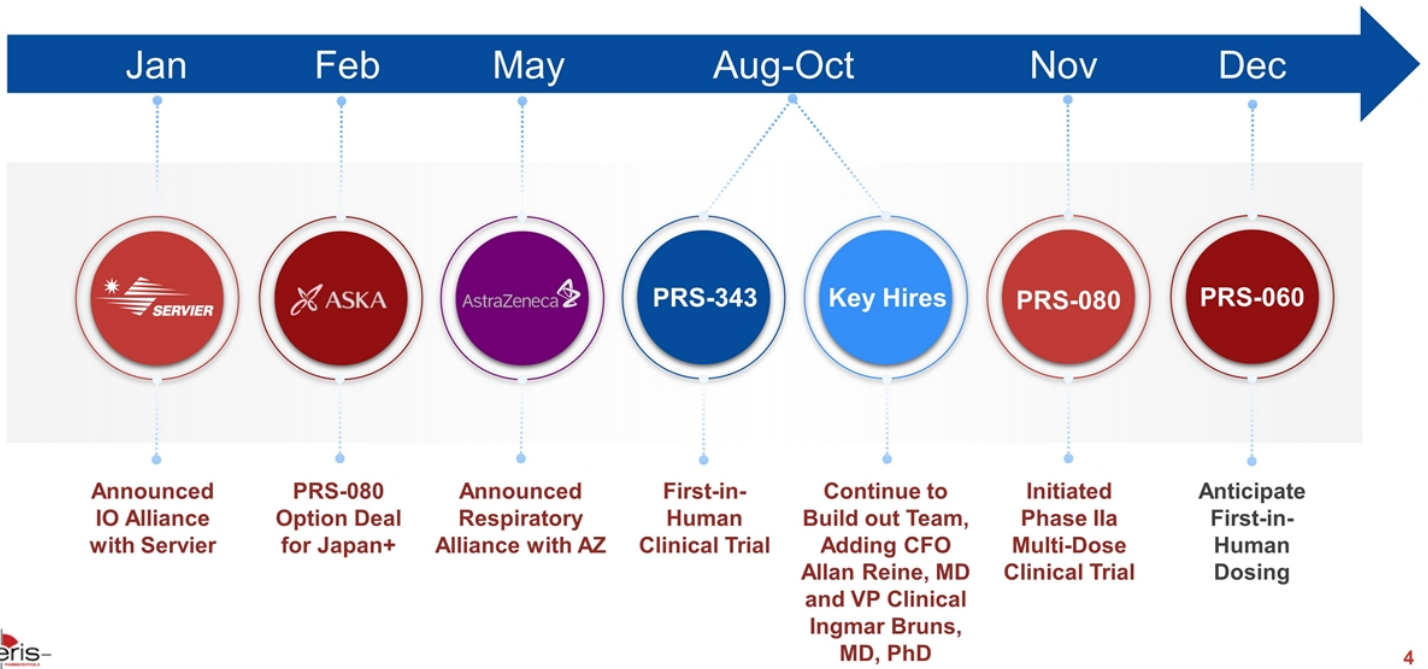
Statements in this presentation that are not descriptions of historical facts are forward-looking statements that are based on management's current expectations and assumptions and are subject to risks and uncertainties. In some cases, you can identify forward-looking statements by terminology including "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 30, 2017. 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 Investment Opportunity

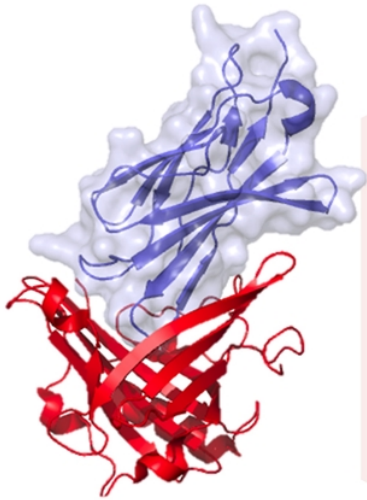
- Robust pipeline of a novel class of therapeutics
 - Anticalin® proteins
- Potentially transformative, wholly owned immuno-oncology (IO) program
 - Tumor-targeted 4-1BB bispecific
- Validating pharmaceutical partnerships in IO, respiratory and other therapeutic areas
 - \$80M in upfront payments in 2017, \$4.5B in milestone potential
- First-in-class, inhaled Anticalin protein targeting IL-4Ra
 - partnered with AstraZeneca
- Next-generation bi/multispecific IO platform
 - To exploit costimulatory and checkpoint targets
- Novel inhaled biologics platform



Pieris has Executed well in 2017 on a Value-Creating Strategy



Anticalin Proteins – A Novel Therapeutic Class



Features

Derived from lipocalins
(human epithelial proteins)

Engineerable binding pocket

Engineerable scaffold

Small size (1/8th the size of a mAb)

Benefits

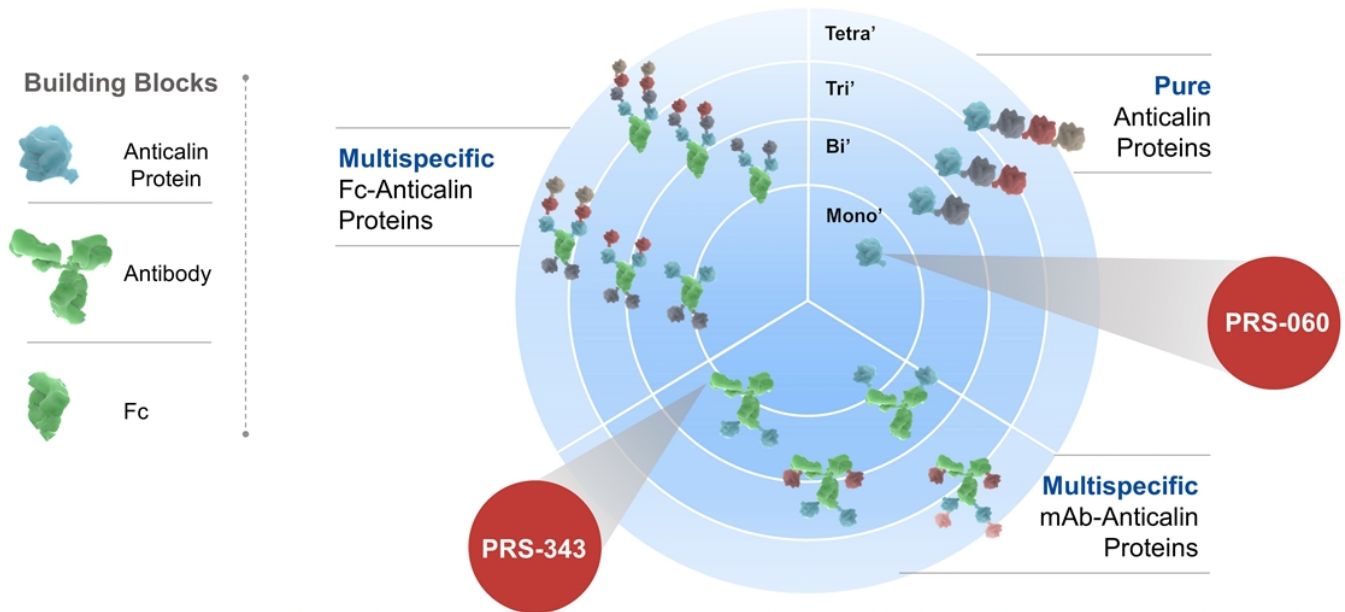
No observed
immunogenicity to date

Potent target engagement

Unique bi/multispecifics

Inhaled therapeutics

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



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

Pipeline Programs

Candidate

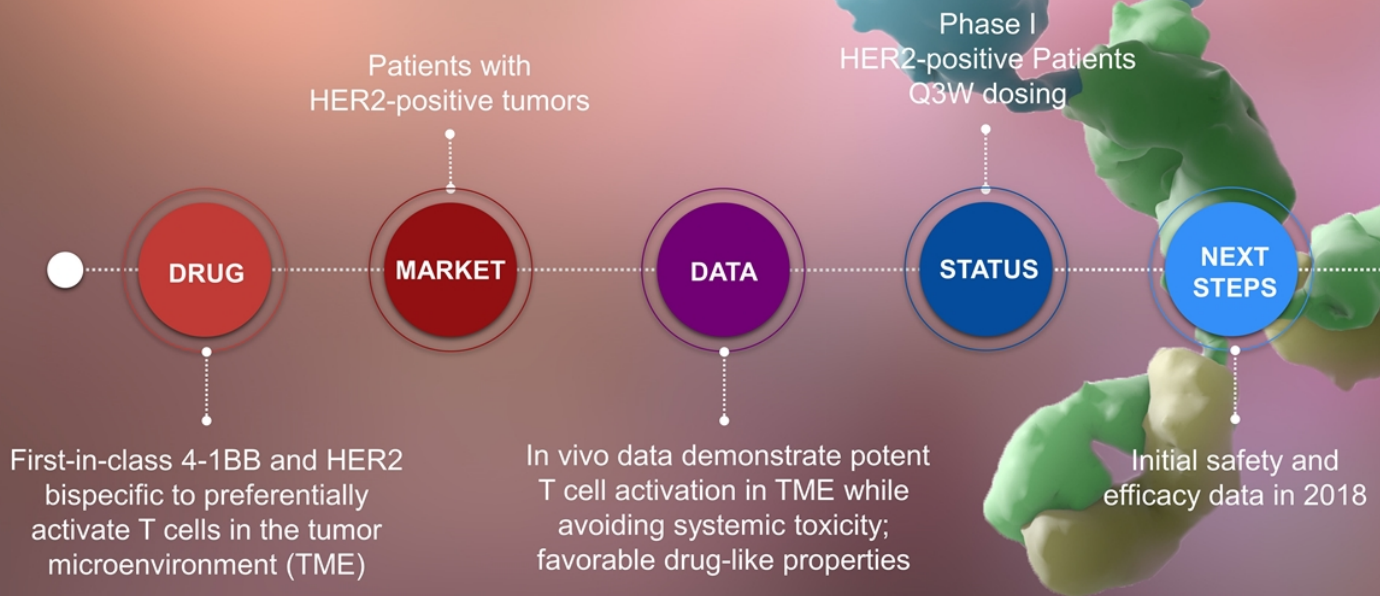
**Target /
Indication**

Phase

		DISCOVERY	PRECLINICAL	IND-ENABLING	CLINICAL
PRS-343 (Pieris)	4-1BB/HER2 Bispecific				✓
PRS-300's (Pieris)	n.d. IO Bi/Multispecifics	✓	✓		
PRS-332 / Servier Alliance	Bispecific Checkpoints & Costims	✓	✓		
PRS-060 (AstraZeneca)	IL-4Ra			✓	
AstraZeneca Alliance	Inhaled Programs	✓			
PRS-080 (Pieris/ASKA)	Hepcidin/Anemia				✓
Roche, Sanofi, Daiichi	Diverse Programs	✓	✓	✓	

PRS-343, IO Drug Candidate for Solid Tumors

100% Proprietary to Pieris



PRS-343 US Market Opportunity



Cancer Type	Prevalence (US) ¹	Line of Therapy	Line of Therapy Size (%)	HER2+ Rate (%)	Addressable Population (US)
Breast Cancer	3,327,552	3 rd Line	~9 %	20 % ²	59,495
Bladder Cancer	696,440	3 rd Line	~4 %	43 % ³	10,705
Gastric Cancer	76,829	2 nd Line	~23 %	22 % ⁴	3,942
Uterine (Endometrial) Cancer	710,228	1 st Line	~12 %	25 % ⁵	20,827
Ovarian Cancer	222,060	2 nd Line	~32 %	7 % ⁶	4,278

Additional potential tumor types include e.g. Biliary, NSCLC, Esophageal, Colorectal and Cervical Cancer

- **Multi-billion dollar market opportunity in HER2-positive cancers, well over 100K addressable patients in the US alone.**

1) Surveillance, Epidemiology, and End Results (SEER) Program 2) Schmidt, C. J Natl Cancer Inst. 2010; 3) Krüger, S. et al. Int. J. Cancer. 2002; 4) Yano et al. J Clin Oncol, 2004; 5) Livasy, CA., et al. Gyn Onc. 2006; 6) Tuefferd M, et al., PLoS ONE. 2007

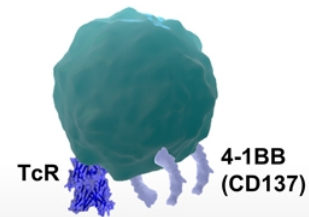
PRS-343 is a First-in-class Bispecific TME-activated Costimulatory Agonist



4-1BB (CD137) – Key Costimulatory Target

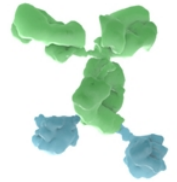
- Marker for tumor-specific T cells in TME
- Ameliorates T cell exhaustion
- Critical for T cell expansion
- Induces anti-tumor cytolytic activity
- Drives central memory T cell differentiation for sustained response

Tumor-specific T Cell



PRS-343

4-1BB-targeting Ac



HER2-targeting mAb

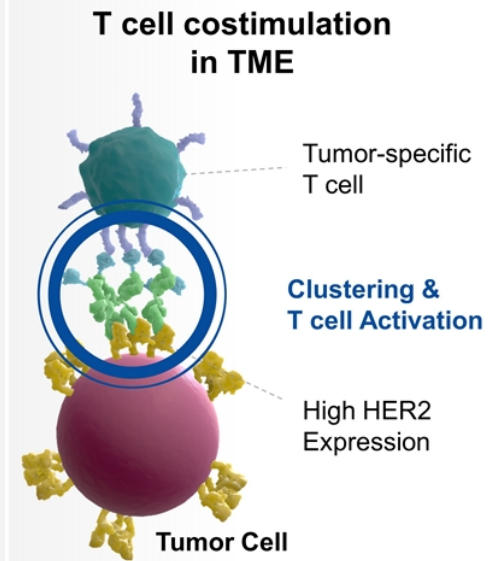
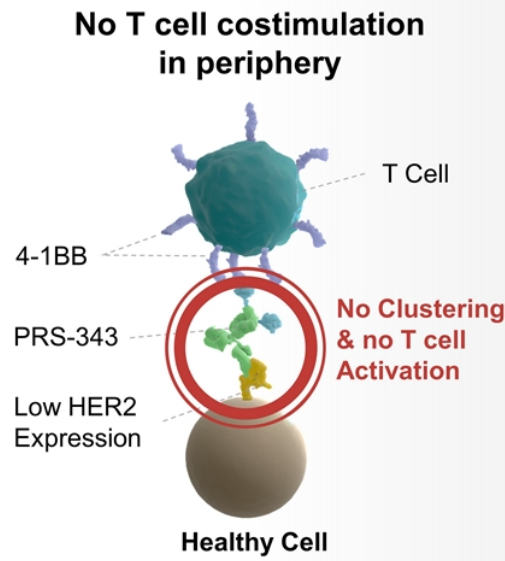
HER2 – Strongly Validated Tumor Target

- Restricted expression on normal tissue
- Multiple HER2+ tumors with high-unmet need
 - Breast, Gastric & Bladder; several others
 - Mediates drug mobilization and immune receptor activation within the tumor bed

Concept: Tumor-localized Costimulation with PRS-343 (Bispecific 4-1BB Engager)



- 4-1BB is activated via high-order clustering
- Tumor receptor-mediated clustering of bispecifics drives 4-1BB-mediated T cell activation
- Maintained tumor antigen specificity by T cell receptor may lead to safety advantages





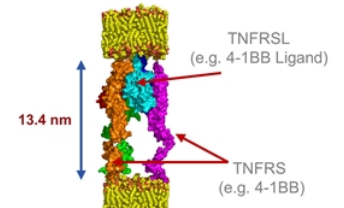
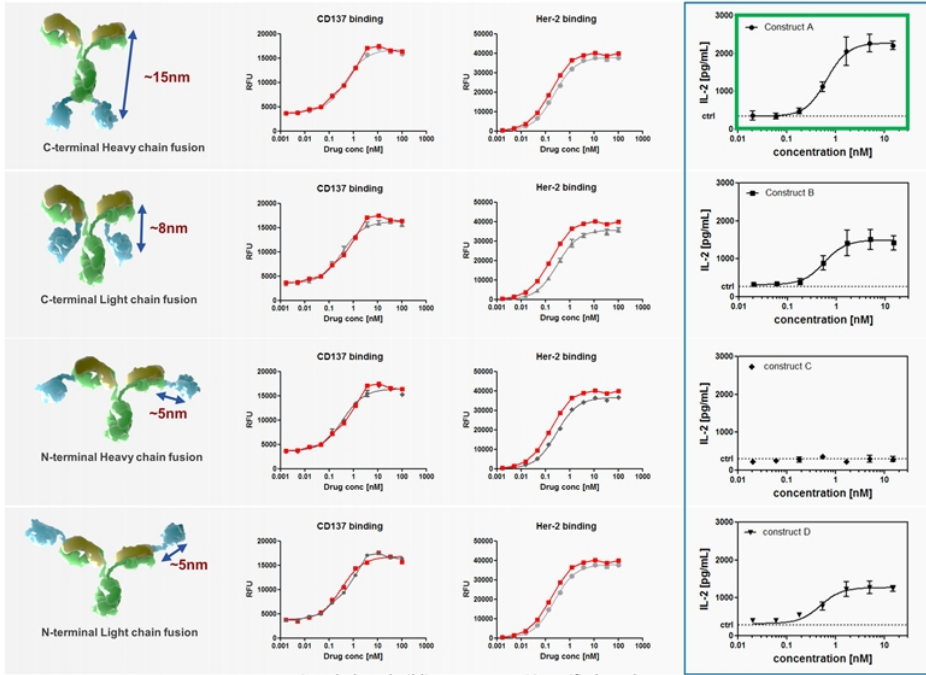
Bispecific Geometry Impacts Immune Synapse, Efficacy

A Varied Immune Synapse...

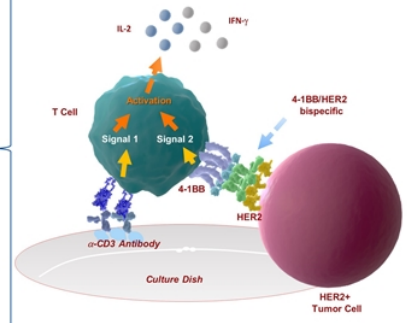
... Does Not Materially Impact Target Engagement...

...But Impacts Efficacy

The Natural Immune Synapse



Efficacy Experimental Design

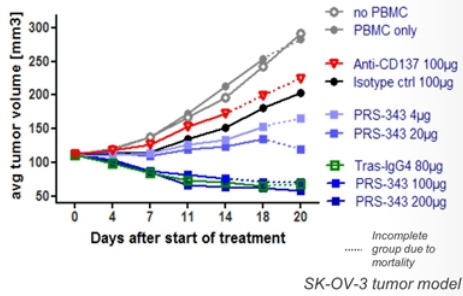


PRS-343 Shows Bifunctional Activity – Dose-dependent Tumor Growth Inhibition & CD8(+)TIL Expansion in HER2+ Ovarian Cancer Model

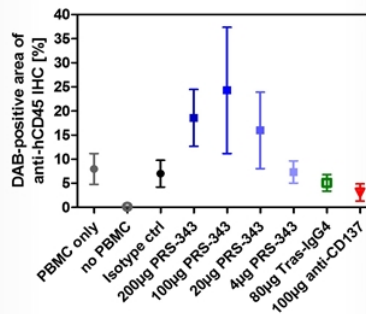


- PRS-343 shows dose-dependent tumor growth inhibition, which is dominated by anti-HER2 activity
- PRS-343 leads to strong and dose-dependent lymphocyte infiltration in tumors; monospecific anti-HER2 mAb (IgG4 backbone) lacks this activity
- Monospecific anti-4-1BB benchmark mAb shows insignificant response compared to isotype control and no significant tumor infiltration of lymphocytes

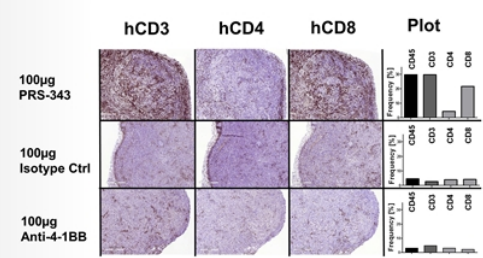
Tumor growth (Median)



TIL frequency (hCD45)



TIL phenotyping by IHC

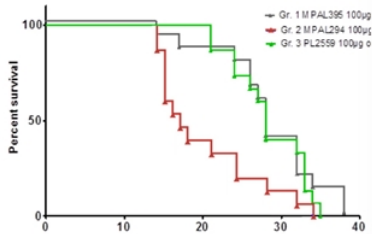


PRS-343 Avoids Unwanted Effect of Peripheral T Cell Activation, Unlike Systemic 4-1BB Agonist mAb



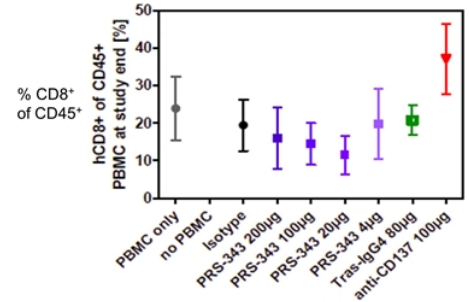
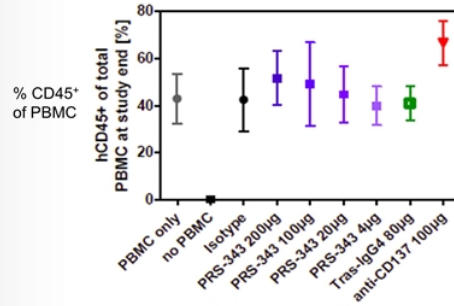
- Unlike PRS-343, anti-4-1BB benchmark mAb shows accelerated graft-versus-host-disease with significant mortality in line with literature data¹
- Toxicity observed with mAb likely corresponds to indiscriminate peripheral T cell activation

Survival



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

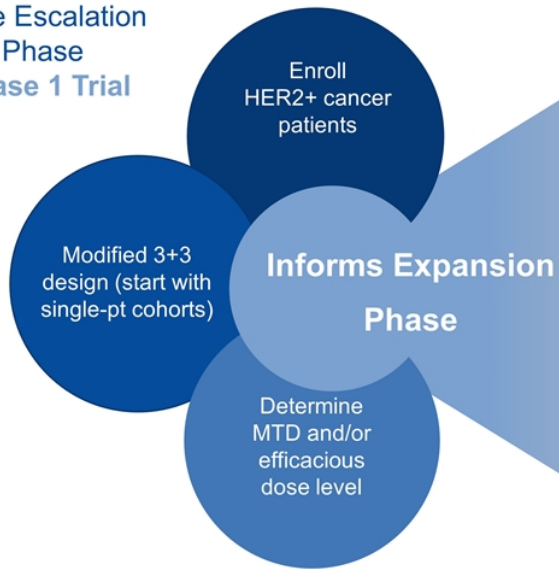
PBMC phenotyping at day 19



PRS-343 First-in-Patient Clinical Trial



Multiple-Ascending
Dose Escalation
Phase
Phase 1 Trial



Data-driven Expansion Phase

Gastric


Bladder

Other (...)

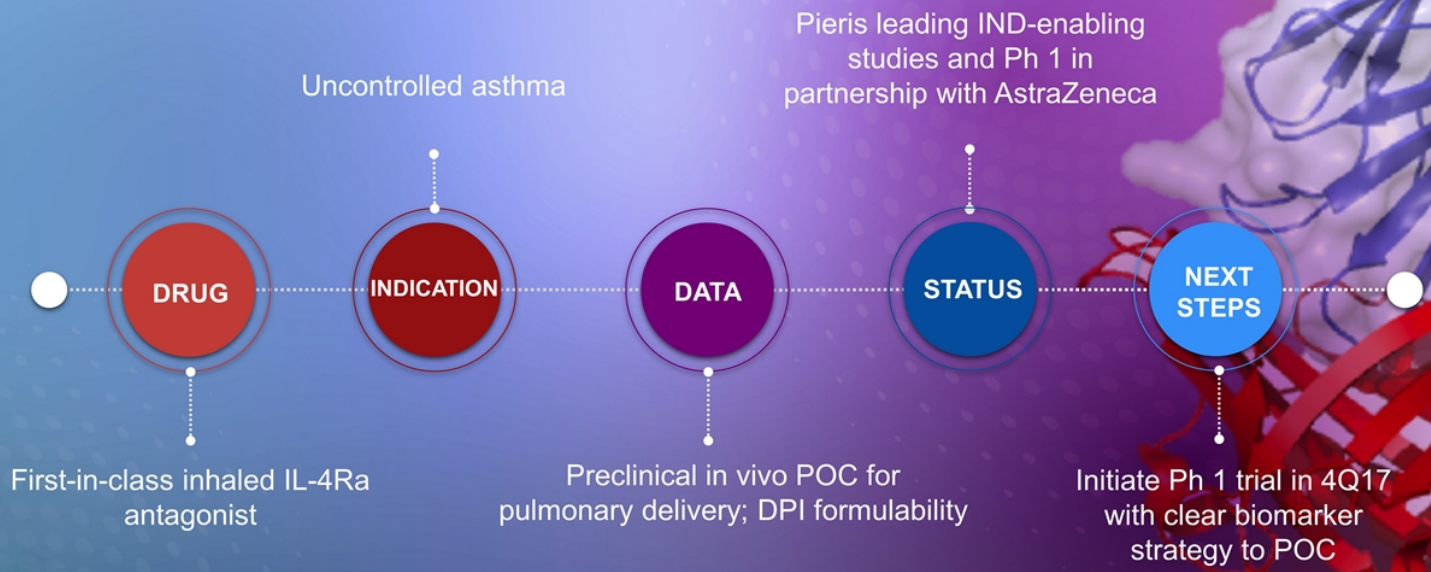
First Patient Dosed 3Q17

Beyond Wholly Owned PRS-343... Pieris has Partnered Several IO Bispecifics with Servier while Retaining US Rights

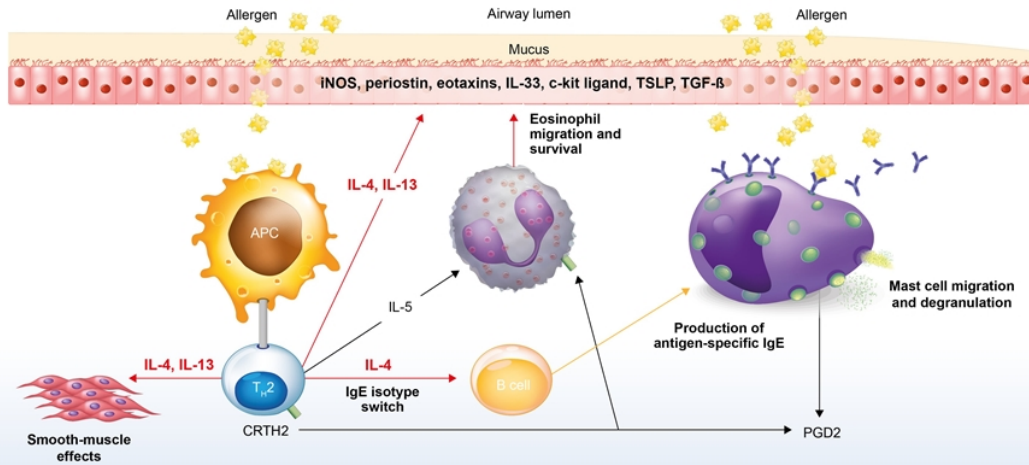


Alliance Highlights	 Partner Overview	Strategic Implications of Partnership
<p>5 committed + 3 optional novel IO programs</p> <p>Including PRS-332 (PD-1-based bispecific)</p> <p>Retained co-development and full US commercial rights on PRS-332 and up to 3 additional programs</p> <p>~\$30M upfront, up to ~\$1.8B in milestones, up to low double-digit royalties</p> <p>“True Partnership” – equal voice, shared strategic vision and resources</p>	<p>France’s second largest pharmaceutical company</p> <p>Deep commitment to R&D with \$1B research budget</p> <p>Oncology as one of its core areas, portfolio includes marketed products such as Lonsurf® and Puxuvri®</p>	<p>Validates Pieris’ unique multispecifics formats and approach</p> <p>Free cash flow extends runway and enables increased investments</p> <p>PRS-343 still 100% Pieris owned</p> <p>Pieris is free to enter into additional IO partnerships</p>

PRS-060 for Asthma



IL-4Ra is the Broadest Established Intervention Point in the Th2 Pathway



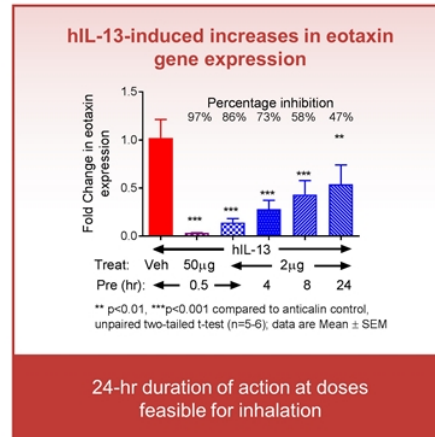
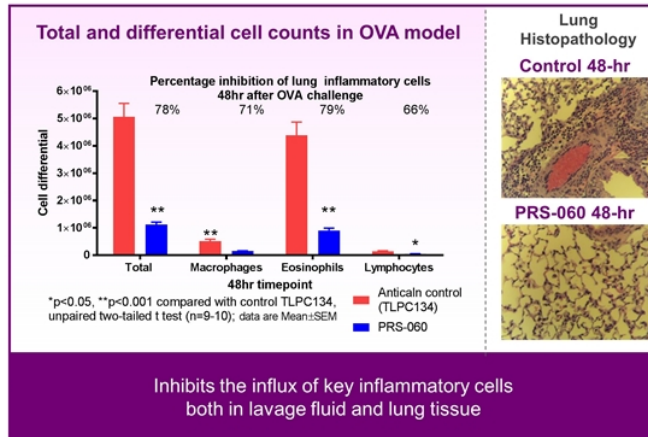
IL-4 & IL-13 are main Th2 cytokines involved in asthma, both signal via IL-4Ra
Anti-IL-4Ra mAb (dupilumab) – best-in-class among late-stage/approved biologics

- 67% reduction in exacerbations in phase III (high eosinophilic asthma)

PRS-060 is a Localized IL-4Ra Antagonist for Uncontrolled Asthma



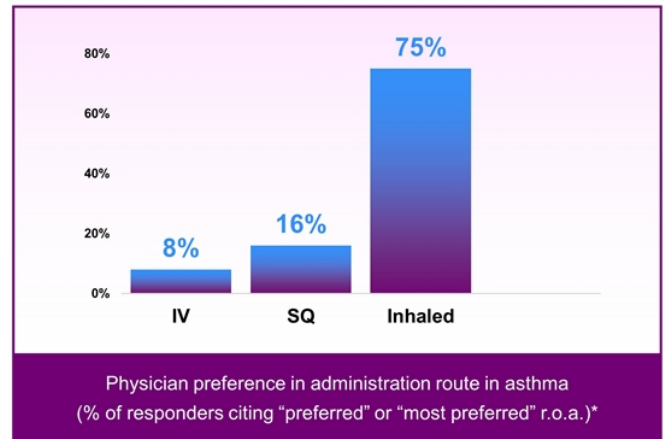
- First inhaled Anticalin protein to potently engage the highly validated asthma target, IL-4Ra
- Localized target engagement in lung tissue supports a rationale for a convenient, low-dose, low-cost alternative to systemically administered antibodies
- Preclinical in vivo POC for pulmonary delivery at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



PRS-060 has the Potential to Transform the use of Biologics in Uncontrolled Asthma



- A fraction of uncontrolled asthmatics are currently treated with biologics
- Uptake of biologics limited by several factors including; inconvenient in-office dosing, high price & biomarker restrictions
- PRS-060 as an inhaled protein is positioned to overcome these challenges
- An inhaled IL-4Ra blocker has the potential to become market leader and create new markets



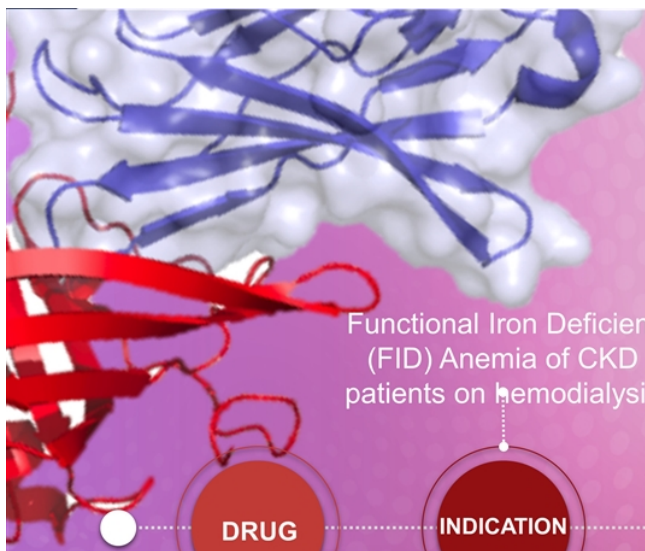
* Primary market research with prescribing physicians by Artisan Healthcare Consulting (on behalf of Pieris) in 2016

Pieris has Partnered PRS-060 and Other Respiratory Programs with AstraZeneca, while Retaining Commercial Rights



Alliance Highlights	AstraZeneca  Partner Overview	Strategic Implications of Partnership
<p>5 committed novel inhaled Anticalin protein programs</p> <p>Including lead asthma program PRS-060 (IL-4Ra)</p> <p>Retained co-development and co-commercialization (US) options on PRS-060 and up to 2 additional programs</p> <p>~\$45M upfront, up to ~\$2.1B in milestones, plus double-digit royalties</p> <p>Access to complementary formulation and device know-how for inhaled delivery</p>	<p>In 2016, AZ's respiratory products generated over \$4.7 billion in worldwide sales</p> <p>The respiratory portfolio includes 12 marketed products, e.g. franchises such as Symbicort® and Pulmicort®</p> <p>Over 40 year experience in developing medicine for respiratory diseases</p>	<p>De-risks and accelerates development of respiratory pipeline</p> <p>High-value opportunity for locally delivered biologics, including potential benefits in cost, convenience, safety and efficacy</p> <p>Ability to forward-integrate into a high-value market beyond IO</p>

PRS-080 for Anemia



Functional Iron Deficient (FID) Anemia of CKD patients on hemodialysis

DRUG

PEGylated Anticalin protein-based hepcidin antagonist

INDICATION

DATA

Well tolerated in patients, dose-dependent PD on serum iron & TSAT and decrease in circulating free hepcidin

STATUS

Option agreement for Japan+ rights with ASKA Pharmaceutical

NEXT STEPS

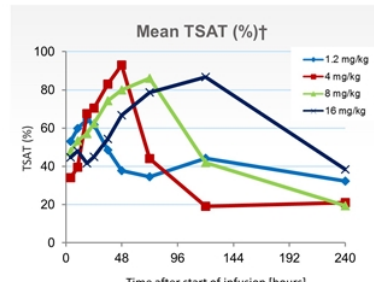
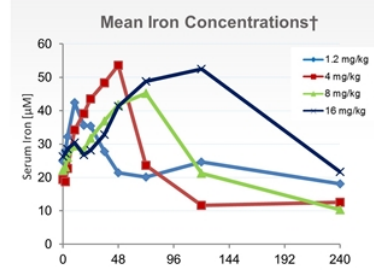
Initiate Phase IIa trial - seek partner for ROW rights after trial

PRS-080 Shows Consistent Effects in Healthy Volunteers & CKD5 Patients – Ongoing Ph IIa Study will Evaluate Hemoglobin



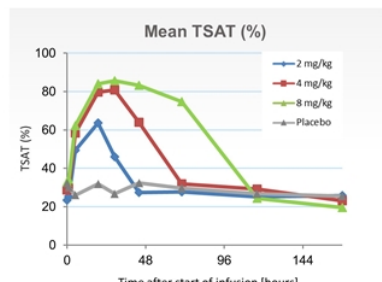
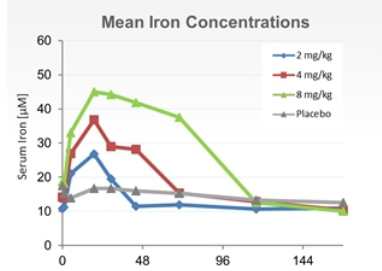
- In both healthy volunteers and CKD5 patients, PRS-080...
 - Was safe and well-tolerated
 - Showed a dose-proportional increase of PK parameters (data not shown)
 - Demonstrated dose-dependent PD effects on serum iron and TSAT
 - Led to an immediate dose-dependent decrease in circulating free Hepcidin (data not shown)
- Ph IIa trial underway in Germany and Czech Republic
 - Planning 5 QW infusions in ESRD FID anemia patients
 - Two dose cohorts: 4 mg/kg and 8 mg/kg body weight (4 drug; 2 placebo per cohort)
 - Safety, tolerability hemoglobin (Hb) and reticulocyte concentration of Hb as endpoints
 - If data are positive, Pieris will seek to out-license beyond Japan

Ph I SAD in Healthy Volunteers*



* Presented at 57th ASH Conference December 2015
 † Subjects achieving iron response > 34.5 µM (avg. 3 out of 6 subjects / dose cohort)

Ph Ib SAD in CKD5 patients**



** Presented at 54th ERA-EDTA Conference June 2017
 N=24 (6 patients per dose cohort, 6 patients on placebo)



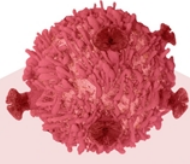
Financials & Milestones



Financial Highlights – As of September 30, 2017

Cash & Cash Equivalents	\$89.9M
Debt	\$0.0M
YTD Operating Expenditure (as of 9/30)	\$29.1
Common Shares Outstanding	44.4M

2017 Expected Milestones



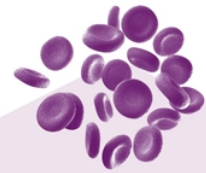
Immuno-Oncology

- Cornerstone Servier alliance incl. PRS-332 and full US rights
- PRS 343 IND accepted
- Progress several preclinical-stage, highly differentiated multispecifics



Respiratory

- Cornerstone AstraZeneca alliance incl. PRS-060 and co-marketing
- PRS-060 first subject dosing 4Q17
- Initiate program on additional target within AZ alliance



Anemia

- Regional partnership in Japan with ASKA
- Disclose Phase Ib results
- Enroll Phase IIa patients and initiate ROW partnering activities

Management and Board

Executive Management Team



Stephen Yoder, J.D.

President & CEO



Louis Matis, M.D.

SVP, Chief Development Officer



Allan Reine, M.D.

SVP, Chief Financial Officer



Claude Knopf

SVP, Chief Business Officer



Board of Directors

Stephen Yoder

President & CEO

Michael Richman

CEO, NextCure, Inc.
Amplimune, Chiron,
MedImmune, Macrogenics

Jean-Pierre Bizzari, M.D.

Director
Celgene, Servier, Rhone-Poulenc,
Sanofi-Aventis

Christopher Kiritsy

CEO
Arisaph Pharmaceuticals
Kos Pharmaceuticals

Chau Khuong (Chairman)

Partner, OrbiMed Advisors

Steven Prelack

SVP, COO, VetCor
Velquest Corp., Galeclin
Therapeutics, BioVex Group

Julian Adams, Ph.D.

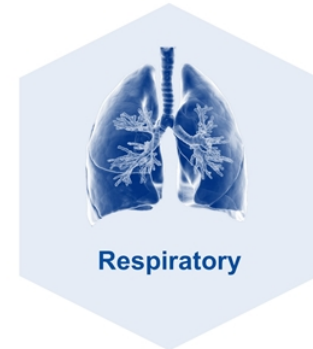
CSO & President Clal BioTech
Industries, Ltd.,
Infinity, Millennium Pharm.,
LeukoSite Inc.

James Geraghty

Director
Third Rock Ventures, Sanofi, Genzyme,
Bain and Company

Pieris Investment Opportunity

- Robust pipeline of a novel class of therapeutics
 - Anticalin® proteins
- Potentially transformative, wholly owned immuno-oncology (IO) program
 - Tumor-targeted 4-1BB bispecific
- Validating pharmaceutical partnerships in IO, respiratory and other therapeutic areas
 - \$80M in upfront payments in 2017, \$4.5B in milestone potential
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 - partnered with AstraZeneca
- Next-generation bi/multispecific IO platform
 - To exploit costimulatory and checkpoint targets
- Novel inhaled biologics platform





Pieris Pharmaceuticals, Inc.

Corporate HQ: 255 State Street, 9th Floor, Boston, MA 02109, USA

Research Hub: Freising, Germany (Munich)



info@pieris.com
www.pieris.com