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): September 9, 2020

PIERIS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Nevada	**001-37471**	**30-0784346**
(State or other jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

225 State Street, 9th Floor	**02109**
Boston, MA	
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: 857-246-8998
N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**PIRS**	**The Nasdaq Capital Market**

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 September 2020 Investor Presentation of Pieris Pharmaceuticals, Inc.

The information set forth under this "Item 7.01. Regulation FD Disclosure," including Exhibit 99.1 attached hereto, shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing. 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, Dated September 2020.

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: September 9, 2020

/s/ Tom Bures

Tom Bures

Vice President, Finance

INVESTOR PRESENTATION

SEPTEMBER 2020

-pieris-

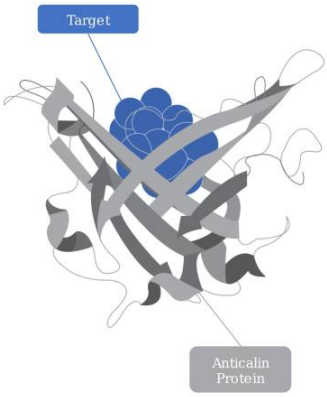
Forward Looking Statements

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 presentation that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the timing for, and outcome of, the additional in-use and compatibility study for PRS-343 as requested by the FDA; whether data from patients enrolled to date will be sufficient to inform the recommended phase 2 dose for the Company's planned proof of concept study of PRS-343 in gastric cancer; the expected timing and potential outcomes of the reporting by the Company of key clinical data from its programs, references to novel technologies and methods and our business and product development plans, including the advancement of our proprietary and codevelopment programs into and through the clinic and the expected timing for reporting data, making IND filings or achieving other milestones related to our programs, including PRS-060/AZD1402, PRS-343, PRS-344, and PRS-352 and the expected timing of the initiation of the next stage of PRS-343's development in gastric cancer. 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, including with respect to the additional in-use and compatibility study for PRS-343, and the resolution of the partial clinical hold relating to that drug candidate; competition in the industry in which we operate; delays or disruptions due to COVID-19; and market conditions. These forward-looking statements are made as of the date of this presentation, 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, 2019 and the Company's Quarterly Reports on Form 10-Q.

The Anticalin® Protein Platform

A Novel Therapeutic Class with Favorable Drug-Like Properties

- Human – Derived from lipocalins (human extracellular binding proteins)
- Small – Monomeric, monovalent, small size (~18 kDa vs 150kDa mAbs)
- Stable – Inhalable delivery
- Simple – Bi/multispecific constructs
- Proprietary – Broad IP position on platform and derived products



Powerful Drug Discovery Platform

- Highly diverse libraries
- Automated screening
- Protein engineering know-how

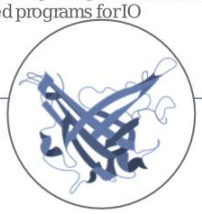
Translational Science Expertise to Deploy Platform in Meaningful Way

- Immunology expertise underpins IO and respiratory focus
- A leader in 4-1BB-related efforts
- Patient phenotyping efforts for improved stratification and novel intervention points in, e.g., asthma

Company Snapshot

Pipeline Highlights

- PRS-060: Inhaled IL4-Rα antagonist for moderate-to-severe asthma (partnered with AstraZeneca)
- PRS-343: 4-1BB/HER2 bispecific for solid tumors
- Next-generation respiratory: Includes 4 discovery-stage inhaled therapeutics programs (2 proprietary, 2 partnered with AstraZeneca)
- 4-1BB-based bispecifics: Multiple proprietary and partnered 4-1BB-based programs for IO



Anchor Partnerships

- Validation through three anchor partnerships
- $120+Mln upfront payments and milestones since January 2017
- Each partnership includes options for co-development & US-focused commercialization rights
- Value-driving opt-in for PRS-060 after phase 2a completion

Upcoming Catalysts

- Respiratory:
  - PRS-060 phase 2a trial initiation
  - Data and rationale for advancement into IND-enabling studies for wholly-owned inhaled program
- IO:
  - PRS-343 complete monotherapy and combination with atezolizumab phase 1 escalation data at ESMO
  - PRS-343 initiation of 2nd line HER2+ gastric cancer PoC study, additive to SoC

Partnerships

AstraZeneca

- PRS-060 + 4 additional novel inhaled Anticalin protein programs
- Retained co-development and co-commercialization (US) options on PRS-060 and up to 2 additional programs
- $57.5M upfront & 2017 milestone
- ~$2.1B in milestone potential, plus double-digit royalties
- AZ funds all PRS-060 development costs through post-phase 2a co-development opt-in decision
- Access to complementary formulation and device know-how for inhaled delivery

SERVIER

- Immuno-oncology partnership based on antibody-Anticalin bispecific protein fusions
- PRS-344: PD-L1/4-1BB antibody-Anticalin bispecific
  - ✓ Pieris opted in for full U.S. rights
- PRS-352: n.d. antibody-Anticalin bispecific
  - Pieris planning handover to Servier in 2020
  - Pieris to receive royalties
- ~$31M upfront payment with significant milestone potential
  - ✓ Two preclinical milestones achieved for PRS-344

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
  - ✓ Achieved $5M milestone payment for first program, a bispecific tumor-targeted costimulatory agonist
- Up to double-digit royalties on non-co-developed products

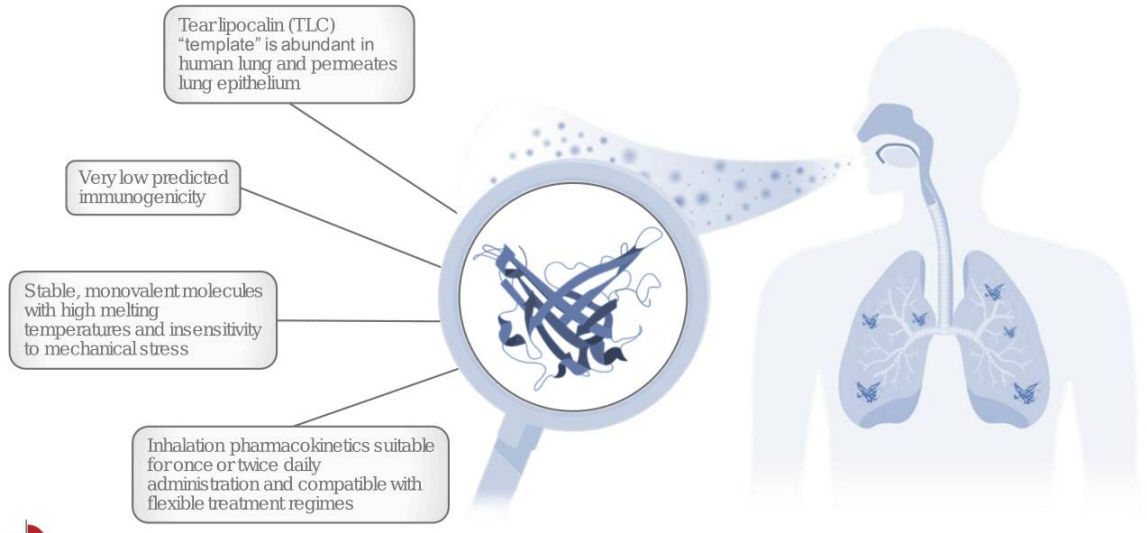
Strong Partners • Significant Cash Flow • Retained Commercial Rights

Pipeline

RESPIRATORY							
CANDIDATE	TARGETS	PARTNER	COMMERCIAL RIGHTS	DISCOVERY	PRECLINICAL	PHASE I	PHASE II
PRS-060/AZD1402	IL4-Rα	AstraZeneca	Pieris Worldwide Profit-Share Option				
AstraZeneca Programs*	n.d.	AstraZeneca	Pieris Worldwide Profit-Share Option*				
Proprietary Programs	n.d.	n/a	Pieris Worldwide				
*4 additional respiratory programs (3 active, 1 forthcoming) in collaboration with AstraZeneca, 2 of which carry co-development and co-commercialization options for Pieris							

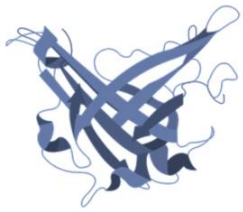
IMMUNO-ONCOLOGY							
CANDIDATE	TARGETS	PARTNER	COMMERCIAL RIGHTS	DISCOVERY	PRECLINICAL	PHASE I	PHASE II
PRS-343	HER2/4-1BB	n/a	Pieris Worldwide				
	+Anti-PD-L1	n/a					
PRS-344	PD-L1/4-1BB	SERVIER	Pieris U.S. Rights				
PRS-352	n.d.	SERVIER	SERVIER				
Proprietary IO Programs	n.d.	n/a	Pieris Worldwide				
Seattle Genetics Program‡	co-stimagonist	SeattleGenetics	Pieris U.S. Option‡				
‡3 bispecific programs (1 active, 2 forthcoming) in collaboration with Seattle Genetics, with Pieris retaining US rights for 1 program							

Anticalin Technology Advantages: Differentiated Respiratory Platform



PRS-060: IL-4Rα Antagonist

Candidate	PRS-060
Function/MoA	Inhibiting IL4-Rα (disrupts IL-4 & IL-13 signaling)
Indications	Moderate-to-severe asthma
Development	Phase 1 multiple-ascending dose trial ongoing; phase 2a to begin in 2H2020
Commercial Rights	Co-development and U.S. co-commercialization rights, including gross margin share



PRS-060

PRS-060 Phase I Multiple Ascending Dose Trial

Strategic Objectives	Ascertain PK/PD with a reliable biomarker to confirm local target engagement and inform Phase II dosage regimen
Trial Design Highlights	Dosing patients with mild asthma with elevated FeNO levels (≥35 ppb), to receive inhaled PRS-060 or pbo b.i.d.* over a 10-day period

*q.d. on Day 10

Initiated in July 2018

Evaluating safety, tolerability, PK, PD and will also evaluate FeNO reduction vs. placebo

Measuring safety, tolerability and FeNO changes days 1-10,17, and 40

Pieris is sponsoring the trial, AstraZeneca is reimbursing Pieris for all associated costs

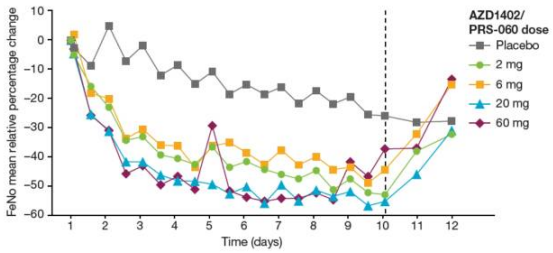
Phase 1b Interim Results: Favorable Safety Profile

- All doses of AZD1402/PRS-060 tested in the study were well tolerated
- No treatment-related serious AEs were observed

System organ class AE Preferred Terms[b]	Placebo (N = 12) n (%) m	AZD1402/PRS-060[c] (N = 30) n (%) m	Overall (N = 42) n (%) m
Gastrointestinal disorders	4 (33.3) 4	13 (43.4) 14	17 (40.5) 18
Dry mouth	1 (8.3) 1	2 (6.7) 2	3 (7.1) 3
Nausea	1 (8.3) 1	3 (10.0) 3	4 (9.5) 4
Infections and infestations	1 (8.3) 1	7 (23.3) 8	8 (19.0) 9
Upper respiratory tract infection	1 (8.3) 1	3 (10.0) 4	4 (9.5) 5
Nervous system disorders	5 (41.7) 9	13 (43.4) 18	18 (42.9) 27
Headache	3 (25.0) 6	5 (16.7) 7	8 (19.0) 13
Presyncope	0	4 (13.3) 6	4 (9.5) 6
Respiratory, thoracic and mediastinal disorders	6 (50.0) 6	14 (46.7) 15	20 (47.6) 21
Cough	1 (8.3) 1	4 (13.3) 4	5 (11.9) 5
Rhinorrhoea	2 (16.7) 2	1 (3.3) 1	3 (7.1) 3
Wheezing	2 (16.7) 2	4 (13.3) 5	6 (14.3) 7

Phase 1b Interim Results: Robust FeNO Reduction

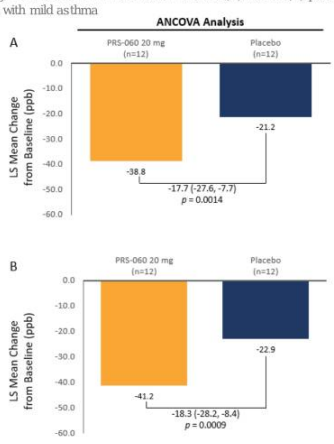
PRS-060 Relative FeNO Reduction (Emax Analysis)



PRS-060, mg (delivered)	n	Reduction vs. placebo, % (95% CI)	p-value
2	6	24.0 (1.8–41)	0.04
6	6	24.3 (2.7–41)	0.03
20	12	36.4 (22–48)	<0.0001
60	6	30.5 (10–46)	0.005
Placebo	12		

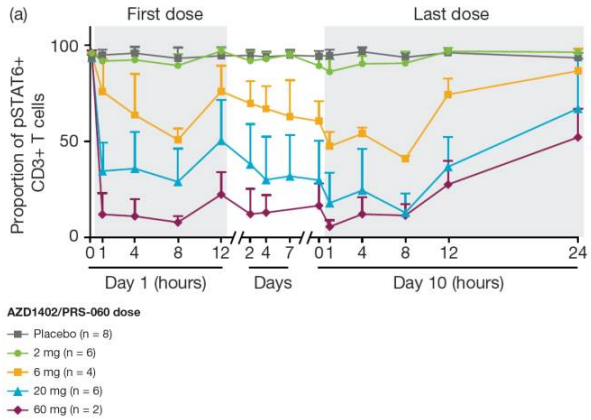
PRS-060 Relative FeNO Reduction (ANCOVA Analysis)

Mean change from baseline in FeNO levels at 0.5h (A) and 2h (B) post-dose on Day 10 in participants with mild asthma



Phase 1b Interim Results: Pharmacological Versatility

pSTAT6 levels over time following inhalation of PRS-060



No systemic target engagement and minimal systemic exposure was observed at the 2mg dose, suggesting that local target engagement by the drug is sufficient to reduce airway inflammation

Pharmacological versatility, given low-dose FeNO reduction with no observed systemic activity (pSTAT6) versus high-dose FeNO reduction with systemic activity

4-1BB Agonism Offers Promise of Material Clinical Benefit

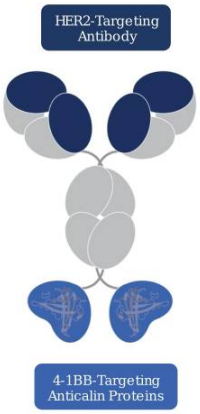
Unique Attributes of 4-1BB Agonism on Tumor-specific T Cells

- ✓ Increases T-cell proliferation to bolster immune repertoire
- ✓ Enhances cytotoxicity for tumor killing
- ✓ Improves metabolic fitness for increased survival of T cells
- ✓ Drives T-cell memory phenotype for increased durability

Pieris' 4-1BB bispecifics recognize that 4-1BB agonists have proven clinical potency, yet must be kept out of the liver to ensure suitable therapeutic index

PRS-343: Proprietary Lead IO Asset

Candidate	PRS-343
Function/MoA	Tumor-targeted 4-1BB agonism and HER2 antagonism
Indications	HER2+ solid tumors
Development	Initiating phase 2 in combination with ramucirumab and paclitaxel in second line gastric
Commercial Rights	Fully proprietary

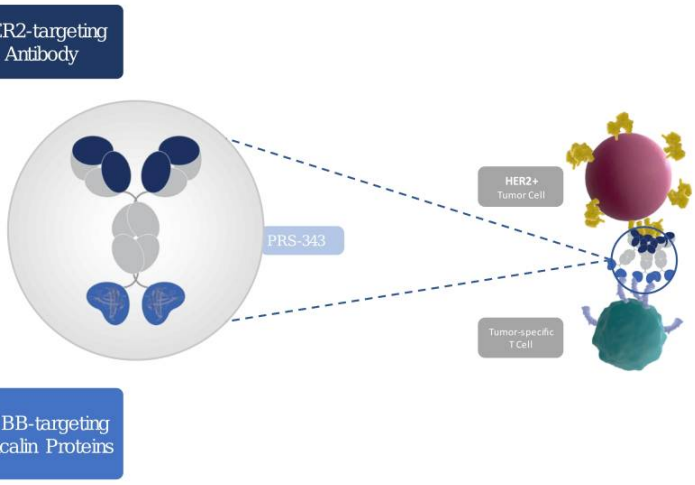


Phase 1 escalation data at ESMO

PRS-343 Localizes 4-1BB Agonism Within HER2+ Tumors

HER2-targeting moiety of the drug localizes to the tumor microenvironment and facilitates 4-1BB cross-linking

4-1BB cross-linking ameliorates T-cell exhaustion and is critical for T-cell expansion



Monotherapy and Combination Studies: Enabled Meaningful Clinical Characterization of PRS-343

Snapshot

- Patients with HER2+ solid tumors
- Monotherapy and combination with atezolizumab
- Interim monotherapy data presented at SITC '19
- Initial combtherapy data presented at R&D Day (Nov '19)

Primary Objectives

- Characterize safety profile
- Identify MTD or RP2D

Secondary Objectives

- Characterize PK profile
- Investigate dosing schedule
- Assess potential immunogenicity and PD effects
- Investigate efficacy

Mono Dose Cohort*	Dose (mg/kg)	Combo Dose Cohort**
1	0.0005 (Q3W)	-
2	0.0015	-
3	0.005	-
4	0.015	-
5	0.05	1
6	0.15	2
7	0.5	3
8	1	4
9	2.5	5
10	5	6
11	8	7
11b	8 (Q2W)	-

9-11b: activate dose cohorts in mono study

*Additional dose cohorts enrolling in monotherapy study

**1200mg flat dose of atezolizumab

Single-agent Clinical Benefit and Enhanced Durability in Checkpoint Combination Therapy

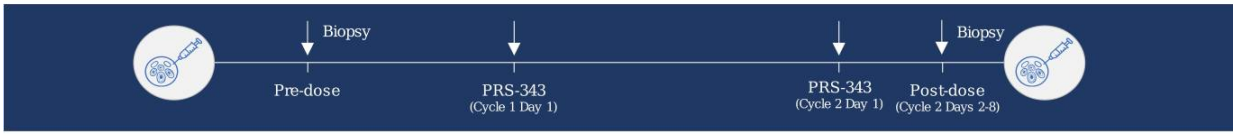
Monotherapy Clinical Benefit

Best Response \ Cohort	11B 8mg/kg, Q2W	11A 8mg/kg, Q3W	10 5mg/kg, Q3W	9 2.5mg/kg, Q3W	Total
Enrolled Patients	8	7	9	6	30
Response Evaluable Patients	7	4	5	5	21
PR	3	-	-	-	3
SD	3	3	2	2	10
ORR	43%	0%	0%	0%	14%
DCR	86%	75%	40%	40%	62%

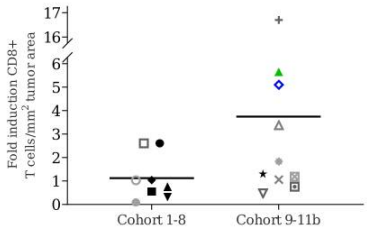
- Additional clinical benefit, including complete response, observed in cohorts beyond 11B (currently enrolling)
- Clinical benefit also observed in combination study, including patients with deep partial responses and durable benefit

Data cut-off: 11-May-20 for subjects up to Cohort 11b; additional cohorts enrolling

Paired Biopsy Analysis Supports 4-1BB-related MoA



Tumor Biopsy



Pronounced increase in CD8⁺ T cell numbers is observed post-treatment in patients receiving doses ≥ 2.5 mg/kg

PD correlates with PK

Patients benefiting from treatment (SD >120 days (blue) and PR (green) had more pronounced increase in CD8⁺ T cell number in tumor vs. stroma

Clinical benefit correlates with PD

Data cut-off: 23-Oct-19 for subjects up to Cohort 11b; additional cohorts enrolling

Phase 2 PoC Study in 2nd Line Gastric Cancer

Phase 2 Initiation in 2H20

PRS-343 in combination with ramucirumab and paclitaxel for 2nd-line HER2+ gastric cancer

Clinical trial collaboration with Eli Lilly; Lilly to supply ramucirumab

Single-arm, up to 60 patients

Primary endpoints: ORR and DCR

HER2+ subgroup from RAINBOW trial as comparator enriched w/ RWD

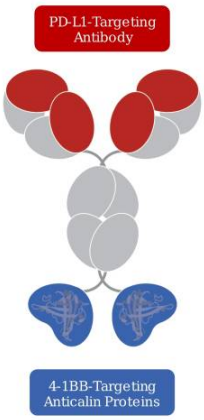
GC 2L PIVOTAL TRIAL

PRS-343 PoC Trial Considers Several Value-driving Elements

Factor	Impact
Biology: Synergistic MoA in IO-amenable Patients	• Vasculature normalization from ramucirumab for improved environment for T-cell infiltration • Tumor debulking and antigen release from paclitaxel for improved disease control and enhanced immune priming
Regulatory: Additive to Standard of Care	• Straightforward path from PoC to pivotal • Reduced patient enrollment hurdles compared to monotherapy study
Commercial: Meaningful Beachhead Indication	• Second line gastric cancer market size in US, EU5, and JP is up to $1.7B • Upside in several other tumors

PRS-344: Meaningfully Building on Localized MoA of PRS-343

Candidate	PRS-344
Function/MoA	Localized 4-1BB agonism with PD-L1 antagonism
Indications	N.D.
Development	2021 IND expected (in co-dev with Servier)
Commercial Rights	Opt-in for co-development with full U.S. commercial rights; royalty on ex-U.S. sales



Financial Overview (As of 6/30/20)

$77.2 M*	$0.0	52.4 M
Cash & Cash Equivalents	Debt	CSO

$125+M non-dilutive capital from anchor partnerships

*Excludes $5M Seattle Genetics milestone achieved in Q3

Recent Milestones and Expected Catalysts

2019 Milestones

- Respiratory: Inhaled IL4-Rα antagonist (PRS-060)
  - ✓ SAD phase 1 data at ATS 2019
  - ✓ MAD phase 1 data, including FeNO reduction vs. placebo, at ERS 2019
- IO: 4-1BB/HER2 bispecific (PRS-343)
  - ✓ Monotherapy phase 1 data at SITC 2019
  - ✓ Initial combination phase 1 data at R&D Day

Upcoming Catalysts

Respiratory:

- ❑ PRS-060 phase 2a trial initiation
- ❑ Data and rationale for advancement into IND-enabling studies for wholly-owned inhaled program

- IO:
  - ❑ PRS-343 complete monotherapy and combination with atezolizumab phase 1 escalation data at ESMO
  - ❑ PRS-343 initiation of focused development in gastric cancer

Appendix

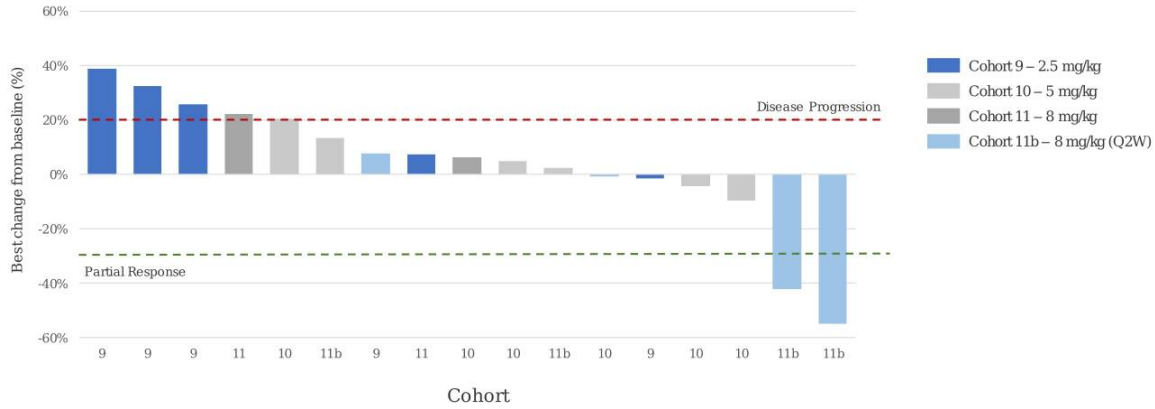
PRS-343 Monotherapy Treatment-Related Adverse Events
Cohorts 9-11b

TRAE	Number (%)	Grade 3 (%)
Infusion related reactions	6 (9%)	2 (3%)
Nausea and vomiting	8 (12%)	0
Chills	5 (8%)	0
Arthralgias	4 (6%)	1 (2%)
Flushing	4 (6%)	3 (5%)
Decreased appetite	3 (5%)	0
Hypotension	3 (5%)	1 (2%)
Increased Lipase	3 (5%)	1 (2%)
Non cardiac chest pain	3 (5%)	1 (2%)

No Grade 4 or 5 Treatment-Related AEs

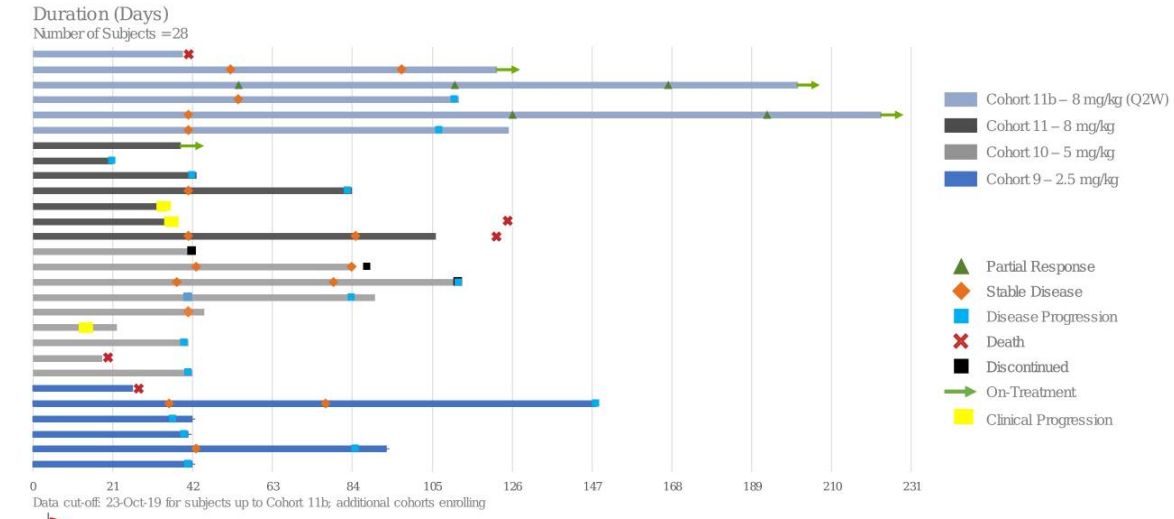
Data cut-off: 23-Oct-19 for subjects up to Cohort 11b; additional cohorts enrolling

Best Response in Target Lesions Cohorts 9-11b



Data cut-off: 23-Oct-19 for subjects up to Cohort 11b; additional cohorts enrolling

Average Time on Treatment with PRS-343
Significantly Increases in Cohort 11b (8 mg/kg Q2W)



Case Study #1: Gastric Cancer Patient with Confirmed Partial Response

Patient Profile, Treatment History and Treatment Outcome

Patient Profile

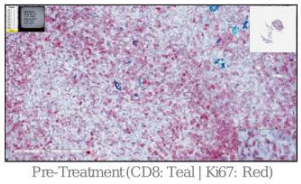
- Cohort 11b | 8 mg/kg every two weeks
- 80-year old woman; initial diagnosis in June 2017
- Stage IV gastric adenocarcinoma
- Metastases to liver, lymph node and adrenal glands
- HER2 IHC 3+; PD-L1 positive (CPS=3)
- NGS: ERBB2 amplification, TP53 mutation, alteration of CDK12 and SF3B1

Oncology Treatment History	Duration	Best Response
Trastuzumab, Pembrolizumab + Capecitabine/oxaliplatin	July 2017 – June 2018	Stable Disease
Nivolumab with IDO1 inhibitor (investigational drug)	Aug 2018 – Jan 2019	Stable Disease

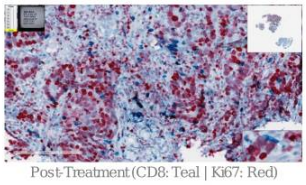
Lesions	Lesion Site	Lesion Size (mm)				
		Baseline	C2 Post-treatment	C3 Post-treatment	C4 Post-treatment	C6 Post-treatment
Target 1	Liver	14	12	10	9	9
Target 2	Liver	20	16	10	8	8
Target 3	Pancreas	19	16	14	14	14
% Change from Baseline			-17%	-36%	-42%	-42%
Non-target 1	Lung	Present	Present	Present	Present	Present
Non-target 2	Stomach	Present	Present	Present	Present	Absent
Non-target 3	Stomach	Present	Present	Present	Present	Absent

PR, partial response; HER2, human epidermal growth factor receptor 2; PD-L1, Programmed Death Ligand 1; CPS, combined positive score; NGS, next-generation sequencing
Data cut-off: 23-Oct-19

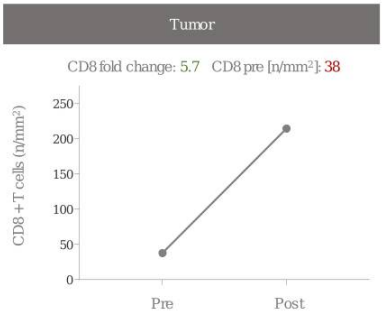
CD8+T Cell Numbers Increase Post-Treatment in Responding Gastric Cancer Patient

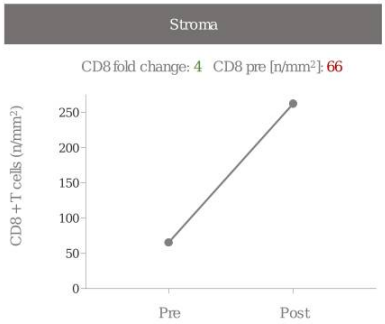


Pre-Treatment (CD8: Teal | Ki67: Red)



Post-Treatment (CD8: Teal | Ki67: Red)





CD8+T cell numbers increase post-treatment. This is more pronounced in tumor tissue and consistent with the predicted MoA of PRS-343.

Case Study #2: Fallopian Tube Cancer Patient with Partial Response
Patient Profile, Treatment History and Treatment Outcome

Cohort 11b
8 mg/kg PRS-343 (Q2W)

- 59 year old female, initial diagnosis on September 19, 2017
- Fallopian tube carcinoma
- ERBB2 2+; MSI stable; TMB 4 Muts/Mb; PDL-1 status not known
- CD8 fold change in tumor: Not known as multiple post-treatment core biopsies did not contain cancer cells

Oncology Treatment History	Duration	Best Response
Taxol/Carboplatin	October 2017 - November 2017	Stable Disease
Taxotere/Carboplatin	December 2017 - May 2018	Stable Disease
Doxil	October 2018 – February 2019	Progressive Disease

Lesions	Lesion Site	Lesion Size (mm)			
		Baseline	C2 Post-treatment	C4 Post-treatment	C6 Post-treatment
Target 1	Liver – Dome of left lobe	18	10	12	8
% Change from Baseline			-44%	-33%	-55%

Data cut-off: 23-Oct-19

Case Study #3: Urothelial Cell Carcinoma Patient with Stable Disease
Patient Profile, Treatment History and Treatment Outcome

Cohort 9
2.5 mg/kg PRS-343 (Q3W)

- 92 year old male, initial diagnosis in August 2015
- Urothelial cell carcinoma Stage 3
- HER2 FISH positive; MSS; TMB high 16 mut/Mbp
- CD8 fold change in tumor: 5.1

Oncology Treatment History	Duration	Best Response
Cisplatin + gemcitabine	September 2015 – September 2015	Toxicity
Carboplatin + gemcitabine	October 2015 – December 2015	Progressive Disease
Atezolizumab	December 2016 – June 2017	Stable Disease
MEDI-0562 + durvalumab	August 2017 – May 2018	Stable Disease

Lesions	Lesion Site	Lesion Size (mm)			
		Baseline	C2 Post-treatment	C4 Post-treatment	C6 Post-treatment
Target 1	Left para-aortic lymph node	27	24	24	25
Target 2	Right para-aortic lymph node	17	18	18	18
Target 3	Paraesophageal lymph node	18	19	19	20
% Change from Baseline			-1.6%	-1.6%	1.6%

–pieris–

Data cut-off: 23-Oct-19

Baseline Characteristics (Combination Trial)
All Subjects (n = 35)

Characteristic	n (%)
Age, Median (range)	59 (26-87)
Gender	
Female	19 (54%)
Male	16 (46%)
ECOG PS	
0	10 (29%)
1	25 (71%)
Prior Therapy Lines	
1	6 (17%)
2	5 (14%)
3	3 (9%)
4	6 (17%)
5+	15 (43%)

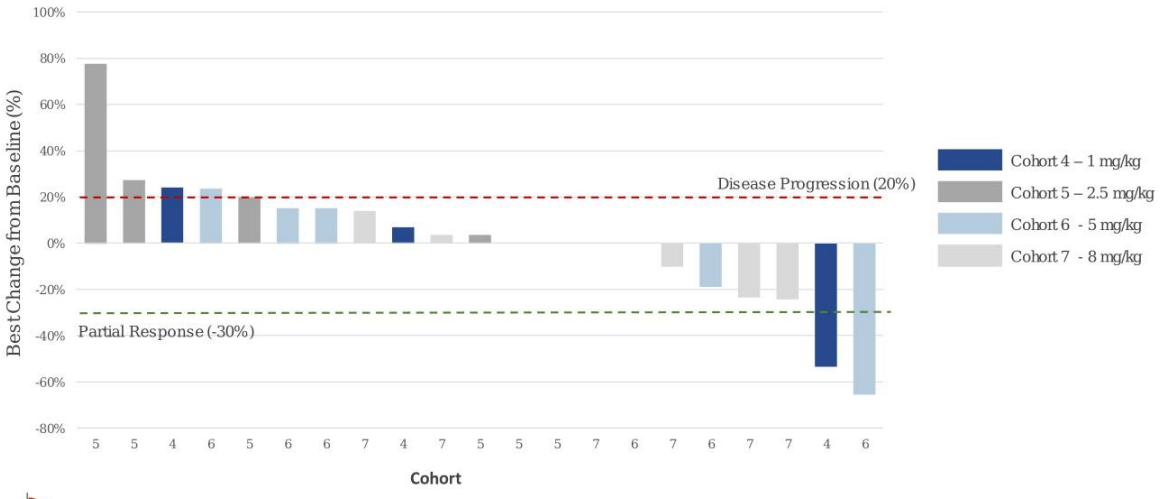
Primary Cancer Type	n (%)
Breast	12 (34%)
Gastroesophageal	6 (17%)
Colorectal	5 (14%)
Gallbladder/ Biliary	4 (11%)
Lung	3 (9%)
Gynecological	2 (6%)
Bladder	1 (3%)
Carcinoma of Unknown Primary	1 (3%)
Pancreatic	1 (3%)

Treatment-Related Adverse Events (Combination Trial)
Cohorts 4-7

TRAE	n = 85	% Grade 3
Infusion related reaction	17 (20%)	
Nausea and Vomiting	7 (9%)	
Diarrhea	6 (7%)	1 (1%)
Fatigue	6 (7%)	
Rash	4 (5%)	
Anemia	3 (4%)	1 (1%)
Chills	2 (2%)	
Decreased appetite	2 (2%)	
Dizziness	2 (2%)	
Dysgeusia	2 (2%)	
Malaise	2 (2%)	
Myalgia	2 (2%)	
Neutrophil count decreased	2 (2%)	1 (1%)
Platelet count decreased	2 (2%)	1 (1%)
Pyrexia	2 (2%)	
White blood cell count decreased	2 (2%)	1 (1%)

No Grade 4 or 5 PRS-343 Treatment-Related AEs

Best Response in Target Lesions (Combination Trial)
Combination Study Cohorts 4-7 (n =21)



Data presented at R&D Day in New York on November 19, 2019; data cut-off: 19-Nov-19

Case Study #1: Breast Cancer Patient with Partial Response

Patient Profile and Treatment History

Cohort 4
1 mg/kg PRS-343 (Q3W) +
atezolizumab 1200 mg

- 64 year old female, initial diagnosis October 16, 2000
- Stage 4 breast carcinoma
- ER/PR-; HER2 3+ (IHC biopsy collected in Jan 2010), FISH+
- PD-L1, MSI and TMB status not known
- CD8 fold change in tumor: 8.5

Oncology Treatment History	Duration	Best Response
AC X4, tamoxifen (X1 yr), arimidex (X5 yrs)	2000-2006	Stable Disease
Carboplatin/Taxotere then Taxotere/Herceptin then Xeloda/ Lapatinib then Herceptin/ Navelbine	May 2006 – September 2009	Complete Response
Vinorelbine and Herceptin	February 2010 – May 2011	Unknown
Trastuzumab/Lapatinib Ditosylate (Tykerb)	May 2011 – May 2012	Progressive Disease
Trastuzumab/Gemzar	May 2012 – Feb 2013	Unknown
ADT (TDM1, Kadcyla)	May 2013 – Jun 2015	Stable Disease
Trastuzumab/Pertuzumab (Perjeta)	Sep 2017 – Dec 2017	Stable Disease
ADT (TDM1, Kadcyla)	Dec 2017 – Jul 2018	Stable Disease
Trastuzumab/Capecitabine (Xeloda)	Aug 2018 – Jan 2019	Stable Disease

Data presented at R&D Day in New York on November 19, 2019; data cut-off: 19-Nov-19

Case Study #1: Breast Cancer Patient with Partial Response

Treatment Outcome

Lesions	Lesion Site	Lesion Size (mm)					
		Baseline	C2 Post-treatment	C4 Post-treatment	C6 Post-treatment	C8 Post-treatment	C12 Post-treatment
Target 1	Sub-cranial lymph node	15	8	5	8	8	6
Target 2	Right neck lymph node	15	9	7	7	6	5
% Change from Baseline			-43%	-60%	-50%	-53%	-63%

Data presented at R&D Day in New York on November 19, 2019; data cut-off: 19-Nov-19

Case Study #2: Breast Cancer Patient with Stable Disease
Patient Profile, Treatment History and Treatment Outcome

Cohort 6
5 mg/kg PRS-343 (Q3W) + atezolizumab 1200 mg

- 53 year old male, initial diagnosis July 28, 2011
- Stage 4 invasive ductal breast carcinoma (metastatic to mediastinal lymph nodes, bones and lung)
- ER+/PR-, HER2- (IHC), FISH+ (biopsy collected in March 2019)
- PD-L1, MSI and TMB status not known
- CD8 fold change in tumor: 8

Oncology Treatment History	Duration	Best Response
Trastuzumab + Carboplatin + Docetaxel + Tamoxifen	September 2011 – July 2013	not known
Trastuzumab + Perjeta + Navelbine	August 2013 – January 2016	not known
TDM-1 + Fulvestrant	November 2017 – March 2018	not known
Lapatinib + Capecitabine	March 2018 – March 2019	not known
Anastrozole + Ibrance	April 2019 – May 2019	not known

Lesions	Lesion Site	Lesion Size (mm)			
		Baseline	C2 Post-treatment	C4 Post-treatment	C6 Post-treatment
Target 1	Lymph node	16	18	15	13
% Change from Baseline			+13%	-6%	-19%

Data presented at R&D Day in New York on November 19, 2019; data cut-off: 19-Nov-19

Case Study #3: NSCLC Patient with Partial Response
Patient Profile, Treatment History and Treatment Outcome

Cohort 6
5 mg/kg PRS-343 (Q3W) +
atezolizumab 1200 mg

- 65 year old male, initial diagnosis Feb 6, 2018
- Stage 4 NSCLC squamous
- Foundation One HER2 amplification
- CD8 fold change in tumor: Results to be presented

Oncology Treatment History	Duration	Best Response
Carboplatin/paclitaxel + RT	March 2018 – April 2018	Partial Response
Atezolizumab	August 2018 – May 2019	Stable Disease (treatment ended upon disease progression)

Lesions	Lesion Site	Lesion Size (mm)		
		Baseline	C2 Post-treatment	C4 Post-treatment
Target 1	Lung	42	26	20
Target 2	Lung	16	0	0
% Change from Baseline			-55%	-66%
Non-target 1	Lung	Present	Absent	Absent
Non-target 2	Lung	Present	Present	Absent

Data presented at R&D Day in New York on November 19, 2019; data cut-off: 19-Nov-19

Pieris Pharmaceuticals

255 State Street
Boston, MA 02109
USA

Zeppelinstraße 3
85399 Hallbergmoos
Germany

IR: kelman@pieris.com
BD: niemeier@pieris.com
www.pieris.com

NASDAQ: PIRS