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 9, 2019

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

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

255 State Street, 9th Floor
Boston, MA **02109**

(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 2.02 Results of Operations and Financial Condition.

On November 11, 2019, Pieris Pharmaceuticals, Inc. (the "Company") issued a press release announcing certain financial results of the Company for the fiscal quarter ended September 30, 2019. A copy of the press release issued by the Company is furnished as Exhibit 99.1 to this report.

The information set forth under this "Item 2.02. Results of Operations and Financial Condition," including Exhibit 99.1 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 8.01: Other Events.

On November 9, 2019, Phase 1 dose escalation data for the Company's 4-1BB/HER2 bispecific, PRS-343, were presented at the Society for Immunotherapy of Cancer 2019 Annual Meeting in a presentation entitled *Phase 1 Dose Escalation Study of PRS-343, a HER2/4-1BB Bispecific Molecule, in Patients with HER2+ Malignancies*. The presentation is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

99.1 Press release announcing financial results for the quarter ended September 30, 2019, dated November 11, 2019.

99.2 PRS-343 Phase 1 dose escalation presentation, dated November 9, 2019.

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 12, 2019

/s/ Tom Bures

Tom Bures

Vice President, Finance

November 11, 2019

Pieris Pharmaceuticals Reports Third Quarter 2019 Financial Results and Provides Corporate Update

Company to Host an Investor Conference Call On Monday, November 11, 2019 At 8:00 AM EST

BOSTON, MA / ACCESSWIRE / November 11, 2019 /*Pieris Pharmaceuticals, Inc.* (NASDAQ:PIRS), a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform for respiratory diseases, cancer, and other indications, today reported its financial results for the third quarter of 2019 ended September 30, 2019, and provided an update on the Company's recent and future developments.

"The recent presentations of clinical data for our two lead programs, PRS-060 and PRS-343, represent critical inflection points in the history of Pieris," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "In October, we presented positive data from our ongoing phase 1b study of PRS-060, an inhaled IL-4 receptor alpha antagonist for moderate-to-severe asthma, and we continue to be excited about the program as we plan with AstraZeneca to move into phase 2 next year. Over the weekend, we presented promising data from our phase 1 dose-escalation study of PRS-343, a 4-1BB/HER2 bispecific for HER2-positive solid tumors, demonstrating single-agent activity that we believe is linked to 4-1BB engagement, and we look forward to initiating an indication-specific expansion study for this drug candidate next year. Our recently-announced financing, supported not only by key existing shareholders but also by fundamental focused new investors, will enable more near-term data-driven clinical development investment and is intended to provide a funding mechanism to facilitate Pieris' ability to opt-into co-development of PRS-060 with AstraZeneca if phase 2a data are positive."

- **PRS-060:** Pieris presented data from the phase 1b placebo-controlled multiple ascending dose study of PRS-060/AZD1402, an inhaled IL-4 receptor alpha antagonist for moderate-to-severe asthma, at the 2019 European Respiratory Society International Congress on October 1st. In that analysis, PRS-060/AZD1402 was found to be safe and well tolerated at all doses, led to a statistically significant reduction in fractional exhaled nitric oxide (FeNO) relative to placebo, and showed dose-dependent systemic target engagement in patients with mild asthma and elevated levels of FeNO (≥ 35 ppb). Following the presentation of these encouraging data, AstraZeneca and Pieris have been preparing to move into a phase 2a study in moderate-to-severe asthmatics next year. Upon completion of that study, which will be sponsored and funded by AstraZeneca, Pieris will have options to co-develop and co-commercialize the drug candidate in the United States.

- **PRS-343:** Pieris presented data from its phase 1 dose-escalation monotherapy study of PRS-343, a 4-1BB/HER2 bispecific for HER2-positive solid tumors, at the Society for Immunotherapy of Cancer 34th Annual Meeting on November 9th. PRS-343 was safe and well tolerated at all doses and schedules tested, demonstrated anti-tumor activity in a heavily pre-treated patient population across multiple tumor types, and showed a potent increase in CD8+ T cell numbers in the tumor microenvironment of responders, indicative of 4-1BB agonism on T cells. Pieris continues to enroll patients in that study at higher dose cohorts and plans to initiate an indication-specific expansion trial next year. The Company also continues to enroll the dose-escalation phase 1 study of PRS-343 in combination with atezolizumab, with the objective of interrogating the synergy between 4-1BB agonism and PD(L)-1 blockade, and will report emerging data from that study at the Pieris R&D day on November 19th.

- **Immuno-oncology Pipeline:** Pieris plans to file an IND application for PRS-344, a 4-1BB/PD-L1 bispecific that the Company is developing as part of its collaboration with Servier, in the first half of next year. Pieris holds exclusive commercialization rights for PRS-344 in the United States and will receive royalties on ex-U.S. sales for this program.

- **R&D Day:** Pieris will host an R&D day in New York on Tuesday, November 19th from 12:00-3:30 PM EST. The event will be accessible via a live webcast through this link beginning at 12:30 PM EST.
- **Private Placement:** The Company completed a $32 million private placement led by BVF Partners L.P., with significant additional participation from EcoR1 Capital, Aquilo Capital Management, Surveyor Capital (a Citadel

company), and Samsara BioCapital. The placement consisted of 9,014,960 units at a price of $3.55 per unit, with each unit consisting of (i) one share of common stock or 0.001 non-voting Series C convertible preferred stock and (ii) one warrant to purchase one share of common stock at an exercise price of $7.10 per share. Each share of non-voting Series C convertible preferred stock is convertible into 1,000 shares of Pieris common stock, provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.99% of the total number of shares of Pieris common stock then outstanding. The warrants are intended to facilitate Pieris' exercise of its co-development option for PRS-060/AZ1402 following the conclusion of a positive phase 2a study. If top-line results of that study disclose achievement of the primary efficacy endpoint and the stock reaches a pre-specified price, then the warrants will expire 60 days following such disclosure and may only be exercised for cash. Otherwise, the warrants will be exercisable for a period of five years from the date of issuance.

Third Quarter Financial Update:

Cash Position - Cash, cash equivalents, and investments totaled $86.2 million as of September 30, 2019, compared to cash equivalents, and investments totaling $128.1 million as of December 31, 2018. This amount excludes the $32 million in gross proceeds from the November 2019 financing. Included in the Company's cash spend during the third quarter of 2019 was a one-time $2.3 million payment to the Technical University of Munich for sub-license royalties due on upfront and milestone payments related to collaboration agreements signed in 2017 and 2018.

R&D Expense - R&D expenses were $13.2 million for the quarter ended September 30, 2019, compared to $11.4 million for the quarter ended September 30, 2018. The Company's increase in R&D expenses reflects higher (albeit reimbursable) manufacturing efforts related to PRS-060/AZD1402 as part of phase 2a readiness activities for the program, as well as higher personnel and allocated facility costs due to growth in the Company's R&D organization to support higher levels of pre-clinical and clinical activities.

G&A Expense - G&A expenses were $4.8 million for the quarter ended September 30, 2019, compared to $4.7 million for the quarter ended September 30, 2018. There was no significant change in the composition of G&A expenses on a quarter over quarter basis.

Net Loss - Net loss was $2.6 million or $(0.05) per share for the quarter ended September 30, 2019, compared to a net loss of $6.6 million or $(0.11) per share for the quarter ended September 30, 2018.

Conference Call:

Pieris management will host a conference call beginning at 8:00 AM EST on Monday, November 11, 2019 to provide a corporate update. Individuals can join the call by dialing +1-877-407-8920 (US & Canada) or +1-412-902-1010 (International). An archived replay of the call will be available by dialing +1-877-660-6853 (US & Canada) or +1-201-612-7415 (International) and providing the Conference ID #: 13661472.

About Pieris Pharmaceuticals:

Pieris is a clinical-stage biotechnology company that discovers and develops Anticalin protein-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes inhalable Anticalin proteins to treat respiratory diseases and immuno-oncology multi-specifics tailored for the tumor microenvironment. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin® is a registered trademark of Pieris. For more information, visit www.pieris.com.

Forward Looking Statements:

This press release 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, the uses of funds received from the Company's private placement; Pieris' plans for a phase 2a study of PRS-060/AZD1402; the expected timing and potential outcomes of the reporting by the Company of key clinical data from its lead programs, 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 and the expected timing for reporting data or making IND filings related to our programs, including PRS-343 and PRS-344. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, our ability to satisfy the closing conditions for the private placement; 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; the timing and nature of data from the phase 2a study of PRS-060/AZD1402; whether or not Pieris opts-into co-development of PRS-060/AZD1402; whether or not any of the warrants to be issued in the private placement will be exercised for cash; the use of any proceeds from any warrant exercise; 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, 2018 and the Company's Quarterly Reports on Form 10-Q.

Investor Relations Contact:
Contact:

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Director of Investor Relations

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PIERIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	September 30, 2019	December 31, 2018
Assets:		
Cash and cash equivalents	$46,068	$74,867
Short term investments	40,175	53,240
Accounts receivable	6,952	2,701
Prepaid expenses and other current assets	4,778	4,574
Total current assets	97,973	135,382
Property and equipment, net	11,008	5,049
Other non-current assets	7,770	910

Total Assets	$116,751	$141,341
Liabilities and stockholders' equity:		
Accounts payable	$5,436	$3,350
Accrued expenses	7,170	9,114
Deferred revenue, current portion	27,242	35,612
Total current liabilities	39,848	48,076
Deferred revenue, net of current portion	44,179	53,303
Other long-term liabilities	12,082	27
Total Liabilities	96,109	101,406
Total stockholders' equity	20,642	39,935
Total liabilities and stockholders' equity	$116,751	$141,341

PIERIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except per share data)

	Three months ended September 30,		**Nine months ended September 30,**	
	2019	**2018**	**2019**	**2018**
Revenues	$15,132	$8,345	$29,009	$24,187
Operating expenses				
Research and development	13,211	11,401	40,880	28,492
General and administrative	4,835	4,748	13,956	13,878
Total operating expenses	18,046	16,149	54,836	42,370
Loss from operations	(2,914)	(7,804)	(25,827)	(18,183)
Interest income	377	504	1,332	1,491

Other income (expense), net	(55)	1,147	(203)	1,472
Loss before income taxes	(2,592)	(6,153)	(24,698)	(15,220)
Provision for income tax	-	-	-	(148)
Net loss	$(2,592)	$(6,153)	$(24,698)	$(15,072)
Basic and diluted net loss per share	$(0.05)	$(0.11)	$(0.50)	$(0.29)
Basic and diluted weighted average shares outstanding	49,353	54,089	49,805	52,721

SOURCE: Pieris Pharmaceuticals, Inc.

View source version on accesswire.com:
https://www.accesswire.com/566024/Pieris-Pharmaceuticals-Reports-Third-Quarter-2019-Financial-Results-and-Provides-Corporate-Update

SITC 2019
Gaylord National Hotel & Convention Center Nov. 6-10
NATIONAL HARBOR, MARYLAND

Phase 1 Dose Escalation Study of PRS-343, HER2/4-1BB Bispecific Molecule, in Patient with HER2+ Malignancies

Sarina Piha-Paul[1], Johanna Bendell[2], Anthony Tolcher[3], Sara Hurvitz[4], Amita Patnaik[5], Anuradha Krishnamurthy[6], Rachna Shroff[7], Paula Pohlmann[8], Noah Hahn[9], Markus Zettl[10], Jian Mei[10], Kayti Aviano[10], Manuela Duerr[10], Rusho Yusuf[10], Louis A Matis[10], Shane Olwill[10], Ingmar Bruns[10], Geoffrey Ku[11]

[1]The University of Texas MD Anderson Cancer Center, Texas, USA
[2]Sarah Cannon Research Institute, LLC, Tennessee, USA
[3]NEXT Oncology, Texas, USA
[4]University of California Los Angeles Jonsson Comprehensive Cancer Center, California, USA
[5]South Texas Accelerated Research Therapeutics, Texas, USA
[6]University of Pittsburgh Medical Center, Pennsylvania, USA
[7]University of Arizona Cancer Center, Arizona, USA
[8]Georgetown University Hospital, Washington DC, USA
[9]Sydney Kimmel Cancer Center at Johns Hopkins, Maryland, USA
[10]Pieris Pharmaceuticals, Inc., Massachusetts, USA
[11]Memorial Sloan Kettering Cancer Center, New York, USA

Disclosures

Geoffrey Ku

Reports relationships with the following:

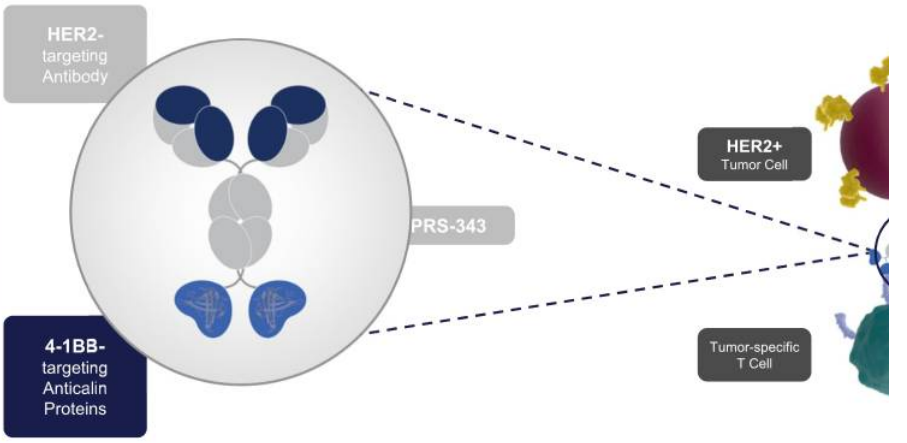
- Arog Pharmaceuticals – research support
- AstraZeneca – research support, consulting
- Bristol-Myers Squibb – research support, consulting
- Daiichi Sankyo – research support
- Eli Lilly – consulting
- Merck – research support, consulting
- Pieris Pharmaceuticals – research support, consulting
- Zymeworks – research support

Study sponsored by Pieris Pharmaceuticals

PRS-343: A HER2 4-1BB Bispecific

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



Study Design

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

Active schedules

Schedule 1: Q3W dosing on Day 1

Schedule 2 : Q2W dosing on Days 1, 15

Current Enrollment

Dose Level	No. Patients	Dose (mg/kg
1	1	0.0005 (Q3W
2	1	0.0015
3	1	0.005
4	2	0.015
5	2	0.05
6	5	0.15
7	7	0.5
8	6	1
9	6	2.5
10	9	5
11	7	8
11b	6	8 (Q2W)
Total	53	

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

Key Enrollment Criteria

Inclusion Criteria

- **Diagnosis of HER2+ advanced/metastatic solid tumor malignancy that has progressed on standard therapy or for which no standard therapy is available**
- **HER2+ solid tumors documented by ASCO, CAP or institutional guidelines**
- **Patients with breast, gastric and GEJ cancer must have received at least one prior HER2-targeted therapy for advanced / metastatic disease**
- Measurable disease per RECIST v1.1
- ECOG 0 or 1
- Adequate liver, renal, cardiac and bone marrow function

Exclusion Criteria

- **Ejection fraction below the lower limit of normal with trastuzumab and/ or pertuzumab**
- **Systemic steroid therapy or any other form of immunosuppressive therapy within seven days prior to registration**
- Known, symptomatic, unstable or progressing CNS primary malignancies
- Radiation therapy within 21 days prior to registration (limited field radiation to non-visceral structures is allowed, e.g., limb bone metasta

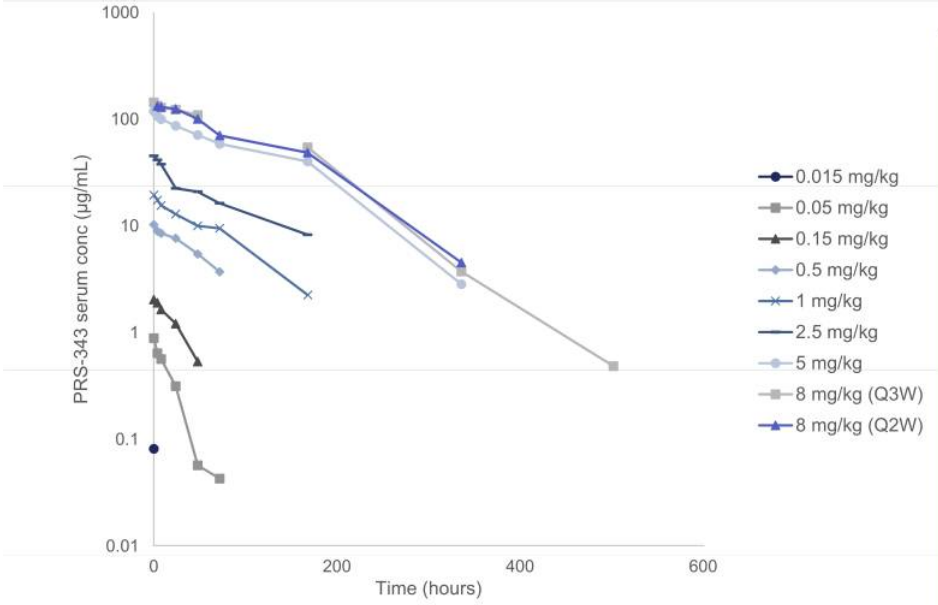
Baseline Characteristics
All Subjects (n = 53)

Characteristic	n (%)
Age, Median (range)	61 (29–92)
Gender	
F	33 (62%)
M	20 (38%)
ECOG PS	
0	12 (23%)
1	41 (77%)
Prior Therapy Lines	
1	6 (11%)
2	5 (9%)
3	11 (21%)
4	10 (19%)
5+	21 (40%)
Median no. of anti-HER2 Treatments	
Breast	4
Gastric	2

Primary Cancer Type	n (%)
Gastroesophageal	19 (36%)
Breast	14 (26%)
Gynecological	6 (11%)
Colorectal	5 (9%)
Gallbladder/ Biliary	4 (8%)
Bladder	2 (4%)
Pancreatic	1 (2%)
Other – Salivary Duct	1 (2%)
Other – Melanoma	1 (2%)

Data cut-off: 23-Oct-19

PRS-343 Clinical Pharmacology



Note: PRS-343 concentrations are below limit of quantification for dose levels < 0.015 mg/kg

Preliminary PRS-343 Pharmacology Profile

- Preliminary PK: Mean terminal half-life of PRS-343 is approximately five days
- 27.8% of patients are ADA+ with titers above 1:150 in cohorts covering active dose range (≥2.5 mg/kg)

Treatment-Related Adverse Events
All Subjects

Occurred in ≥ 1 Patient	n = 111 | n (%)	% Grade 3
Infusion Related Reaction	10 (9%)	2 (2%)
Fatigue	10 (9%)	1 (1%)
Chills	7 (6%)	0
Flushing	7 (6%)	3 (3%)
Nausea	7 (6%)	0
Diarrhea	7 (6%)	0
Vomiting	6 (5%)	0
Non-Cardiac Chest Pain	5 (4%)	1 (1%)

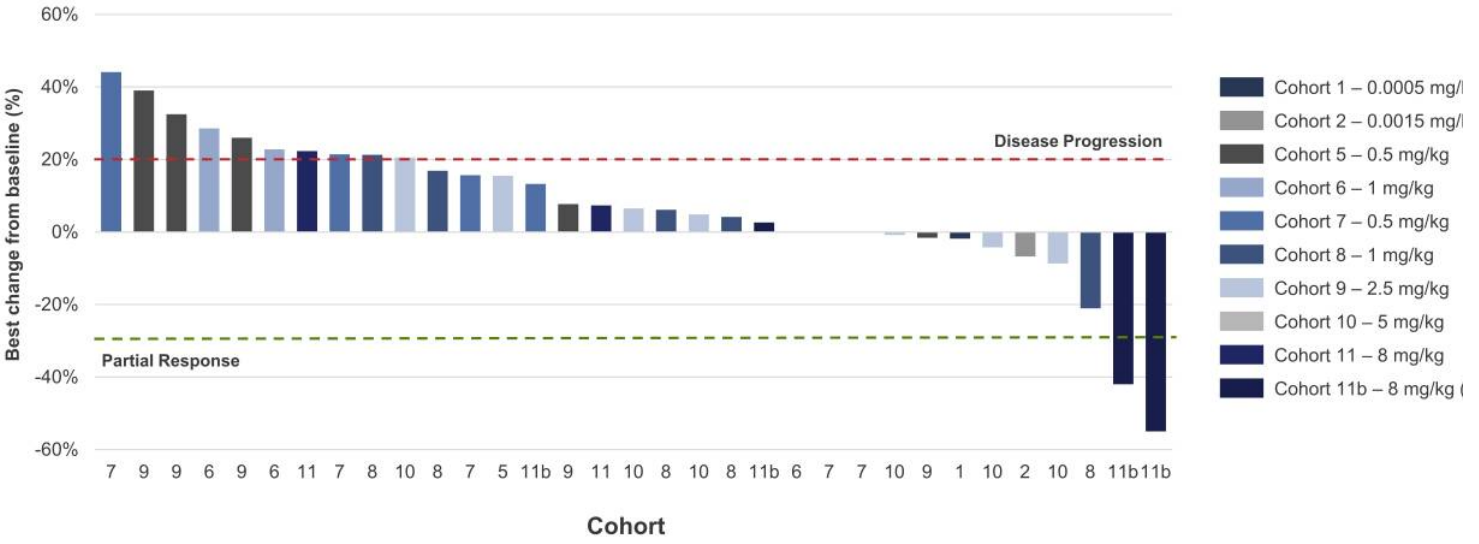
No Grade 4 or 5 Treatment-Related AEs

Summary of Responses at Active Dose Range of PRS-343

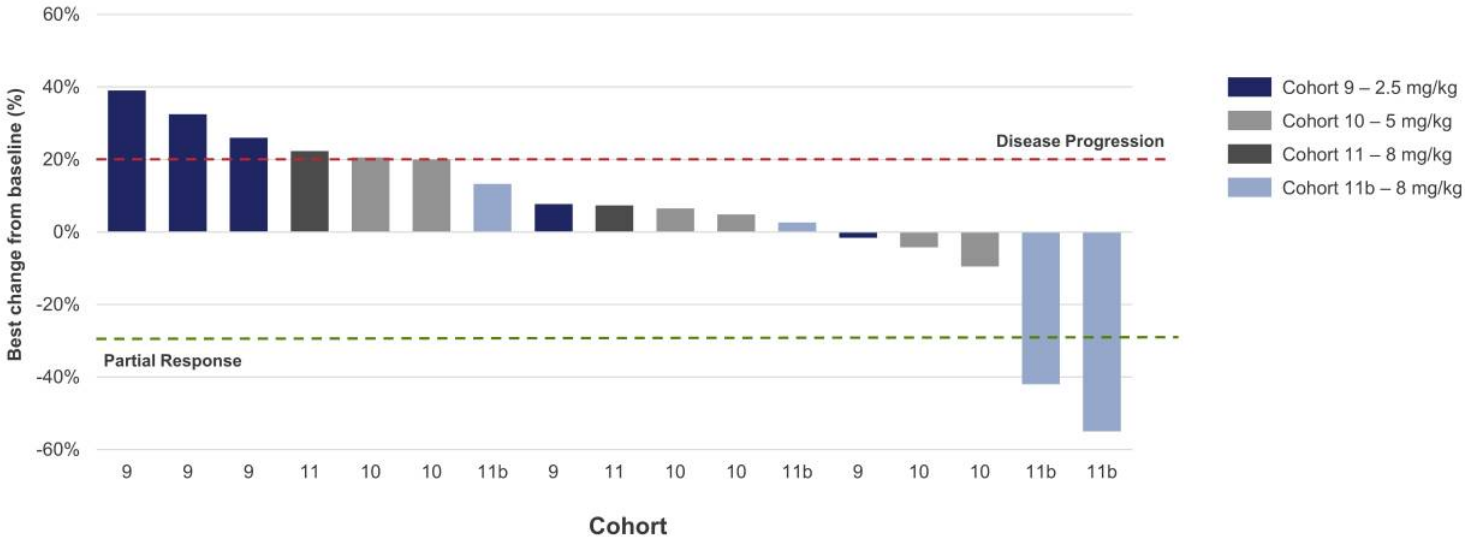
Based on clinical data, serum concentration of > 20 µg/ml defines active dose range (beginning at Cohort 9)

Cohort	11b	11	10	9	Total
Best Response	8 mg/kg, Q2W	8 mg/kg, Q3W	5 mg/kg, Q3W	2.5 mg/kg, Q3W	
Response Evaluable Patients	5	4	4	5	18
PR	2	-	-	-	2
SD	3	2	1	2	8
PD	-	2	3	3	8
ORR	40%	0%	0%	0%	11%
DCR	100%	50%	25%	40%	55%

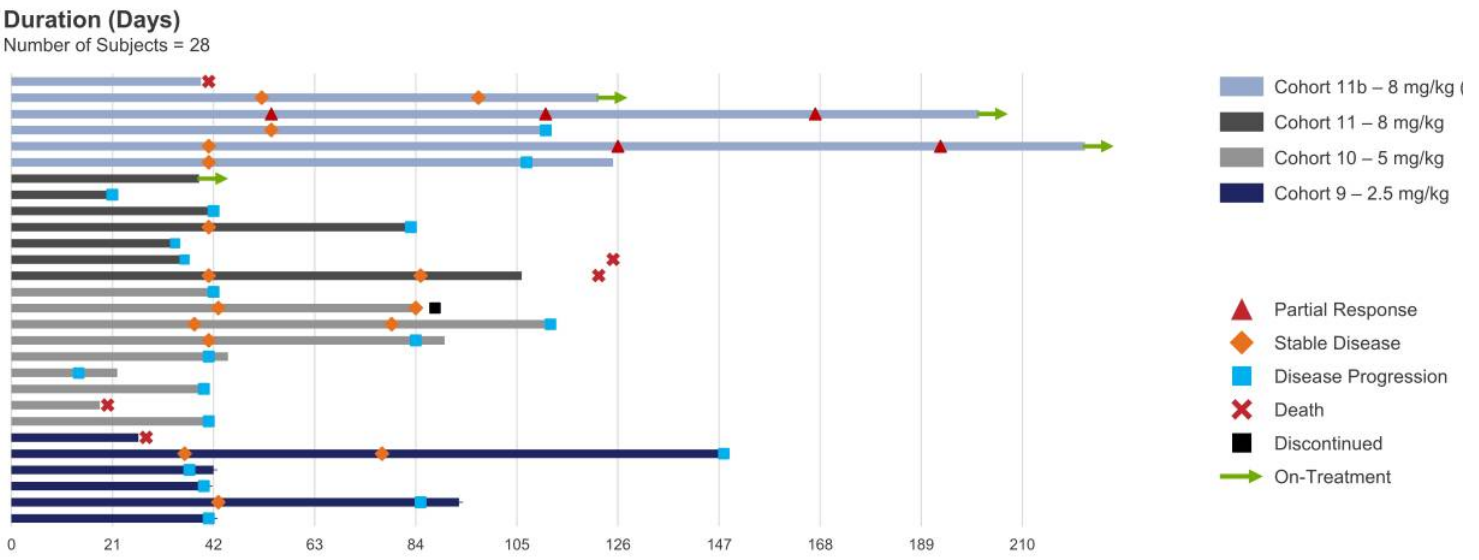
Best Response in Target Lesions
Monotherapy Study Cohorts 1-11b



Best Response in Target Lesions
Monotherapy Study Cohorts 9-11b

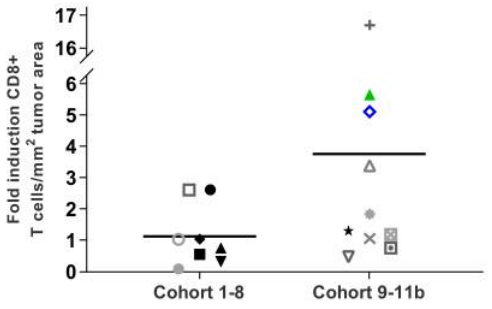


Average Time on Treatment with PRS-343 Significantly Increases in Cohort 11b (8 mg/kg Q2W)

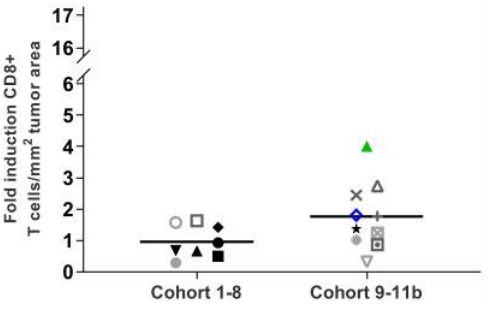


Increased CD8⁺ T Cell Numbers in Tumor Biopsies Post-Treatment

Tumor



Stroma



Pronounced increase in CD8⁺ T c
numbers is observed post-treatme
patients receiving doses ≥ 2.5 mg

Patients benefiting from treatmen
> 120 days (blue) and PR (green)
more pronounced increase in CD
cell number in tumor vs. stroma

Gastric Cancer Patient with Confirmed PR

Patient Profile, Treatment History and RECIST

Patient Profile

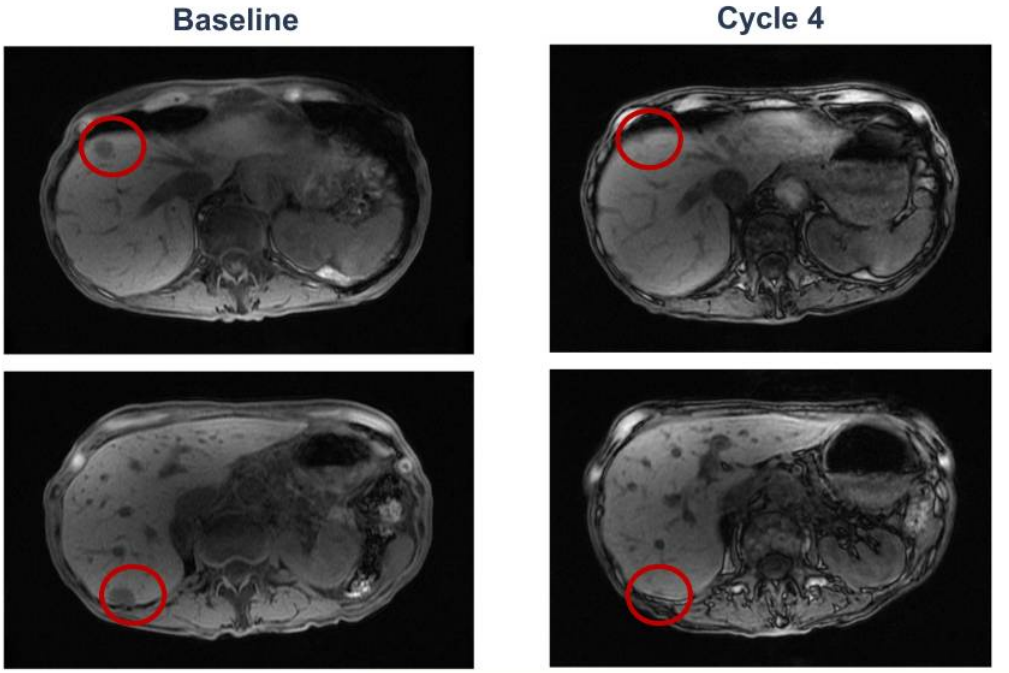
- Cohort 11b | 8 mg/kg every two weeks
- 80-year old woman; initial diagnosis on June 2017
- Stage IV gastric adenocarcinoma
- Metastases to liver, lymph node and adrenal glands
- HER2 IHC 3+; PD-L1 positive (CPS=3)
- NGS: ERBB2 amplification, TP53 mutation, alteration of CDK12 and SF3B1

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

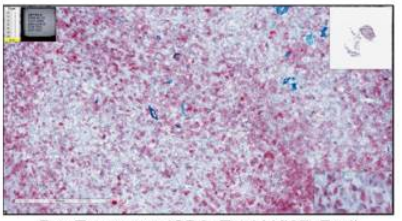
Lesions	Lesion Site	Lesion Size (mm)				
		Baseline	C2 Post-treatment	C3 Post-treatment	C4 Post-treatment	C6 Post-trea
Target 1	Liver	14	12	10	9	9
Target 2	Liver	20	16	10	8	8
Target 3	Pancreas	19	16	14	14	14
% Change from Baseline			-17%	-36%	-42%	-42%

PR, partial response; HER2, human epidermal growth factor receptor 2; PD-L1, Programmed Death Ligand 1; CPS, combined positive score; NGS, next-generation sequencing

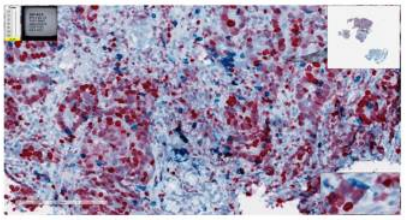
Gastric Cancer Patient with Confirmed Partial Response



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



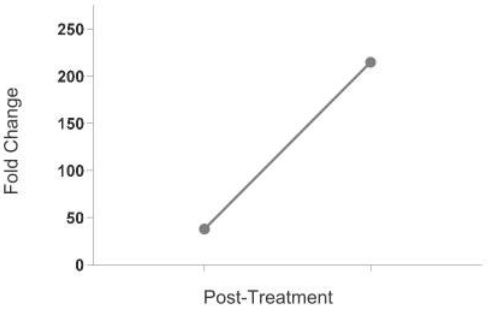
Pre-Treatment (CD8: Teal | Ki67: Red)



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

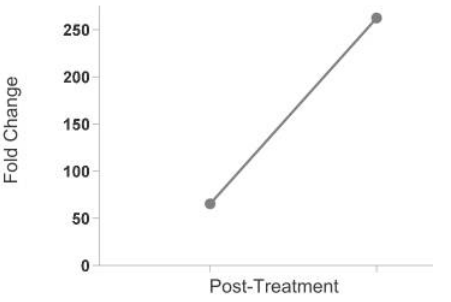
Tumor

CD8 fold change: **5.7** CD8 pre [n/mm²]: **38**



Stroma

CD8 fold change: **4** CD8 pre [n/mm²]: **6**



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

Conclusions: PRS-343 as Monotherapy

Well-tolerated, with a good safety profile in all doses and schedules tested

Demonstrated anti-tumor activity in heavily pre-treated patient population across multiple tumor types; treatment history indicative of 4-1BB-driven mechanism-of-action

Showed a clear increase in $CD8^+$ T cell numbers and proliferative index in the tumor microenvironment of responders

Future studies are planned for continued development in defined HER2+ indications

Acknowledgements

- Patients, their families and caregivers

- Investigators, as well as their site personnel
  - The University of Texas MD Anderson Cancer Center – S. Piha-Paul, B. Bruggman
  - Sarah Cannon Research Institute, LLC – J. Bendell, J. Costin
  - NEXT Oncology – A. Tolcher, K. Dotson
  - University of California Los Angeles Jonsson Comprehensive Cancer Center – S. Hurvitz, M. Rocha, R. Rubin
  - South Texas Accelerated Research Therapeutics – A. Patnaik, K. Rivas
  - University of Pittsburgh Medical Center – A. Krishnamurthy, B. Foster, A. Blasko
  - University of Arizona Cancer Center – R. Shroff, D. Pennington
  - Georgetown University Hospital – P. Pohlmann, S. Wagner
  - Sydney Kimmel Cancer Center at Johns Hopkins – N. Hahn, E. Lee
  - Memorial Sloan Kettering Cancer Center – G. Ku, T. Shrivastav, P. Collins

Appendix

Adverse Events Unrelated to Treatment
All Subjects

Adverse Events Unrelated to Treatment	n = 303 | n (%)
Fatigue	14 (5%)
Abdominal pain	11 (4%)
Anemia	10 (3%)
Constipation	9 (3%)
Decreased appetite	9 (3%)
Dyspnea	9 (3%)
Diarrhea	7 (2%)
Dysphagia	6 (2%)
Nausea	6 (2%)

Adverse Events Unrelated to Treatment	n = 303 | n (%)
Alanine aminotransferase increased	5 (2%)
Blood bilirubin increased	5 (2%)
Headache	5 (2%)
Hyperglycemia	5 (2%)
Pain	5 (2%)
Pruritus	5 (2%)
Vomiting	5 (2%)
Weight decreased	5 (2%)