

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): January 8, 2018

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 January 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: January 8, 2018

/s/ Allan Reine

Allan Reine

Chief Financial Officer



Investor Presentation

January 2018
(Nasdaq: PIRS)

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.

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

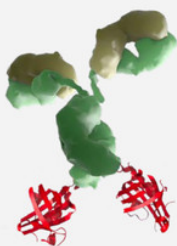
Unique bi/multispecifics

Inhaled therapeutics

Our pipeline addresses clinically-validated targets in new ways by leveraging unique features of the Anticalin® protein drug class, effectively taking reduced target biology risk

Core Value Drivers: Anticalin Proteins Targeted Locally in Two Therapeutic Areas

Industry Validation - Commercial opportunities within Alliances - Fully Proprietary Assets

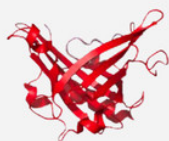
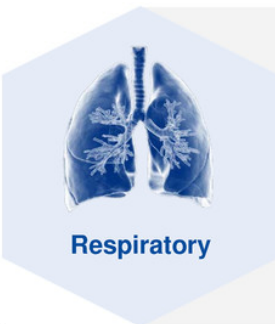


Proprietary

- Clinical-stage 4-1BB/HER2 bispecific (PRS-343) is fully owned
- Additional preclinical IO bispecifics

Alliance

- Several bispecific multi-checkpoint blockers and targeted costim agonists
 - Full US rights retained on several assets



AstraZeneca Alliance

- Clinical-stage inhaled IL-4Ra antagonist (PRS-060) with retained US co-dev/co-commercialization rights
- Additional programs will initiate this year
 - US co-dev/co-comm rights on several assets



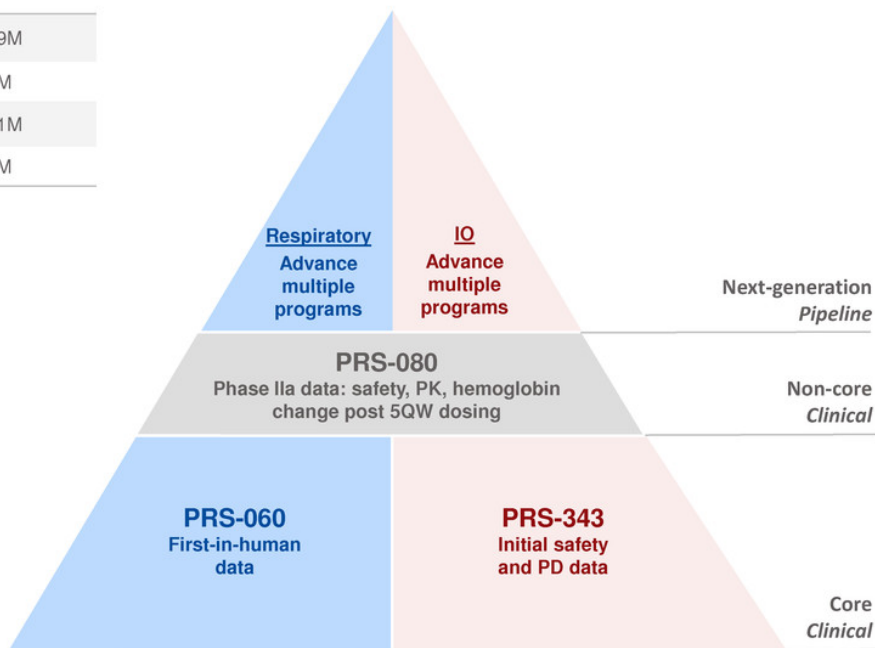
Financial Update (9/30/17)

2018 Anticipated Milestones

Cash & Cash Equivalents	\$89.9M
Debt	\$0.0M
YTD Opex (as of 9/30)	\$29.1M
CSO	44.4M

Pipeline Highlights

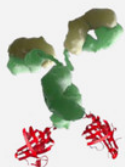
	DISCOVERY	PRECLINICAL	PHASE I	PHASE II
PRS-343			✓	
PRS-060			✓	
PRS-080				✓
Servier		✓		
AZ	✓			
PRS-300s	✓	✓		



Immuno-oncology Franchise



HER2-targeting mAb



4-1BB-targeting Ac

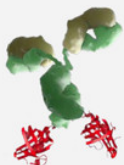
Proprietary Clinical

- **PRS-343**
 - First-in-class bispecific to preferentially activate T cells in the tumor microenvironment (TME)
 - In Phase I – HER2-positive patients
 - Safety and PD data in 2018

Proprietary Research

- Multiple ongoing research and preclinical programs with bispecific and multi-specific antibody/Anticalin protein constructs

Checkpoint/costim mAbs



Checkpoint/costim Ac

Servier Alliance

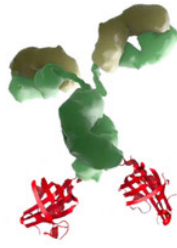
- 5-program deal (all bispecifics)
- Pieris retains full U.S. rights for 3 out of 5 programs
- \$31M upfront payment
- \$1.8B milestone potential
- Up to low double-digit royalties on non-codev products



PRS-343: Why did we design this?



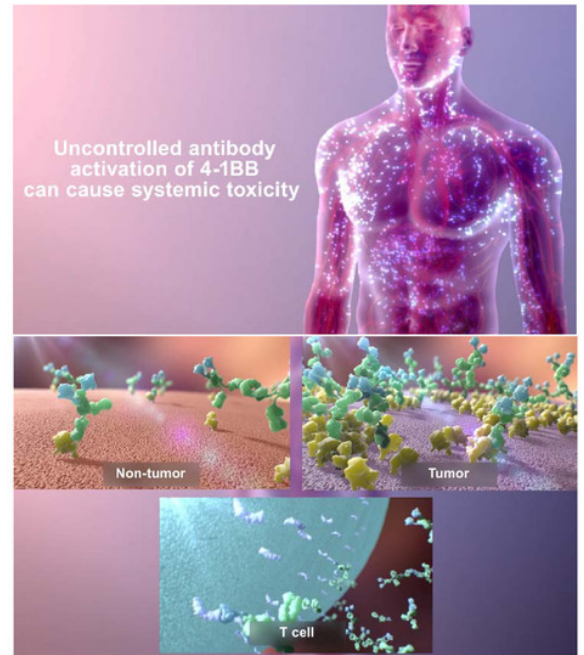
HER2-targeting mAb



4-1BB-targeting Abs

4-1BB systemically agonizing antibody has shown mono-therapy efficacy yet significant toxicity in the clinic (narrow therapeutic window)

PRS-343 preferentially agonizes 4-1BB in the TME by using its anti-HER2 component to drive drug clustering and, therefore, 4-1BB cross-linking



PRS-343 Targets Local Biology

4-1BB (CD137) – Key Costimulatory Target

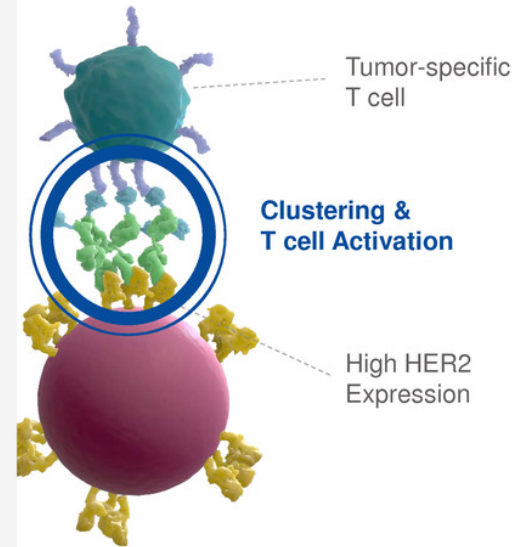
- Marker for tumor-specific T cells in TME
- Ameliorates T cell exhaustion
- Critical for T cell expansion
- Induces anti-tumor cytolytic activity
- Drives central memory T cell differentiation for sustained response

HER2 – Strongly Validated Tumor Target

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



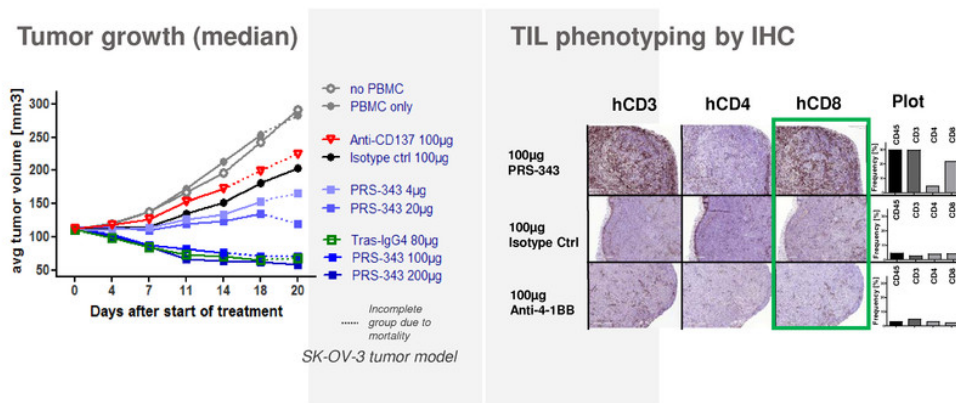
T cell costimulation in TME



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



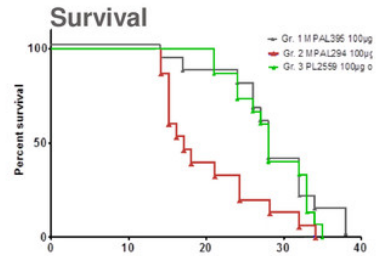
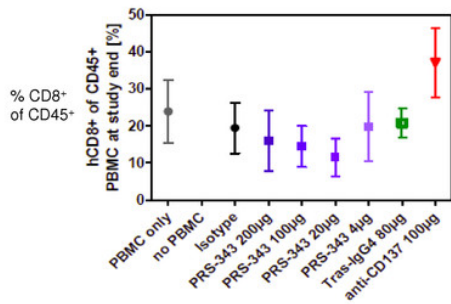
- PRS-343 shows dose-dependent tumor growth inhibition in HER2-sensitive model
- PRS-343 leads to strong and dose-dependent lymphocyte infiltration in tumors; monospecific anti-HER2 mAb (IgG4 backbone) inhibits tumor growth but lacks this immuno-stimulatory activity
- Monospecific anti-4-1BB benchmark mAb shows insignificant response compared to isotype control and no significant tumor infiltration of lymphocytes





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

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



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

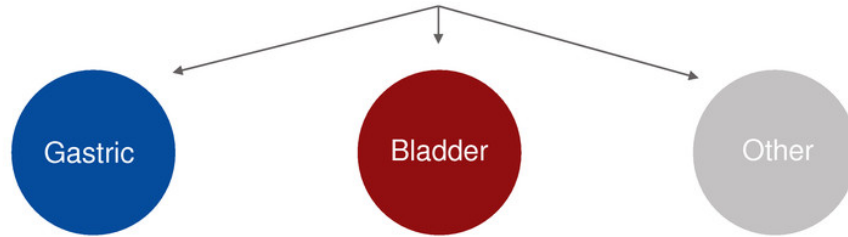


Phase I Trial (Initiated 3Q17)

Multiple Ascending Dose Escalation Phase

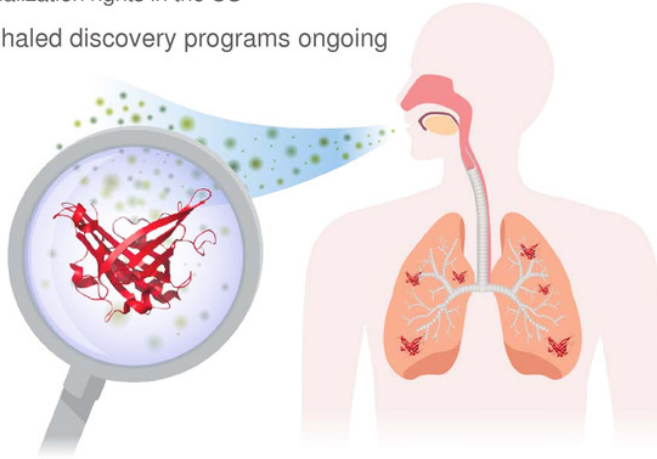
- Enrolling HER2+ cancer patients
- Starting with single patient cohorts (modified 3+3 design)
- Determine MTD and/or efficacious dose level
- Initial safety and PD data 2H18

Expansion Phase



Novel Inhaled Biologics Platform: Targeting Lung Diseases Locally

- PRS-060 (Part of AstraZeneca alliance)
 - First-in-class inhaled IL-4Ra antagonist for asthma
 - Phase I initiated in 4Q17
 - Pieris retains opt-in for co-development/co-commercialization rights in the US
- Proprietary inhaled discovery programs ongoing



AstraZeneca 

Alliance Highlights

5 committed novel inhaled Anticalin protein programs

Including lead asthma program PRS-060 (IL-4Ra)

Retained co-development and co-commercialization (US) options on PRS-060 and up to 2 additional programs

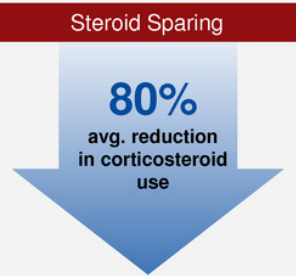
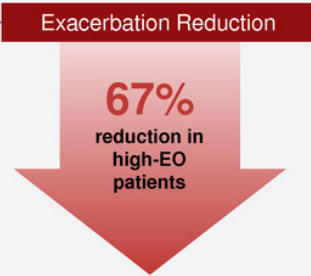
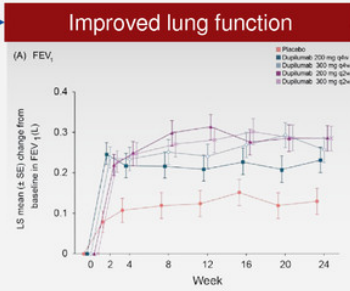
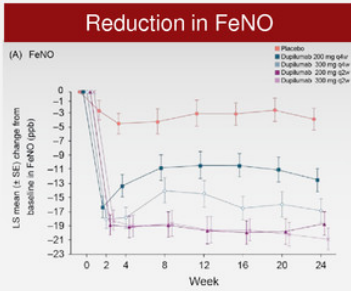
\$57.5M upfront & Phase I MS in 2017; up to ~\$2.1B in milestones, plus double-digit royalties

Access to complementary formulation and device know-how for inhaled delivery

PRS-060 For Uncontrolled Asthma: Why Did We Design This?

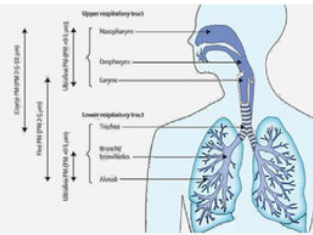
What We Know

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



What We Are Testing

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



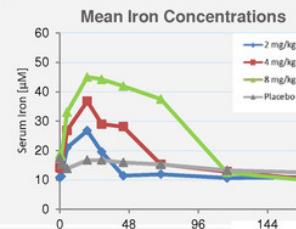
PRS-080 for Anemia – Why We Made This?

What We Know

Hepcidin is up-regulated in functional iron deficiency anemia

Antagonizing hepcidin with single-dose PRS-080 in CKD5 patients led to Fe mobilization

Ph Ib SAD in CKD5 patients



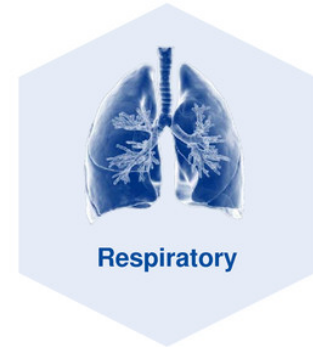
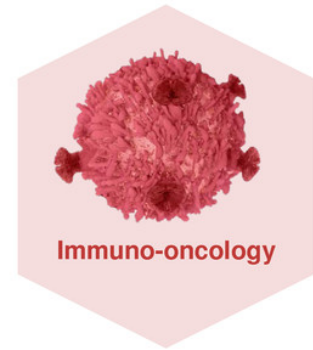
What We Are Testing

Will antagonizing hepcidin with PRS-080 lead to a hemoglobin increase after 5 q/wk. doses?

- Phase IIa study underway testing two dose cohorts: 4mg/kg and 8mg/kg vs. pbo
- Data expected 2H18

Pieris Investment Opportunity

- An industry-validated class of novel therapeutics
 - Anticalin proteins
 - \$90+M in upfront payments and milestones in 2017 with billions of milestone potential
- Potentially transformative, wholly owned IO program
 - Clinical-stage, tumor-targeted 4-1BB bispecific
- High-value, inhaled targeted respiratory program
 - Clinical-stage inhaled IL-4Ra antagonist
 - partnered with AstraZeneca – retained US co-dev/comm rights
- Robust IND engine that has yielded several clinical-stage candidates with excellent drug-like properties
- Proven management team





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R&D Hub: Freising, Germany (Munich)



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