# 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 15, 2015

# 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.)

Lise-Meitner-Strasse 30 85354 Freising-Weihenstephan, Germany (Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: +49 81 6114 11400

ck 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 risions:
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))

#### Item 8.01 Other Events.

Attached hereto as Exhibits 99.1 and 99.2 and incorporated by reference herein are press releases of Pieris Pharmaceuticals, Inc.

### Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

- 99.1 Press release dated September 15, 2015.
- 99.2 Press release dated September 21, 2015.

#### **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: September 21, 2015

### PIERIS PHARMACEUTICALS, INC.

By: /s/ Darlene Deptula-Hicks
Name: Darlene Deptula-Hicks
Title: Chief Financial Officer

## EXHIBIT INDEX

Exhibit No.	Description
99.1	Press dated September 15, 2015.
99.2	Press dated September 21, 2015.



#### PRESS RELEASE

# PIERIS PHARMACEUTICALS' COLLABORATOR PRESENTS PROMISING PRECLINICAL DATA ON TETRASPECIFIC INFECTIOUS DISEASE ANTICALIN PROGRAM AT ASM CONFERENCE

-First-in-Class Multispecific Protein Offers High Differentiation Over Antibodies-

**Boston, Massachusetts, September 15, 2015 – Pieris Pharmaceuticals, Inc.** (NASDAQ: <u>PIRS</u>), a biotechnology company advancing novel biotherapeutics through its proprietary <u>Anticalin</u><sup>®</sup> technology platform, announced today that one of its partners, Sanofi, presented preclinical data on the companies' multispecifics program at an infectious disease conference. The tetraspecific Anticalin-based protein comprises four distinct Anticalin proteins, each specific for one of four different families of siderophores from *Pseudomonas aeruginosa*, collectively engaging twenty targets with high affinity and specificity.

The data presented September 10, 2015 at the American Society for Microbiology (ASM) Conference on *Pseudomonas* in Washington, DC, by Dr. Carsten Corvey, Global Sanofi Project leader, provided an overview of the drug-like properties of this complex protein, as well as promising *in vivo* activity in a chronic *Pseudomonas aeruginosa* infection animal model. The data demonstrate that the individual Anticalin polypeptides of the tetraspecific construct specifically bind to their respective targets in the low to sub nM range, achieving the desired efficacy in vitro and in a chronic infection rat model, in addition to exhibiting desired manufacturability and stability criteria.

Dr. Laurent Fraisse, Vice President Infectious Diseases, Sanofi R&D commented, "Anticalins are optimally suited for addressing several targets with a multispecific protein and have shown great promise to address infectious diseases, in particular. We look forward to further advancing this program into IND-enabling studies."

Pieris President and CEO, Stephen Yoder, commented, "Our tetraspecific Anticalin program with Sanofi is one of the best examples of how our proprietary protein drug class is highly differentiated over antibody approaches. The benefits of engaging multiple targets with a single protein under one IND could be numerous and, in this case, has the potential to address a huge unmet need in patients suffering from *Pseudomonas* infections."

#### **About Pieris Pharmaceuticals:**

Pieris is a clinical-stage biotechnology company advancing its proprietary Anticalin® technology to create differentiated drugs that have the potential to be safer and more effective than conventional approaches. Anticalins show promise in addressing high-unmet

medical needs and expanding the potential of targeted therapeutics. The company currently has a diverse proprietary pipeline and has ongoing R&D collaborations with Daiichi Sankyo, the Sanofi Group, Zydus Cadila, Stelis Biopharma and Allergan. Anticalin®, Anticalins® are registered trademarks of Pieris. For more information visit www.pieris.com.

#### About the Pieris-Sanofi infectious disease program:

Under a collaboration and license agreement Pieris has used its proprietary Anticalin® technologies to identify drug candidates against certain targets, with further development and commercialization activities to be conducted by Sanofi. The partnered Pieris-Sanofi infectious disease program is a tetraspecific Anticalin-based protein that engages several bacterial siderophores from *Pseudomonas aeruginosa* as therapeutic targets. Bacterial infections depend on available iron levels, and bacteria such as Pseudomonas use siderophores for iron scavenging. The siderophores of Pseudomonas encompass three different classes of pyoverdins, each class comprising three different members, and pyochelin, altogether defining ten distinct targets. As the Anticalins in this program bind to these siderophores in an iron-bound and – unbound state, the multispecific Anticalin protein effectively engages twenty targets. Pseudomonas is the most common pathogen isolated from patients who have been hospitalized longer than one week and is a frequent cause of nosocomial infections.

#### **Forward Looking Statements**

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1934 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to novel technologies and methods; our business and product development plans; our liquidity and ability to fund our future operations; or market information. 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; competition in the industry in which we operate and market conditions. These forward-looking statements are made as of the date of this press release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents we file with the SEC available at www.sec.gov, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and the Company's Quarterly Reports on Form 10-Q.

#### **Company Contact:**

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PRESS RELEASE

# PIERIS PHARMACEUTICALS PRESENTS POSITIVE PRECLINICAL DATA ON LEAD BISPECIFIC IMMUNO-ONCOLOGY PROGRAM

— Tumor-targeting CD137/HER2 Bispecifics Exhibit Desired Drug-Like Properties and Tumor-Dependent T Cell Activation—

**Boston, Massachusetts, September 21, 2015 – Pieris Pharmaceuticals, Inc.** (NASDAQ: <u>PIRS</u>), a biotechnology company advancing novel biotherapeutics through its proprietary <u>Anticalin</u>® technology platform, announced today the presentation of new preclinical data for its Anticalin-based CD137/HER2 bispecific drug candidates in the PRS-343 immuno-oncology program. The data demonstrate potent CD137-driven T cell activation that is dependent upon drug-mediated HER2 engagement on the tumor cell surface. The Company reconfirmed its intent to achieve drug candidate nomination for this program by the end of the year.

Presented September 18, 2015 during a poster session at CRI-CIMT-EATI-AACR - The Inaugural International Cancer Immunotherapy Conference, the data provide an overview of the drug-like properties and pharmacodynamic activity of four distinct CD137/HER2 bispecific molecules comprised of an anti-HER2 monoclonal antibody genetically linked to an agonist CD137-targeting Anticalin® protein. All four bispecific molecules demonstrated not only desired biophysical properties, but also the ability to activate T cells ex vivo as a function of HER2 engagement. Importantly, the unique geometries of each drug candidate led to pronounced differences in levels of T cell activation, highlighting the importance of structure in designing bispecifics. A copy of the poster can be viewed and downloaded by clicking <a href="https://c.eqcdn.com/pierisag/db/164/1975/pdf/150914+CRI+Poster+postFinal.pdf">https://c.eqcdn.com/pierisag/db/164/1975/pdf/150914+CRI+Poster+postFinal.pdf</a>.

Pieris President and CEO, Stephen Yoder, commented, "In contrast to traditional bispecific antibody efforts that utilize a one-size-fits-all format, Anticalin-based bispecifics enable tailored approaches to derive drug candidates with superior structure and function. We look forward to advancing our PRS-343 program through IND-enabling studies and into clinical trials."

CD137 is a costimulatory immunoreceptor and a highly promising target for cancer therapy. However, conventional CD137-targeting antibodies suffer from a lack of tumor-selective activity, which may lead to peripheral toxicity, reducing the available therapeutic window. Pieris' bispecifics are designed to promote CD137 clustering by bridging T cells with HER2-positive tumor cells, and to thereby provide a localized costimulatory signal to tumor antigen-specific T cells.

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