# 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): December 8, 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

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))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 1.01 Entry into a Material Definitive Agreement.

On December 8, 2015, Pieris Pharmaceuticals, Inc. (the "Company") and Pieris Pharmaceuticals GmbH, a wholly-owned subsidiary of the Company (together with the Company, "Pieris"), entered into a Research Collaboration and License Agreement (the "Agreement") with Hoffmann-La Roche Inc. and its affiliate, F. Hoffmann-La Roche Ltd (collectively, "Roche"), in cancer immune therapy for the research, development and commercialization of Anticalin-based drug candidates against a predefined, undisclosed target.

Under the terms of the Agreement, Pieris will receive an upfront payment of CHF 6.5 million (approximately \$6.4 million USD) and committed research funding, and may receive development and regulatory-based milestone payments, sales-based milestone payments as well as mid-single-digit to low double-digit royalties on any future product sales. If all milestones and other conditions are met, the total payments to Pieris could surpass CHF 415 million (~\$409.3 million USD), excluding royalties.

The parties will jointly pursue a preclinical research program with respect to the identification and generation of Anticalins that bind to a specific target for an expected period of 20 months, which may be extended by Roche for up to an additional 12 months. A joint research committee consisting of an equal number of representatives from each party, chaired by a Roche representative, will be responsible for overseeing and directing the development activities pursuant to an agreed-upon research plan. During the research term of the Agreement, Roche will fund the work to be performed by Pieris pursuant to the research plan. Following the research program, Roche will be responsible for subsequent pre-clinical and clinical development of any product and will have worldwide commercialization rights.

Unless earlier terminated, the term of the Agreement continues until no royalty or other payment obligations are or will become due under the Agreement. The Agreement may be terminated (i) by either party based on insolvency or breach by the other party and such insolvency proceeding is not dismissed or such breach is not cured within 90 days; or (ii) after 15 months from the effective date of the Agreement, by Roche as a whole or on a product-by-product and/or country-by-country basis upon 90 days prior written notice before the first commercial sale of a product or upon 180 days prior written notice after the first commercial sale of a product. Roche may also, in its sole discretion, terminate the Agreement upon a change of control of Pieris involving a company that develops or commercializes biopharmaceutical products.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, which Pieris intends to file as an exhibit to its Annual Report on Form 10-K for the year ending December 31, 2015. A copy of the press release announcing the Agreement is attached to this Current Report as Exhibit 99.1 and is incorporated herein by reference.

#### Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

99.1 Press Release of Pieris Pharmaceuticals, Inc., dated December 8, 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: December 14, 2015

### PIERIS PHARMACEUTICALS, INC.

By: /s/ Darlene Deptula-Hicks

Name: Darlene Deptula-Hicks Title: Chief Financial Officer

## EXHIBIT INDEX

#### Exhibit No. Description 99.1 Proce Poleoco of Dioris Dharmacouticals Inc. dated Do

99.1 Press Release of Pieris Pharmaceuticals, Inc., dated December 8, 2015.



PRESS RELEASE

#### Pieris Pharmaceuticals Announces First Cancer Immunotherapy Collaboration

#### Agreement with Roche Leverages Proprietary Anticalin® Technology Platform

**Boston, MA, December 8, 2015 – Pieris Pharmaceuticals, Inc.** (NASDAQ: PIRS), a biotechnology company advancing novel bio therapeutics through its proprietary Anticalin<sup>®</sup> technology platform, today announced a research collaboration and license agreement with Roche in cancer immunotherapy (CIT). Under the terms of the agreement, Pieris will discover, characterize and optimize Anticalin<sup>®</sup>-based drug candidates against an undisclosed target. Roche and Pieris will evaluate different drug formats against this target and advance them through preclinical development, with Roche being responsible for IND-enabling activities, clinical development and worldwide marketing of any resulting products. Pieris will receive an upfront payment of CHF 6.5 million (~\$6.4 million USD) and committed research funding, and may receive development and regulatory-based milestone payments, sales-based milestone payments as well as mid single-digit to low double-digit royalties on any future product sales. If all milestones and other conditions are met, the total payments to Pieris could surpass CHF 415 million (~\$409.3 million USD), excluding royalties.

"Our partnership with Roche is a significant step forward for Pieris," commented Stephen Yoder, President and CEO of Pieris. "The decision by the leader in the development and commercialization of cancer biologics to collaborate with Pieris underscores the unique potential of Anticalin-based proteins as a differentiated class of immuno-oncology drugs. As we initiate this collaboration, we will continue to vigorously advance our fully proprietary programs, including our lead CD137-HER2 bispecific."

With its immuno-oncology PRS-300 Series, which remains proprietary to the Company, Pieris is developing bispecific Anticalin-based protein therapeutics against a variety of tumor and immunomodulatory targets. These compounds, including its lead program PRS-343 (CD137/HER2 bispecific), aim to activate the immune system in the tumor microenvironment, with the goal of increasing efficacy as well as improving safety compared to existing approaches. This collaboration represents Pieris' first partnered immuno-oncology program and leverages Pieris' capability to address a target in multiple ways through Anticalin-based drug candidates in different formats.

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

Pieris Pharmaceuticals is a clinical stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immuno-oncology multi-specifics tailored for the tumour micro-environment, an inhaled Anticalin to treat uncontrolled asthma and a half-life-optimized Anticalin to treat anemia. Proprietary to Pieris, Anticalins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin®, Anticalins® are registered trademarks of Pieris. For more information visit www.pieris.com.

#### **About Anticalins:**

Anticalins are derived from lipocalins, small human proteins that naturally bind, store and transport a wide spectrum of molecules. Anticalins feature the typical four-loop variable region and a rigidly conserved beta-barrel backbone of lipocalins, which, together, form a shapeable cup-like binding pocket. Proprietary to Pieris, Anticalins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies.

Anticalin<sup>®</sup>, Anticalins<sup>®</sup> are registered trademarks of Pieris.

#### **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, references to novel technologies and methods; our business, research and product development plans; our liquidity and ability to fund our future operations; our ability to achieve certain milestones and receive future milestone or royalty payments; 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, research 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.

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