# 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 4, 2017

# 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 (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))

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

On January 4, 2017, Pieris Pharmaceuticals, Inc. (the "Company") and Pieris Pharmaceuticals GmbH, a wholly-owned subsidiary of the Company (together with the Company, "Pieris"), entered into a License and Collaboration Agreement (the "Collaboration Agreement") and a Non-Exclusive Anticalin® Platform Technology License Agreement (the "License Agreement" and together with the Collaboration Agreement, the "Agreements") with Les Laboratoires Servier and Institut de Recherches Internationales Servier (collectively, "Servier"), pursuant to which Pieris and Servier will initially pursue five bispecific therapeutic programs, led by Pieris' PRS-332 program, a PD-1-targeting bispecific checkpoint inhibitor. Pieris and Servier will jointly develop PRS-332 and split commercial rights geographically, with Pieris retaining all commercial rights in the United States and Servier having commercial rights in the rest of the world. The four additional committed programs have been defined, which may combine antibodies from the Servier portfolio with one or more Anticalin proteins based on Pieris' proprietary platform to generate innovative immuno-oncology bispecific drug candidates. The collaboration may be expanded by up to three additional therapeutic programs. Pieris has the option to co-develop and retain commercial rights in the United States for up to three programs beyond PRS-332, while Servier will be responsible for development and commercialization of the other programs worldwide.

Under the Agreements, Pieris will receive an upfront payment of EUR30 million (approximately 31.3 million USD). Pieris may also receive FTE funding for specific projects, as well as development-dependent and commercial milestone payments for PRS-332 and each additional program. The total development, regulatory and sales-based milestone payments to Pieris could exceed EUR1.7 billion (approximately 1.8 billion USD) over the life of the collaboration and are dependent on the final number of projects pursued and the number of co-development options exercised by Pieris. Pieris and Servier will share preclinical and clinical development costs for each co-developed program. In addition, Pieris will be entitled to receive tiered royalties up to low double digits on the sales of commercialized products in the Servier territories.

The term of each Agreement ends upon the expiration of all of Servier's payment obligations under such Agreement. The Agreements may be terminated by Servier for convenience beginning 12 months after their effective date upon 180 days' notice. The Agreements may also be terminated by Servier or Pieris for material breach upon 90 days' or 120 days' notice of a material breach, with respect to the Collaboration Agreement and License Agreement, respectively, provided that the applicable party has not cured such breach by the applicable 90-day or 120-day permitted cure period, and dispute resolution procedures specified in the applicable Agreement have been followed. The Agreements may also be terminated due to the other party's insolvency or for a safety issue and may in certain instances be terminated on a product-by-product and/or country-by-country basis. The License Agreement will terminate upon termination of the Collaboration Agreement, on a product-by-product and/or country-by-country basis.

The foregoing description of the Agreements does not purport to be complete and is qualified in its entirety by reference to the Agreements, which Pieris intends to file as exhibits to its Annual Report on Form 10-K for the year ending December 31, 2016. A copy of the press release announcing the Agreements 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 Joint Press Release, dated January 5, 2017.

#### **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: January 5, 2017

### PIERIS PHARMACEUTICALS, INC.

By: /s/ Darlene Deptula-Hicks

Name: Darlene Deptula-Hicks

Title: Senior Vice President and Chief Financial Officer

## EXHIBIT INDEX

Exhibit No. Description

99.1 Joint Press Release, dated January 5, 2017.





#### PRESS RELEASE

#### Pieris Pharmaceuticals and Servier Forge Strategic Immuno-oncology Co-development Alliance

- Pieris and Servier, an independent international pharmaceutical company headquartered in France with annual sales of more than EUR4 billion, to jointly pursue several bispecific therapeutic programs including Pieris' proprietary dual checkpoint inhibitor PRS-332
- Alliance includes four additional bispecific programs and may be expanded to a total of eight immuno-oncology programs (including PRS-332); Pieris has option to co-develop and retain US rights for 4 of these programs, including PRS-332
- Pieris to receive EUR30 million (\$31.3 million USD) upfront, up to EUR324 million (\$338 million) in success-based payments for PRS-332, up to EUR193 million (\$201 million) in success-based payments for each of the other programs and up to double-digit royalties
- Pieris will host an investor conference call on Thursday, January 5, 2017 at 8:30 AM (EST) to discuss the collaboration

**Boston, MA, and Suresnes, France, 5 January 2017 – Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS),** a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin<sup>®</sup> technology platform, and Servier, an independent international pharmaceutical company, today announced a broad collaboration in immuno-oncology (IO). Despite the impressive clinical efficacy of checkpoint inhibitors to date, a majority of patients fail to respond to approved therapies. The collaboration seeks to address this significant unmet clinical need by advancing a series of novel molecules, including multiple dual immune checkpoint blockade approaches.

Under the collaboration, Pieris and Servier will initially pursue five bispecific therapeutic programs, led by Pieris' PRS-332 program, a potentially best-in-class PD-1-targeting bispecific checkpoint inhibitor. Pieris and Servier will jointly develop PRS-332 and split commercial rights geographically, with Pieris retaining all commercial rights in the United States and Servier having commercial rights in the rest of the world. The four additional committed programs have been defined, which may combine antibodies from the Servier portfolio with one or more Anticalin proteins based on Pieris' proprietary platform to generate innovative immuno-oncology bispecific drug candidates. The collaboration may





be expanded by up to three additional therapeutic programs. Pieris has the option, at a predefined time point, to co-develop and retain commercial rights in the United States for up to three programs beyond PRS-332, while Servier will be responsible for development and commercialization of the 4 other programs worldwide.

The financial terms of the collaboration include an upfront payment to Pieris of EUR30 million (approximately \$31.3 million USD). Pieris may also receive FTE funding for specific projects, an option fee upon potential expansion of the collaboration as well as development-dependent and commercial milestone payments for PRS-332 and each additional program. The total development, regulatory and sales-based milestone payments to Pieris could reach EUR324 million (approximately \$338 million USD) for PRS-332, and up to EUR193 million (approximately \$201 million USD) for each of the other programs. Pieris and Servier will share preclinical and clinical development costs for each co-developed program. In addition, Pieris will be entitled to receive tiered royalties up to low double digits on the sales of commercialized products in the Servier territories.

Pieris' multispecific technology allows simultaneous checkpoint inhibition on the same cell, which could have a clear advantage over monoclonal antibody cocktails against different checkpoint targets. PRS-332 is a novel PD-1-based bispecific, comprising an anti-PD-1 antibody genetically linked to an Anticalin protein targeting an undisclosed checkpoint target. Pieris has developed PRS-332, which is currently in preclinical development, with the intent to simultaneously block two immune checkpoints co-expressed on exhausted T cells to further improve on existing PD-1 therapies.

"Servier is a highly complementary partner for Pieris, with a very clear commitment to oncology and outstanding development capabilities," stated Dr. Louis Matis, Senior Vice President and Chief Development Officer of Pieris. "The synergies of building unique bispecifics from Servier's antibodies and Pieris' Anticalin proteins are multifold, as the versatility of our platform allows for extensive combinatorial target opportunities with the numerous IO 'building blocks' our team has discovered to date."

"This alliance will significantly enhance Servier's portfolio in immuno-oncology, which already comprises 5 products in late preclinical or early development. Servier's recognized expertise in drug development will efficiently complement Pieris' innovative technology, allowing both companies to bring innovative solutions to cancer patients," stated Jean-Pierre Abastado, PhD, Director of Oncology R&D at Servier.

"Servier has built a diversified and innovative portfolio in oncology that includes small molecules, engineered antibodies, and cell therapies for the treatment of both hematological malignancies and solid tumors. Today's alliance with Pieris adds another dimension to our strategy of becoming a key player in oncology, providing several next-generation bispecific IO drugs to our pipeline," added Emmanuel Canet, M.D., Ph.D., President of Servier R&D.





"Our alliance with Servier is clearly a transformative one for Pieris and is the type of partnership we deliberately set out to achieve to create significant long-term value. This collaboration provides not only an opportunity to advance multiple programs with retained rights in the number one oncology market, but also provides significant funding and flexibility for Pieris to balance financial and operational resources as we enter the next stage of corporate development," stated Stephen Yoder, President and Chief Executive Officer of Pieris. "The Servier alliance will act as a significant building block of our pipeline expansion in immuno-oncology and demonstrates the value of our proprietary Anticalin drug class."

#### **Conference Call:**

Pieris will host an investor conference call on Thursday, January 5, 2017 at 8:30 AM (EST) to discuss the collaboration. To access the call, participants may dial 1-877-407-8920 (US & Canada) or 1-412-902-1010 (International) at least 10 minutes prior to the start of the call.

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 #13652361.

#### **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 multispecifics tailored for the tumor micro-environment, an inhaled Anticalin protein to treat uncontrolled asthma and a half-life-optimized Anticalin protein to treat anemia. Proprietary to Pieris, Anticalin proteins are a novel class of protein 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.

#### **About Servier:**

Servier is an international pharmaceutical company governed by a non-profit Foundation and headquartered in France. With a strong international presence in 148 countries and a turnover of 4 billion euro in 2016, Servier employs over 21,000 people worldwide. Corporate growth is driven by Servier's constant search for innovation in five areas of





excellence: cardiovascular diseases, diabetes, cancers, immune-inflammatory diseases and neurodegenerative diseases, as well as by its activities in high quality generic drugs. Being completely independent, the Group reinvests 25% of Servier's products turnover in Research and Development, and all its profits in its growth.

Becoming a key player in oncology is part of Servier's long-term strategy. Currently, there are nine new molecular entities in clinical development in this area, targeting breast and lung cancers, and other solid tumors, as well as various leukemias and lymphomas. This portfolio of innovative cancer treatments is being developed with partners worldwide, and covers different cancer hallmarks and modalities, including cytotoxics, proapoptotics, targeted, immune, and cellular therapies, to deliver life-changing medicines to patients. For more information visit <a href="https://www.servier.com">www.servier.com</a>.

#### **About Anticalin Therapeutics:**

Anticalin proteins are derived from lipocalins, small human proteins that naturally bind, store and transport a wide spectrum of molecules. Anticalin proteins 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, Anticalin proteins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin® is a registered trademark 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 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 and timelines; the timing and progress of our studies, development of therapeutic programs; ability to receive research funding; our liquidity and ability to fund our future operations; our ability to achieve certain milestones and receive future milestone or royalty payments; current or future partnerships; 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, 2015 and the Company's Quarterly Reports on Form 10-Q.

#### **Contacts at Pieris:**

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