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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 2, 2017

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**PIERIS PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in its Charter)

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Nevada  
(State of Incorporation)

001-37471  
(Commission  
File Number)

EIN 30-0784346  
(IRS Employer  
Identification No.)

255 State Street, 9<sup>th</sup> Floor  
Boston, MA 02109  
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: 857-246-8794

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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.

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

On May 2, 2017, Pieris Pharmaceuticals, Inc. (the “Company”) and wholly-owned subsidiaries Pieris Pharmaceuticals GmbH and Pieris Australia Pty Ltd. (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 AstraZeneca AB (“AstraZeneca”), pursuant to which the parties will advance several novel inhaled biologic molecules leveraging the unique properties of Pieris’ Anticalin® proteins, including Pieris’ lead inhaled drug candidate, PRS-060.

Under the Agreements, Pieris and AstraZeneca will pursue up to five therapeutic programs, including PRS-060, a first-in-class inhaled IL-4Ra receptor antagonist for the treatment of asthma. Pieris will receive \$57.5 million USD in up-front and near-term milestone payments, including \$45 million USD of up-front payments and \$12.5 million USD for the initiation of the PRS-060 Phase 1 trial. Pieris may receive development, regulatory and sales-based milestone payments not exceeding \$2.1 billion USD if all five programs are successfully commercialized. In addition, Pieris will be entitled to receive tiered royalties up to the mid-teens, depending on the product, on sales of products commercialized by AstraZeneca or royalties up to the high teens or a gross margin share on worldwide sales, determined by the level of investment to which Pieris commits, for any co-developed programs. For co-developed programs, the milestone payments are structured to provide Pieris with income in stages in order to contribute to the ensuing phases of development.

Pieris will be responsible for advancing PRS-060 into clinical trials in the second half of 2017 and will conduct a Phase 1 trial, with clinical development costs covered by AstraZeneca. The parties will collaborate thereafter to conduct a Phase 2a clinical trial in asthma patients, with AstraZeneca continuing to fund development costs. After completion of the Phase 2a trial, Pieris has the option to co-develop and subsequently co-commercialize the program in the United States with AstraZeneca. For the other four programs, Pieris will be responsible for the initial discovery of novel Anticalin proteins, after which AstraZeneca will take the lead on continued development. Pieris has the option to co-develop two of these programs beginning at a pre-defined preclinical stage and would also have the option to co-commercialize these programs in the United States, while AstraZeneca will be responsible for development and commercialization of the other programs worldwide.

The term of each Agreement ends upon the expiration of all of AstraZeneca’s payment obligations under such Agreement. The Collaboration Agreement may be terminated by AstraZeneca in its entirety for convenience beginning 12 months after its effective date upon 90 days’ notice or, if Pieris has obtained marketing approval for the marketing and sale of a product, 180 days’ notice. Each program may be terminated at AstraZeneca’s option; if any program is terminated by AstraZeneca, Pieris will have full rights to such program. The Collaboration Agreement may also be terminated by AstraZeneca or Pieris for material breach upon 180 days’ notice of a material breach (or 30 days with respect to payment breach), provided that the applicable party has not cured such breach by the permitted cure period (including an additional 180 days if the breach is not susceptible to cure during the initial 180-day period) and dispute resolution procedures specified in the applicable Agreement have been followed. The Collaboration Agreement may also be terminated due to the other party’s insolvency and may in certain instances be terminated on a product-by-product and/or country-by-country basis. Each party may also terminate the agreement if the other party challenges the validity of patents related to certain intellectual property licensed under the Agreements, subject to certain exceptions for infringement suits, acquisitions and newly-acquired licenses. The License Agreement will terminate upon termination of the Collaboration Agreement, on a product-by-product and/or country-by-country basis.

The Agreements are conditioned upon the expiration or early termination of the applicable waiting period (and any extension thereof) under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

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 Quarterly Report on Form 10-Q for the quarter ending June 30, 2017. 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.

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**Item 9.01 Financial Statements and Exhibits**

(d) *Exhibits.*

99.1 Press Release, dated May 3, 2017.

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**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: May 3, 2017

**PIERIS PHARMACEUTICALS, INC.**

By: /s/ Lance Thibault

Name: Lance Thibault

Title: Acting Chief Financial Officer

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**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release, dated May 3, 2017.

**PRESS RELEASE****Pieris Pharmaceuticals and AstraZeneca Collaborate to Develop and Commercialize Anticalin-Based Inhaled Treatments for Respiratory Diseases**

- Pieris to receive \$57.5 million USD in upfront and near-term milestone payments
- Pieris has the potential to receive development-dependent milestones and eventual commercial payments for all products not exceeding \$2.1 billion as well as tiered royalties
- For programs co-developed by Pieris, the Company will be entitled to receive increased royalties or a gross margin share on worldwide sales, dependent on the level of investment to which Pieris commits
- Pieris will host a conference call on Wednesday, May 3<sup>rd</sup> at 10am EDT to discuss the collaboration

**Boston, MA, May 3, 2017** – Pieris today announced a strategic collaboration in respiratory diseases with AstraZeneca to develop novel inhaled drugs that leverage Pieris' Anticalin® platform, including its lead preclinical drug candidate, PRS-060.

Anticalin molecules are engineered proteins which can mimic antibodies by binding to sites either on other proteins or on small molecules. They are smaller than monoclonal antibodies, offering the potential of direct delivery to the lung.

Under the collaboration, Pieris will be responsible for advancing its preclinical lead candidate, PRS-060, into Phase 1 clinical trials in 2017. PRS-060 is an Anticalin against interleukin-4 receptor alpha (IL-4Ra) with potential in asthma. AstraZeneca will fund all clinical development and subsequent commercialization programs and Pieris has the option of co-development and co-commercialization in the US from Phase 2a onwards. In addition, the parties will collaborate to progress four additional novel Anticalins against undisclosed targets for respiratory diseases with Pieris having the option to co-develop and co-commercialize in the US two of these programs.

Mene Pangalos, Executive Vice President, Innovative Medicines and Early Development Biotech Unit and Business Development, said: "At AstraZeneca, discovering and developing innovative new medicines to treat respiratory diseases is a key strategic priority. Our alliance with Pieris adds an important new modality to our respiratory portfolio and builds on our scientific expertise in inhaled formulation technologies. Pieris shares our passion for ground-breaking science and we look forward to working together to develop new, life-changing treatment options for patients."



Stephen Yoder, President and Chief Executive Officer of Pieris, said: “Our partnership with AstraZeneca accelerates the transformation of Pieris into a fully-integrated drug development and commercial organization, comprising two main pillars in immunology: respiratory diseases and immuno-oncology, each of which is now anchored by a major alliance. We recognize AstraZeneca’s unparalleled expertise in the development of inhaled drugs, which will maximize the potential of PRS-060 and other inhaled Anticalin molecules to become valuable assets for both companies.”

AstraZeneca will make an upfront and near term milestone payments to Pieris in the amount of \$57.5 million - \$45 million USD of upfront payments and \$12.5 million USD for the initiation of the PRS-060 Phase 1 trial. Pieris has the potential to receive development-dependent milestones and eventual commercial payments for all products not exceeding \$2.1 billion as well as tiered royalties on the sales of any potential products commercialized by AstraZeneca. For programs co-developed by Pieris, the Company stands to receive increased royalties or a gross margin share on worldwide sales equal, dependent on the level of investment to which Pieris commits.

Louis Matis, M.D., Senior Vice President and Chief Development Officer of Pieris, said: “AstraZeneca, a leading innovator in respiratory diseases with considerable expertise in the development of inhaled products, is the ideal partner to exploit the potential of our platform in respiratory diseases. Based on the limitations of many types of biologic molecules, direct delivery to the lungs via inhalation has been challenging to date for other classes of therapeutic proteins. Anticalin proteins have unique properties, not least of which is their size and stability, and show considerable promise for this route of delivery.”

The collaboration agreement is conditional upon the expiration or early termination of the applicable waiting period (and any extension thereof) under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

PRS-060, an Anticalin protein potently engaging IL-4Ra, is being developed for patients suffering from moderate to severe asthma, many of whom are not able to control their asthma well with currently available medications. In a large proportion of asthma patients, the Th2 pathway plays an important role. IL-4 and IL-13 are the main cytokines involved in Th2-mediated asthma. Both signal *via* IL-4Ra, making IL-4Ra a cornerstone intervention point. PRS-060 differentiates from antibody approaches through inhaled delivery directly into the lungs, potentially resulting in efficacy and safety benefits. The local delivery may allow for lower doses than systemically administered antibodies, potentially also resulting in a significant cost of goods advantage over those therapies. Pieris has demonstrated proof of concept in animals as well as feasibility for pulmonary delivery with PRS-060.

#### **Conference Call**

Pieris will host an investor conference call on Wednesday, May 3, 2017 at 10:00 AM (EDT) 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 #13661472.

#### **About Pieris Pharmaceuticals**

Pieris Pharmaceuticals (NASDAQ: PIRS) 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. Pieris has partnerships with Servier, ASKA, Roche, Sanofi, Daiichi Sankyo and Zydus. For more information visit [www.pieris.com](http://www.pieris.com).

#### **About AstraZeneca in Respiratory Disease**

Respiratory disease is one of AstraZeneca's main therapy areas, and we have a growing portfolio of medicines that reached more than 17 million patients in 2015. Our aim is to transform asthma and COPD treatment through inhaled combinations at the core of care, biologics for the unmet needs of specific patient populations, and scientific advancements in disease modification. We are building on a 40-year heritage in respiratory disease, and our capability in inhalation technology spans both pressurized metered-dose inhalers (pMDIs) and dry powder inhalers (DPIs), as well as our innovative Co-Suspension™ Delivery Technology. Our research is focused on four key biological pathways: eosinophilic disease, Th2-driven disease, epithelial-driven pathobiology and autoimmunity.

#### **About AstraZeneca**

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit [www.AstraZeneca.com](http://www.AstraZeneca.com) and follow us on Twitter [@AstraZeneca](https://twitter.com/AstraZeneca).

#### **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 and product development plans and timelines; the timing and progress of our studies and development of therapeutic programs; ability to receive research funding; our liquidity and ability to fund our future operations; our investments in our programs, including co-developed or co-commercialized programs; our ability to achieve certain milestones and receive future milestone or royalty payments; current or future partnerships; the potential benefits of our therapies; 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](http://www.sec.gov), including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and the Company's Quarterly Reports on Form 10-Q.

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