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): May 19, 2021

PIERIS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Nevada	001-37471	30-0784346
(State or other jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

225 State Street, 9th Floor Boston, MA	02109
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: 857-246-8998
N/A
(Former name or former address, if changed since last report.)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	PIRS	The Nasdaq Capital Market

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 1.01: Entry into a Material Definitive Agreement.

On May 19, 2021, Pieris Pharmaceuticals, Inc. and Pieris Pharmaceuticals GmbH (together, “Pieris” or the “Company”) and Genentech, Inc. (“Genentech”), entered into a Research Collaboration and License Agreement (the "Agreement"), to discover, develop and commercialize locally delivered respiratory and ophthalmology therapies that leverage Pieris’ proprietary Anticalin® technology.

Under the terms of the agreement, Pieris will receive $20 million in an upfront payment and may be eligible to receive up to approximately $1.5 billion in additional milestone payments across multiple programs, as well as tiered royalty payments on net sales at percentages ranging from the mid-single to low double-digits, subject to certain standard reductions and offsets. Pieris will be responsible for discovery research and early development of two initial programs, each of which is eligible for $11 million in preclinical milestones. Genentech has an option to expand the collaboration to encompass two additional programs with the payment of a $10 million fee per additional program. Genentech will be responsible for IND-enabling activities, clinical development, and commercialization of those programs. The collaboration does not include any of Pieris’ internal programs.

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 9 months from the effective date of the Agreement, by Genentech 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.

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 Quarterly Report on Form 10-Q for the quarter ending June 30, 2021. 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, Dated May 25, 2021.

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: May 25, 2021

/s/ Tom Bures

Tom Bures

Vice President, Finance

Pieris Pharmaceuticals Announces Respiratory and Ophthalmology Collaboration with Genentech

- **Pieris will receive $20 million as an upfront payment and is eligible to receive more than $1.4 billion in additional potential milestone payments plus royalties for commercialized programs**

- **Collaboration includes initial programs in respiratory disease and ophthalmology, with opportunity to nominate additional programs**

BOSTON, MA / ACCESSWIRE / May 25, 2021 / ***Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS)***, a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform for respiratory diseases, cancer, and other indications, today announced it has entered into a multi-program research collaboration and license agreement with Genentech, a member of the Roche Group, to discover, develop and commercialize locally delivered respiratory and ophthalmology therapies that leverage Pieris' proprietary Anticalin® technology.

The research collaboration will enable Pieris to combine its robust discovery engine with Genentech's targets, as well as its preclinical and clinical development expertise, to create novel therapies for the treatment of respiratory and ophthalmological diseases. These two focus areas of the collaboration are uniquely suited to the advantages offered by the small size of Anticalin proteins when delivered locally.

"We look forward to working closely with Genentech on the development of new inhaled and ophthalmological treatments based on the Anticalin platform. This collaboration further expands our partnered efforts in respiratory diseases and opens a new avenue for our Anticalin technology to potentially provide patient benefit through local biological effects. This is our second respiratory alliance with a major biopharma company, and we remain deeply committed to inhaled biologics, which have already shown benefit in the clinic. We also look forward to pursuing another local application of our technology in ophthalmology, where Genentech has extensive capabilities," said Stephen S. Yoder, President and Chief Executive Officer of Pieris.

"Genentech has a longstanding commitment to understanding the underlying biology of respiratory and ocular diseases and translating this expertise into treatments for patients," said James Sabry, M.D., Ph.D., Global Head of Pharma Partnering, Roche. "We are excited to partner with Pieris Pharmaceuticals to advance potential new therapies that we hope could make a significant difference in the lives of people who need them."

Under the terms of the agreement, Pieris will receive $20 million as an upfront payment and may be eligible to receive more than $1.4 billion in additional milestone payments across multiple programs, as well as tiered royalties for commercialized programs. Pieris will be responsible for discovery research and early preclinical development of the programs, and Genentech will be responsible for IND-enabling activities, clinical development, and commercialization of those programs. Genentech will also have the option to select additional targets in return for an option exercise fee. The collaboration does not include any of Pieris' internal programs.

About Pieris Pharmaceuticals*:*

Pieris is a clinical-stage biotechnology company that discovers and develops Anticalin protein-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes inhalable Anticalin proteins to treat respiratory diseases and immuno-oncology multi-specifics tailored for the tumor microenvironment. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies, including AstraZeneca, Seagen, and

Servier. Anticalin® is a registered trademark of Pieris. For more information, visit www.pieris.com.

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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, whether the research collaboration with Genentech will result in the creation of novel therapies for the treatment of respiratory and ophthalmological diseases; whether the Company will achieve any of the milestones or royalty payments provided for in the agreement with Genentech; whether the combination of cinrebafusp alfa with other therapies could address a high medical need in HER2 gastric cancer patients who do not respond to traditional HER2-targeted therapies; whether the effects of the combination of cinrebafusp alfa with other therapies seen in preclinical studies will be observed in clinical trials; whether data from patients enrolled to date will be sufficient to inform the recommended phase 2 dose for the Company's planned proof of concept study of cinrebafusp alfa in gastric cancer; the expected timing and potential outcomes of the reporting by the Company of key clinical data from its programs, references to novel technologies and methods and our business and product development plans, including the Company's cash resources, the advancement of our proprietary and co-development programs into and through the clinic and the expected timing for reporting data, making IND filings or achieving other milestones related to our programs, including PRS-060/AZD1402, cinrebafusp alfa, PRS-344, and PRS-352 and the expected timing of the initiation of the next stage of cinrebafusp alfa's development in gastric cancer. 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, including our ability to recruit and enroll patients in our studies; our ability to address the requests of the U.S. Food and Drug Administration; competition in the industry in which we operate; delays or disruptions due to COVID-19; 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 Securities and Exchange Commission available at www.sec.gov, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and the Company's Quarterly Reports on Form 10-Q.

Investor Relations Contact:

Pieris Pharmaceuticals, Inc.

Maria Kelman

Executive Director, Investor Relations

+1 857 362 9635

kelman@pieris.com