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): August 10, 2020

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	**02109**
Boston, MA	
(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 August 10, 2020, Pieris Pharmaceuticals, Inc. (“Pieris”) entered into a Clinical Trial Collaboration and Supply Agreement (the “Agreement”) with Eli Lilly and Company (“Lilly”) pursuant to which Pieris and Lilly will collaborate in a Phase 2 Clinical Study to determine the safety and efficacy of Pieris' PRS-343 in combination with the standard of care regimen for advanced or metastatic gastric cancer in the second line, ramucirumab (Cyramza®) and paclitaxel, for the second-line treatment of HER2+ gastric cancer (the “Study”).

Under the terms of the non-exclusive Agreement, Pieris shall sponsor the Study and Lilly shall supply Pieris with ramucirumab as well as provide input on certain clinical and regulatory aspects of the Study in exchange for jointly owning clinical data and inventions relating to the combination regimen that may arise from the Study. Any material changes to the protocol for the Study, and any changes relating to ramucirumab, shall require Lilly’s prior written consent, which shall not be unreasonably withheld, conditioned or delayed.

The Agreement shall expire upon completion of the parties’ contractual obligations. The Agreement may also be terminated (a) by either party for an uncured material breach by the other party upon 60 days’ notice, subject to a reasonable extension if such material breach requires more than 60 days to cure; (b) by either party in the event that the Study unreasonably affects patient safety, provided that the terminating party promptly notifies the other party and the other party is given the opportunity to propose modifications to the Study to address the safety issues; (c) by either party, following 15 days’ written notice, if regulatory action is taken preventing the terminating party from providing its compound or if the terminating party decides to discontinue development of its compound; (d) by either party, immediately upon written notice to the other party for breach by the other party of its material obligations under certain sections of the Agreement, or breach of certain of the other party's representations and warranties; and (e) by Lilly in the event of certain safety concerns related to the use of ramucirumab in the Study.

The foregoing description of the Agreement does not purport to be a complete description of all the terms of the Agreement 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 September 30, 2020. 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 August 10, 2020.

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: August 10, 2020

/s/ Tom Bures

Tom Bures

Vice President, Finance

PIERIS AND LILLY ENTER INTO A CLINICAL TRIAL COLLABORATION TO EVALUATE COMBINATION OF PRS-343 WITH RAMUCIRUMAB AND PACLITAXEL IN GASTRIC CANCER

BOSTON, MA, August 10, 2020 - ***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 that it has entered into a clinical trial collaboration and supply agreement with **Eli Lilly and Company** to evaluate the safety and efficacy of combining Pieris' PRS-343, a 4-1BB/HER2 bispecific for HER2-positive tumors, with Lilly's ramucirumab, a VEGFR2 antagonist FDA-approved for multiple types of solid tumors, and paclitaxel for the second-line treatment of patients with HER2-positive gastric cancer in a phase 2 study.

Under the terms of the agreement, Lilly will supply Pieris with ramucirumab for the study as well as collaborate on data from the trial. Pieris is working towards initiation of a phase 2 single-arm combination study for the second-line treatment of HER2-positive gastric cancer later this year.

"We have seen impressive single-agent activity in the phase 1 trial of PRS-343, including a complete response and many patients experiencing a clinical benefit, and believe there is a compelling biology and clinical rationale to adding PRS-343 to the current standard of care regimen for advanced or metastatic gastric cancer in the second line, ramucirumab and paclitaxel," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "Today's announcement further supports exploring this clinical rationale while managing costs efficiently."

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

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, the timing for, and outcome of, the additional in-use and compatibility study for PRS-343 as requested by the FDA; 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 PRS-343 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 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, PRS-343, PRS-344, and PRS-352 and the expected timing of the initiation of the next stage of PRS-343'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 FDA, including with respect to the additional in-use and compatibility study for PRS-343, and the resolution of the partial clinical hold relating to that drug candidate; 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 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, 2019 and the Company's Quarterly Reports on Form 10-Q.

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