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): July 20, 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 8.01: Other Events.

On July 20, 2020 Pieris Pharmaceuticals, Inc. issued a press release related to its drug candidate PRS-343. The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits.*

99.1 Press Release Dated July 20, 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: July 20, 2020

/s/ Tom Bures

Tom Bures

Vice President, Finance

PRESS RELEASE

PIERIS PHARMACEUTICALS ANNOUNCES PARTIAL CLINICAL HOLD ON PRS-343

- **FDA requested a confirmatory laboratory-based in-use and compatibility study before enrolling new patients**
- **Currently-enrolled patients may continue to receive PRS-343**
- **In its telephonic communication, FDA did not cite any adverse events in connection with its request**
- **Company reiterates intent to initiate planned phase 2 study of PRS-343 in HER2-positive gastric cancer later this year pending successful completion of the requested study**

BOSTON, MA, July 20, 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 its phase 1 studies of PRS-343 have been placed on partial clinical hold by the U.S. Food and Drug Administration (FDA) while Pieris conducts an additional in-use and compatibility study requested by the Agency. Currently-enrolled patients may continue to receive treatment, although no new patients can be enrolled until resolution of this partial hold.

The partial hold follows discussions with FDA regarding the Company's in-use study supporting the technical setup for clinical administration of PRS-343. Specifically, FDA has requested that Pieris conduct an additional in-use and compatibility study of PRS-343 with various infusion materials under specific conditions to confirm suitability of PRS-343 for administration in clinical settings. In its telephonic communication, the Agency did not cite any adverse events in connection with its request. In-use and compatibility studies are laboratory-based studies typically conducted to evaluate the impact of product handling on a drug candidate's behavior, including effects of dilution media, hold times, and adsorption to materials such as tubing and infusion bags before administration to patients. As part of the development of PRS-343, Pieris conducted in-use and compatibility studies prior to phase 1 and thereafter, the results of which were shared with the Agency.

Separately, the Company has received a written response from the Agency to its Type C meeting request related to the planned phase 2 proof of concept study of PRS-343 in combination with ramucirumab and paclitaxel. Based on this response, Pieris continues to believe it can initiate this clinical study later this year, pending successful completion of the requested in-use and compatibility study.

"We share FDA's commitment to product quality and will continue to engage with the Agency to initiate and complete the requested in-use and compatibility study with the highest priority," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "Pending satisfactory completion of this laboratory study, we remain committed to continuing the development of PRS-343, including the initiation of a phase 2 study in second-line gastric cancer in combination with the standard of care this year, as previously communicated. We also remain on track to present comprehensive data from both the monotherapy and atezolizumab combination phase 1 studies at a medical conference later this year."

About PRS-343:

PRS-343 is a 4-1BB/HER2 fusion protein comprising a 4-1BB-targeting Anticalin protein and a HER2-targeting antibody. The drug candidate is currently in development for the treatment of HER2-positive solid tumors. Ongoing phase 1 studies of PRS-343 include a monotherapy study and a combination study with atezolizumab. Based on encouraging initial results from both studies, which demonstrated clinical benefit and biomarker data indicative of a 4-1BB-driven mechanism of action, the Company is actively working towards initiating a phase 2 study of PRS-343 in combination with ramucirumab and paclitaxel for the treatment of HER2-positive gastric cancer in a second line setting later this year.

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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