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 14, 2022

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.)**

255 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 7.01 Regulation FD Disclosure.

On January 14, 2022, Pieris Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the first patient has been dosed in the phase 2 study of cinrebafusp alfa (PRS-343), a 4-1BB/HER2 Anticalin-based bispecific for the treatment of HER2-expressing gastric cancer. A copy of the press release issued by the Company is furnished hereto as Exhibit 99.1.

The information set forth under this "Item 7.01. Regulation FD Disclosure," including Exhibit 99.1 furnished hereto, shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

99.1 Press Release, dated January 14, 2022.

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: January 14, 2022

/s/ Tom Bures

Tom Bures

Chief Financial Officer

PRESS RELEASE

PIERIS PHARMACEUTICALS ANNOUNCES DOSING OF FIRST PATIENT IN PHASE 2 GASTRIC CANCER TRIAL OF 4-1BB/HER2 BISPECIFIC CINREBAFUSP ALFA

BOSTON, MA, January 14, 2022 - ***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 the first patient has been dosed in the phase 2 study of cinrebafusp alfa (PRS-343), a 4-1BB/HER2 Anticalin-based bispecific for the treatment of HER2-expressing gastric cancer. The two-arm, multicenter, open-label phase 2 study is evaluating the efficacy, safety, and tolerability of cinrebafusp alfa in combination with ramucirumab and paclitaxel in patients with HER2-high gastric cancer and in combination with tucatinib in patients with HER2-low gastric cancer.

Patients in the phase 2 study will receive a loading dose of 18 mg/kg in week one and three, followed by maintenance doses of 8 mg/kg (Q2W) for both arms in the study. The Company is targeting an ORR of at least 40% with meaningful durability in the HER2-low arm, for which it intends to present data later this year. In the HER2-high arm, the Company is targeting an ORR of at least 50% with meaningful durability. Pieris intends to present data for the HER2-high arm in 2023. Collaboration partners Lilly and Seagen will supply ramucirumab and tucatinib, respectively, under previously announced drug supply agreements.

"The dosing of the first patient in this next phase of development of cinrebafusp alfa marks an important milestone for patients afflicted by gastric cancer without adequate treatment options, and we look forward to further evaluating the potential of this drug," said Tim Demuth, M.D., Ph.D., Chief Medical Officer of Pieris. “We believe cinrebafusp alfa can provide differentiated treatment options for patients with gastric cancer via 4-1BB-mediated T-cell engagement, both in terms of efficacy and safety.”

About Cinrebafusp Alfa*:*

Cinrebafusp alfa (PRS-343) is a 4-1BB/HER2 fusion protein comprising 4-1BB-targeting Anticalin proteins and a HER2-targeting antibody. The drug candidate is currently in phase 2 development for the treatment of HER2-expressing solid tumors. In phase 1 studies, cinrebafusp alfa has shown an acceptable safety profile at all doses tested with no dose-limiting toxicities. The bispecific also showed a dose response and a 4-1BB-driven mechanism of action based on clinical benefit and pharmacodynamic correlates.

About Pieris Pharmaceuticals*:*

Pieris is a clinical-stage biotechnology company that combines leading protein engineering capabilities and deep understanding into molecular drivers of disease to develop medicines that drive local biology to produce superior clinical outcomes for patients. Our pipeline includes inhalable Anticalin proteins to treat respiratory diseases and locally-activated bispecifics for immuno-oncology. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by respiratory and immuno-oncology focused partnerships with leading pharmaceutical companies. 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, 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, the expected timing of the data from the phase 2 study of cinrebafusp alfa, whether the profile of PRS-060/AZD1402 in part 1a of the phase 2a study will be seen in part 2a of the study, the expected timing of completion of the phase 2a study and potential outcomes of the reporting by the Company of key clinical data from the phase 2a study, 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, and the potential success of the collaboration between Pieris

and AstraZeneca. 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; the fact that results of early-stage clinical trials may not be predictive of the results of later-stage clinical trials; 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.

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