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): November 1, 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 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 7.01 Regulation FD Disclosure.

On November 1, 2022, Pieris Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the first patient has been dosed in the phase 1 study of PRS-220, an oral inhaled Anticalin® protein targeting connective tissue growth factor for the treatment of idiopathic pulmonary fibrosis and other fibrotic diseases. 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 November 1, 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: November 1, 2022

/s/ Tom Bures
Tom Bures
Chief Financial Officer

PRESS RELEASE

PIERIS PHARMACEUTICALS ANNOUNCES DOSING OF FIRST SUBJECT IN PHASE 1 TRIAL OF INHALED CTGF INHIBITOR PRS-220

BOSTON, MA, November 1, 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 subject has been dosed in the phase 1 study of PRS-220, an oral inhaled Anticalin protein targeting connective tissue growth factor (CTGF) for the treatment of idiopathic pulmonary fibrosis (IPF) and other forms of fibrotic lung disease. The phase 1 dose escalation study will evaluate the safety, tolerability, and pharmacokinetics of PRS-220 in heathy volunteers.

IPF affects over three million patients worldwide and approximately 130,000 patients in the United States. Median survival is three to five years from the time of diagnosis, with standard of care conferring only modest benefit. CTGF, a protein localized in the extracellular matrix, is a driver of fibrotic tissue remodeling as a consequence of an aberrant wound healing process. Over-expression of this target in lung tissue is observed in patients suffering from IPF, and clinical data indicate inhibition of CTGF reduces the decline in lung function among these patients. Direct administration of PRS-220 to the lung via inhalation should achieve high local concentrations, and hence a more effective inhibition of CTGF than systemically administered interventions.

“The initiation of this trial is an important step in the development of PRS-220, a fully proprietary program that we believe has the potential to offer a meaningful improvement in the quality of life for patients suffering from this rare and, ultimately, terminal disease,” said Stephen S. Yoder, President and CEO of Pieris. “PRS-220 is the second inhaled respiratory program we have brought into the clinic, and we look forward to reporting the results from this study next year.”

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 potential for Pieris' development programs such as PRS-220 to address our core focus areas such as respiratory diseases; 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; the therapeutic potential of our Anticalin platform; our continued progress in the areas of co-stim bispecifics and inhaled therapeutics; and the advancement and funding of our developmental programs generally. Actual results could differ from those projected in any forward-looking statement due to numerous factors. Such factors include, among others, the amounts of anticipated funding actually received for our continued development programs and our actual reductions in spending as compared to anticipated cost reductions; 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; competition in the industry in which we operate; delays or disruptions due to COVID-19 or geopolitical issues, including the conflict in Ukraine; 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, 2021 and the Company's Quarterly Reports on Form 10-Q.

Investor Relations Contact:
Pieris Pharmaceuticals, Inc.
Maria Kelman
Executive Director, Investor Relations
+1 857 327 7631
kelman@pieris.com