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): June 21, 2023

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 Franklin Street, 26th Floor Boston, MA	**02110**
(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 2.02 Results of Operations and Financial Condition.

As of May 31, 2023, Pieris Pharmaceuticals, Inc.'s (the “Company”) certain unaudited financial results included a cash balance of $53.2 million.

The information set forth under this “Item 2.02. Results of Operations and Financial Condition,” furnished hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On June 21, 2023, the Company issued a press release announcing that partner AstraZeneca yesterday communicated to the Company its decision to discontinue and cease dosing in the ongoing clinical studies of elarekibep, an inhaled IL-4 receptor alpha inhibitor under development for the treatment of asthma. This decision was based on lung findings from a non-clinical 13-week GLP toxicology study with dry powder inhaler-formulated elarekibep, which are not a concern for the active clinical studies but do not support long-term use and progression to later-stage development. AstraZeneca's decision was made independent of any data from the Phase 2a study. The Company will expedite a review of the implications of the data and AstraZeneca's decision on the program and will review its overall corporate priorities prior to sharing a further update.

A copy of the press release issued by the Company is attached as Exhibit 99.1 to this report and is incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

99.1 Press Release, dated June 21, 2023.
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: June 21, 2023

/s/ Tom Bures
Tom Bures
Chief Financial Officer

Exhibit 99.1

June 21, 2023

Pieris Pharmaceuticals Announces AstraZeneca Discontinuation of Phase 2a Trial of Elarekibep (PRS-060/AZD1402) Due to New Non-Clinical Safety Findings From 13-week Toxicology Study

BOSTON, MA, June 21, 2023 – **Pieris Pharmaceuticals, Inc. (Nasdaq:PIRS)**, a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform for respiratory diseases and cancer indications, announced that partner AstraZeneca yesterday communicated to Pieris its decision to discontinue and cease dosing in the ongoing clinical studies of elarekibep, an inhaled IL-4 receptor alpha inhibitor under development for the treatment of asthma. This decision was based on lung findings from a non-clinical 13-week GLP toxicology study with dry powder inhaler-formulated elarekibep, which are not a concern for the active clinical studies but do not support long-term use and progression to later-stage development. AstraZeneca's decision was made independent of any data from the Phase 2a study. Pieris will expedite a review of the implications of the data and AstraZeneca's decision on the program and will review its overall corporate priorities prior to sharing a further update.

The 13-week non-human primate study included three active dose cohorts. AstraZeneca concluded that there were no clinical observations across any of the doses but that there were respiratory tract pathology findings. These findings included inflammation-mediated lung tissue damage, which did not appear to be dose related.

"We are disappointed with these non-clinical study results. Although elarekibep had begun enrolling in the efficacy portion of the Phase 2a study, later-stage development of this program requires supportive longer-term non-clinical toxicology data," stated Stephen Yoder, Pieris' President and CEO. "We will now reassess our priorities and communicate a corporate update as quickly as possible following a thorough review of our options. We have greatly valued the expertise and resources AstraZeneca committed to elarekibep and are grateful to the many physicians, patients and caregivers who have supported this study."

***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 strong 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 including elarekibep to address our 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, including elarekibep; the therapeutic potential, safety profile, and market opportunity of our Anticalin platform; our continued progress in the area 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, our ability to satisfy any closing conditions for the financing; 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; including in collaboration with other parties, 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; the fact that data and results from clinical studies may not necessarily be indicative of future results; 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, or the SEC, available at www.sec.gov, including, without limitation, the Company's most recent Annual Report on Form 10-K, the Company's Quarterly Reports on Form 10-Q, and subsequent filings with the SEC.

Investor Relations Contact:

Pieris Pharmaceuticals, Inc.
Investors@pieris.com or

Joe Patneaude
Kendall Investor Relations
Joe@kendallir.com