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 3, 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.)**

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 January 3, 2022, the Company issued a press release announcing the successful completion of the sponsor safety review of part 1a of the multi-center, placebo-controlled phase 2a study of dry powder inhaler-formulated PRS-060/AZD14022. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits.*

99.1 Press Release, Dated January 3, 2022.

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 3, 2022

/s/ Tom Bures

Tom Bures

Chief Financial Officer

PRESS RELEASE

PIERIS PHARMACEUTICALS ANNOUNCES SUCCESSFUL COMPLETION OF SAFETY MILESTONE AND INITIATION OF EFFICACY PORTION OF PHASE 2A TRIAL OF PRS-060/AZD1402

BOSTON, MA, January 3, 2021 - ***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 the successful completion of the sponsor safety review of part 1a of the multi-center, placebo-controlled phase 2a study of dry powder inhaler-formulated PRS-060/AZD1402. PRS-060/AZD1402 is an IL-4 receptor alpha inhibitor under development in collaboration with AstraZeneca for the treatment of moderate-to-severe asthma. Completion of part 1a allows the start of enrollment for part 2a (efficacy of the low and medium doses) and part 1b (safety of the high dose) of the study.

In part 1a of the study, 31 asthma patients, controlled on standard of care (medium dose inhaled corticosteroids (ICS) with long-acting beta agonists (LABA)), received PRS-060/AZD1402 twice daily over four weeks to establish the safety profile and pharmacokinetics of the dry powder formulation of PRS-060/AZD1402. The safety review following completion of part 1a included an evaluation, compared to placebo, of the incidence of adverse events, changes in laboratory markers (immuno-biomarkers, clinical chemistry, and hematology), and forced expiratory volume in one second (FEV1). AstraZeneca is now expected to begin enrollment of part 2a of the study to evaluate efficacy, safety, and pharmacokinetics of PRS-060/AZD1402 administered twice daily to asthma patients, uncontrolled on medium dose ICS/LABA, that have a blood eosinophil count of ≥ 150 cells/μL and FeNO ≥ 25 ppb in two active arms and a placebo arm. Following a four-week run-in period, patients will be dosed and monitored over four weeks. FEV1 improvement compared to placebo will be the primary endpoint in this portion of the study. AstraZeneca is also now expected to begin enrollment of part 1b of the study to evaluate the safety of the high dose in asthma patients controlled on standard of care who will receive PRS-060/AZD1402 twice daily over four weeks. Upon completion of the phase 2a study and availability of topline data, which Pieris aims to announce this year, the Company will have 30 days to opt into co-development of the program with AstraZeneca.

“We are excited about the progression into the efficacy portion of the study of PRS-060/AZD1402. We believe this drug candidate has the potential to expand the access of asthmatics worldwide to highly effective therapies,” said Stephen S. Yoder, President and Chief Executive Officer of Pieris. “The successful completion of the phase 2a study would serve as a key value inflection point in the development of this large market opportunity program and inform our decision to co-develop PRS-060/AZD1402 alongside AstraZeneca.”

About PRS-060/AZD1402*:*

PRS-060/AZD1402 is Pieris’ lead respiratory Anticalin®-based drug candidate, being developed in collaboration with AstraZeneca. PRS-060/AZD1402 blocks the IL-4Rα immunoreceptor, inhibiting small IL-4 and IL-13 proteins that drive a cascade of inflammatory responses in the lungs.

The small size and stability of PRS-060/AZD1402 allow it to be inhaled directly into the lungs, rather than injected, potentially achieving the same benefits as systemic treatments, but with lower doses and fewer side effects. Phase 1 trials of PRS-060/AZD1402 have shown significantly reduced levels of fractional exhaled nitric oxide (FeNO), a biomarker of lung inflammation, in patients with mild asthma as shown in poster PA309 of the 2019 European Respiratory Society International Congress, October 1, 2019.

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, whether the benefits of PRS-060/AZD1402 in treating moderate-to-severe asthma demonstrated 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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