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): September 20, 2019

PIERIS PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Nevada	**001-37471**	**EIN 30-0784346**
(State or other jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

225 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 September 20, 2019, Pieris Pharmaceuticals, Inc.'s abstracts related to the phase 1 single and multiple ascending dose studies of PRS-060 were released for the European Respiratory Society 2019 International Congress. The abstracts are furnished as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. In addition to the PRS-060 single and multiple ascending dose study presentations, Professor Gary Anderson will give a talk at the European Respiratory Society 2019 International Congress entitled “Advances in treatment of complex lung disease: will targeted therapy with anticalins be clinically applied in the near future?”.

The information set forth under this “Item 7.01. Regulation FD Disclosure,” including Exhibit 99.1 attached 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 PRS-060 Single Ascending Dose Study Abstract, Dated September 20, 2019.

99.1 PRS-060 Multiple Ascending Dose Study Abstract, Dated September 20, 2019.

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: September 23, 2019

/s/ Tom Bures

Tom Bures

Vice President, Finance

Phase 1 evaluation of the inhaled IL-4Ra antagonist, AZD1402/PRS-060, a potent and selective blocker of IL-4Ra

Ingmar Bruns, Mary Fitzgerald, Katerina Pardali, Gardiner Philip, Keeling David, Axelsson Lena, Jiang Fanyi, Lickliter Jason, Close David

AZD1402/PRS-060 is a novel inhaled Anticalin® molecule that antagonizes the IL-4 receptor alpha (IL-4Ra). A first-in-human study in healthy subjects was conducted to assess the safety, tolerability and pharmacokinetics (PK) of inhaled single ascending doses and intravenous infusion (IV) doses. In this study (NCT03384290), the drug was administered by nebulized oral inhalation at delivered doses between 0.1mg and 160mg (corresponding to device doses between 0.25mg and 400mg) or intravenous infusion (IV) at 1mg and 2mg. AZD1402/PRS-060 was found to be safe and well tolerated at all dose levels via both routes of administration and no serious adverse events were reported and no anti-drug antibodies were detected. Systemic, dose-dependent exposure was observed after inhaled delivered doses ≥8mg. Inhaled PK showed slow and prolonged absorption into the systemic circulation. Clearance and volume of distribution values after IV doses were indicative of clearance by renal filtration and a low tissue distribution. Target engagement, as assessed by inhibition of systemic STAT6 phosphorylation was dose-dependent and closely aligned with systemic exposure of the drug. Near complete and sustained inhibition of pSTAT6 was observed at higher inhaled doses. In the ongoing MAD study in mild asthmatics (NCT03574805), systemic target engagement (pSTAT6) will be compared with lung target engagement, assessed by measuring fractional nitric oxide in exhaled breath. This will help set inhaled doses for future studies of this first-in-class inhaled Anticalin molecule. The overall profile of the drug demonstrates its suitability for development as an inhaled drug for the treatment of asthma.

Late Breaking Abstract - Multiple ascending dose study of the inhaled IL-4Ra antagonist, AZD1402/PRS-060, in mild asthmatics demonstrates robust FeNO reduction and a promising clinical profile for the treatment of asthma

Ingmar Bruns, Mary Fitzgerald, George Mensing, Mei Tsung, Katerina Pardali, Philip Gardiner, David Keeling, Lena Axelsson, Marita Olsson, Cyrus Ghobadi, Oscar Walsh, Kristi Mclendon, Nicholas Farinola, Lara Hatchuel, David Close

AZD1402/PRS-060 is a novel inhaled Anticalin® molecule antagonizing IL-4Ra. A multiple ascending dose clinical study (NCT03574805) was conducted in mild asthmatics (fractional exhaled nitric oxide (FeNO) levels ≥ 35ppb), to assess the safety, tolerability, pharmacokinetics and pulmonary and systemic IL-4Ra target engagement of AZD1402/PRS-060. The drug candidate was administered by nebulized oral inhalation at delivered doses between 2 and 20mg, twice daily for 9 days with one dose on day 10. All doses of AZD1402/PRS-060 were found to be safe and well tolerated; no serious adverse events were observed. Lung target engagement was determined by reduction of FeNO levels and systemic target engagement was determined ex vivo by inhibition of IL-4-stimulated signal transducer and activator of transcription 6 (STAT6) phosphorylation in whole blood.

Significant and pronounced (≥25%) inhibition of FeNO was observed at all doses, including the 2mg delivered dose, where no systemic target engagement and minimal systemic exposure was observed. This suggests that local target engagement by the drug is sufficient to reduce airway inflammation, as measured by FeNO. The onset of FeNO reduction was rapid (after a single dose) and the maximum effect (day 4-5) vs placebo was sustained until dosing completion. Systemic target engagement was dose-dependent and closely aligned with systemic exposure of the drug. Pulmonary target engagement as shown by a substantial reduction in FeNO and the overall profile of the drug demonstrates its suitability for continued development as an inhaled therapy for asthma.