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): April 1, 2019

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))

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 April 1, 2019, Pieris Pharmaceuticals, Inc.'s 2019 American Thoracic Society International Conference abstract related to the phase 1 single ascending dose study of PRS-060 was released. The abstract is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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 Conference Abstract, Dated April 1, 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: April 1, 2019

/s/ Allan Reine

Allan Reine

Chief Financial Officer

ATS INTERNATIONAL CONFERENCE
May 17-May 22, 2019
dallas tx

(https://www.thoracic.org/)
Session D101 - CLINICAL AND TRANSLATIONAL STUDIES IN ASTHMA AND COPD

A7476 / 524 - First-in-Human Data for the Inhaled IL-4Ra Antagonist, AZD1402/PRS-060, Reveals a Promising Clinical Profile for the Treatment of Asthma

May 22, 2019, 1:30 PM - 3:30 PM | Room D222-D224 (Level 2), KBHCCD

Participant

I. Bruns[1], M. Fitzgerald[2], K. Pardali[3], P. Gardiner[4], D. Keeling[5], L. Axelsson[4], F. Jiang[5], J. Lickliter[6], D. Close[7]; [1]Pieris Inc, BOSTON, MA, United States, [2]Pieris Pharmaceuticals GmbH, Freising, Germany, [3]Respiratory Inflammation and Autoimmunity IMED unit, AstraZeneca, Mölndal, Sweden, [4]Respiratory, Inflammation and Autoimmunity, Early Clinical Development, AstraZeneca, Gothenburg, Sweden, [5]Respiratory, Inflammation and Autoimmunity, IMED Biotech Unit, AstraZeneca, Gothenburg, Sweden, [6]Nucleus Network Pty Ltd, Melbourne, Australia, [7]Respiratory, Inflammation and Autoimmunity, Early Clinical Development, AstraZeneca, Royston, United Kingdom.

Abstract

Rationale

AZD1402/PRS-060 is the first treatment of its type for asthma. This novel Anticalin® molecule antagonizes the IL-4 receptor alpha (IL-4Rα) and is designed for inhalation. Anticalins® are derived from endogenous low-molecular weight human tear lipocalin proteins. This 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. Following inhalation of AZD1402/PRS-060, systemic target engagement was determined by inhibition of IL-4 stimulated STAT6 phosphorylation (pSTAT6).

Methods

In a placebo-controlled single ascending dose study (NCT03384290), AZD1402/PRS-060 was administered by nebulized oral inhalation to seven cohorts at delivered doses between 0.1mg and 160mg (corresponding to nebulized doses between 0.25mg and 400mg) or intravenous infusion (IV) to two cohorts at 1mg and 2mg. Safety and tolerability were assessed, levels in plasma and urine were analyzed, and PK parameters determined. Production of anti-AZD1402/PRS-060 antibodies were monitored. To determine systemic target engagement a real-time whole blood ex-vivo assay was established utilizing flow cytometry, assessing AZD1402/PRS-060-mediated inhibition of IL-4 stimulated STAT6 phosphorylation (pSTAT6) in peripheral CD3+ T cells.

Results

No serious adverse events were reported; AZD1402/PRS-060 was found to be safe and well tolerated at all dose levels via both routes of administration.

No anti-AZD1402/PRS-060 antibodies were detected.

Systemic exposure was observed after inhaled delivered doses ≥8mg with a dose-dependent increase.

The PK profiles showed slow and prolonged absorption into the systemic circulation (T_{max} around 5 hours) after inhalation.

Clearance and volume of distribution values after IV doses were indicative of clearance by renal filtration and a low tissue distribution. Absolute pulmonary bioavailability was determined to be approximately 10%.

Inhibition of systemic pSTAT6 was dose-dependent and closely aligned with systemic exposure of AZD1402/PRS-060. Near complete and sustained inhibition was observed at higher inhaled doses (Figure 1).

Conclusion

The novel IL-4Rα antagonist, AZD1402/PRS-060, was safe and well tolerated when given as single inhaled or IV

doses to healthy subjects. Demonstration of its retained systemic target engagement following nebulization indicates its stability and suitability for development as an inhaled drug for the treatment of asthma.
These systemic target engagement (pSTAT6) data will be compared with local, lung target engagement from the ongoing multiple ascending dose study in mild asthmatics (NCT03574805), where inflammation will be evaluated

by measuring fractional nitric oxide in exhaled breath (FeNO). This will help determine the inhaled dose levels for evaluation in future studies of this first-in-class inhaled Anticalin molecule.

Figure 1:
Systemic pSTAT6 following inhalation of AZD1402/PRS-060