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 5, 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 November 5, 2019, Pieris Pharmaceuticals, Inc.'s abstract related to the phase 1 dose escalation study of PRS-343 was released for The Society for Immunotherapy of Cancer's (SITC) 34th Annual Meeting. 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 PRS-343 Phase 1 Dose Escalation Study Abstract, Dated November 5, 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: November 5, 2019

/s/ Tom Bures

Tom Bures

Vice President, Finance

A Phase 1 Dose Escalation Study of PRS-343, a HER2/4-1BB Bispecific Molecule, in Patients with HER2-positive Malignancies

Sarina A. Piha-Paul, MD, MD Anderson Cancer Center, Johanna Bendell, MD, Anthony Tolcher, Sara Hurvitz, MD, Amita Patnaik, MD FRCP(C), Rachna T. Shroff, Paula R. Pohlmann, Markus Zettl, Noah M. Hahn, MD, Anuradha Krishnamurthy, MD, Manuela Duerr, Jian Mei, Kayti Aviano, Rushdia Z. Yusuf, MD, MPH, Louis Matis, MD, Shane Olwill, PhD, Ingmar Bruns, Geoffrey Y. Ku

Background

Anticalin® proteins are recombinantly engineered human proteins based on lipocalins. PRS-343 is a first-in-class bispecific antibody-Anticalin fusion protein targeting the oncogenic tumor antigen HER2 and the costimulatory immune receptor 4-1BB on T and other immune cells. Here, we report the results of a phase 1 single-agent dose escalation trial in patients with HER2+ solid tumors.

Methods

PRS-343 has been evaluated in sequential dose cohorts from 0.0005 to 8 mg/kg i.v. Doses were administered Q3W and the 8 mg/kg dose was also given Q2W. An accelerated titration design was utilized for the initial dose escalation followed by a modified 3+3 design and the option to back-fill cohorts. Dose-limiting toxicities (DLTs) were reported during the first cycle of each schedule. The primary study objectives include the safety profile and RP2D of PRS-343. Secondary objectives include ORR and DCR, PD biomarker response and PK profile. PD response was assessed in tumor biopsies (CD8+ T cell IHC) pre- and post- PRS-343 treatment.

Results

51 patients (median age 61.2 years, 61% female, 82% caucasian, 57% with more than three lines of prior therapy) with a variety of solid tumor indications [gastric/GEJ (n=19); BC (n=12); gynecological cancer (n=6); CRC (n=5); BTC (n=4); UC (n=2); melanoma, pancreatic and salivary duct (n=1 each)] have been treated with PRS-343. Based on pharmacokinetic analyses and observed kinetics of the CD8+ T cell expansion post-treatment, the low end of the active dose range is considered 2.5 mg/kg. 19 patients treated at active dose levels before the data cut-off on 09-06-2019 were evaluable for response [DCR 58% (11% confirmed PR) as per RECIST 1.1]. At the active doses, we observed significant and pronounced post-treatment expansion of CD8+ T cells particularly in the tumor nests, consistent with the MoA of PRS-343, while there was no increase in the doses below 2.5mg/kg. The post-treatment expansion of CD8+ T cells was more pronounced in patients with a confirmed PR or prolonged SD. PRS-343 was very well tolerated, with no SAEs reported. The most frequent TRAEs were fatigue (9%), chills (6%) and diarrhea (5%) of mild to moderate severity. None qualified as a DLT.

Conclusions

PRS-343 is the first molecule of its kind to demonstrate encouraging evidence of safety and clinical benefit with a correlative PD effect in a heavily pre-treated population. These initial data suggest that PRS-343, the first 4-1BB bispecific to enter clinical development, merits further investigation in clinical trials.

Trial Registration

NCT03330561