

**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): March 12, 2019

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

Nevada
(State of
Incorporation)

001-37471
(Commission
File Number)

EIN 30-0784346
(IRS Employer
Identification No.)

**255 State Street, 9th Floor
Boston, MA 02109
United States**
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: 857-246-8998

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 2.02 Results of Operations and Financial Condition.

On March 12, 2019, Pieris Pharmaceuticals, Inc. (the “Company”) issued a press release announcing certain financial results for the fiscal year ended December 31, 2018. A copy of the press release issued by the Company is furnished as Exhibit 99.1 to this report.

The information set forth under this “Item 2.02. Results of Operations and Financial Condition,” including the exhibit attached 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 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

99.1 [Press release announcing 2018 year-end cash position and providing corporate update, dated March 12, 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: March 12, 2019

/s/ Allan Reine

Allan Reine

Chief Financial Officer



PRESS RELEASE

PIERIS PHARMACEUTICALS REPORTS 2018 YEAR-END CASH POSITION AND PROVIDES CORPORATE UPDATE

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON
TUESDAY, MARCH 12, 2019 AT 8:00 AM EDT

BOSTON, MA, March 12, 2019 - 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 reported its cash position for the fiscal year ended December 31, 2018 and provided an update on the Company's recent and future developments.

"2018 was an important year for the development of our two core franchises: respiratory diseases and immuno-oncology. On the respiratory front, we announced that PRS-060, an inhaled IL-4 receptor alpha antagonist for moderate-to-severe asthma that we are developing with AstraZeneca and our first respiratory program to enter the clinic, was safe and well-tolerated in healthy volunteers in a single ascending dose phase 1 study. We also initiated a multiple ascending dose phase 1 study of PRS-060 in mild asthmatics, in addition to launching discovery efforts for two proprietary respiratory programs and two additional respiratory programs as part of the AstraZeneca collaboration. On the immuno-oncology front, we continue to enroll and dose patients in the phase 1 dose-escalation study of PRS-343, a 4-1BB/HER2 bispecific for HER2-positive solid tumors, and the phase 1 combination study of PRS-343 with atezolizumab. We also advanced PRS-344, a PD-L1/4-1BB bispecific drug candidate we are developing with Servier, into IND-enabling studies and plan to file an IND application for that program later this year," said Stephen S. Yoder, President and CEO of Pieris. "We believe that the tireless effort of our team and partners across our clinical and preclinical pipeline last year has created an opportunity for many catalysts this year."

- **PRS-060:** Pieris continues to enroll subjects with mild asthma and elevated levels of fractional exhaled nitric oxide (FeNO) in a multiple ascending dose phase 1 study of PRS-060, an inhaled IL-4 receptor alpha antagonist for moderate-to-severe asthma. This study is evaluating the safety, tolerability and FeNO-reducing potential of PRS-060 versus placebo. The data from the PRS-060 phase 1 studies will be presented at upcoming medical meetings, including detailed data from the PRS-060 phase 1 single-ascending dose study, for which the Company reported topline data last year. PRS-060 is the lead candidate in Pieris' respiratory collaboration with AstraZeneca. Pieris is sponsoring the phase 1 studies and AstraZeneca is funding the costs. Assuming successful completion of the ongoing phase 1 study, AstraZeneca would sponsor and fund the phase 2a study, after which Pieris will have options to co-develop and, subsequently, to co-commercialize the drug candidate.
- **Respiratory Pipeline:** Pieris initiated an additional discovery-stage program in its alliance with AstraZeneca in the fourth quarter, bringing the total number of active programs to three; AstraZeneca may initiate up to two additional programs within the alliance. The Company also continues to advance the two proprietary discovery-stage respiratory programs initiated last year and intends to initiate additional proprietary respiratory programs in 2019.
- **PRS-343:** Pieris continues to enroll and treat patients in a phase 1 dose-escalation study of PRS-343, a 4-1BB/HER2 bispecific for HER2-positive solid tumors, and intends to report comprehensive data from the study later this year. The Company also continues to enroll the dose-escalation phase 1 study of PRS-343 in combination with atezolizumab and intends to report data from this trial later this year.
- **PRS-344:** Pieris has exercised its opt-in right to co-develop and retain U.S. rights for PRS-344, a PD-L1/4-1BB antibody-Anticalin bispecific molecule, and achieved two preclinical milestones as part of the development of the drug candidate, receiving milestone payments totaling €2.0 million from Servier. In collaboration with Servier, Pieris plans to file an IND application for the candidate this year. PRS-344 is one of five bispecific programs that Pieris is developing as part of its immuno-oncology alliance with Servier and is the first program within the alliance scheduled to enter clinical development.
- **Seattle Genetics Collaboration:** Pieris has generated and characterized the first tumor-targeting bispecific for further evaluation and development by Seattle Genetics as part of the companies' three-program immuno-oncology collaboration.
- **PRS-080:** Pieris has completed dosing all patients in the phase 2a multiple ascending dose study of PRS-080, a half-life-optimized hepcidin antagonist for anemia. This study is intended to evaluate the safety, tolerability, and pharmacological activity of 5 once-weekly doses of PRS-080 as well as the effect of repeated dosing on hemoglobin levels in this patient population. Pieris intends to present the full data set from this study in the first half of 2019. In addition, following delivery of a final study report, ASKA will decide whether to exercise its option to develop and commercialize PRS-080 in Japan and other Asian territories.
- **Cash Position:** Cash, cash equivalents and investments totaled \$128.1 million as of December 31, 2018, compared to a cash, cash equivalents and investments balance of \$82.6 million as of December 31, 2017. The increase was driven primarily by the \$47.2 million in net proceeds from the Company's February 2018 equity financing, the \$30.0 million in upfront payments received as part of the

Seattle Genetics immuno-oncology collaboration, and the \$12.5 million milestone payment from AstraZeneca that was triggered during the fourth quarter of 2017 and received during the first quarter of 2018.

- **Additional Financials:** Our 2018 full-year audited financials will be released with our Annual Report on Form 10-K, expected to be filed by Monday, March 18, 2019.

Conference Call:

Pieris management will host a conference call beginning at 8:00 AM Eastern Daylight Time on Tuesday, March 12, 2019, to provide a corporate update. Individuals can join the call by dialing +1-877-407-8920 (US & Canada) or +1-412-902-1010 (International). An archived replay of the call will be available by dialing +1-877-660-6853 (US & Canada) or +1-201-612-7415 (International) and providing the Conference ID #: 13661472.

About Pieris Pharmaceuticals:

Pieris is a clinical-stage biotechnology company that discovers and develops Anticalin protein-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes inhalable Anticalin proteins to treat respiratory diseases, immuno-oncology multi-specifics tailored for the tumor microenvironment, and a half-life-optimized Anticalin protein to treat anemia. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin[®] is a registered trademark of Pieris. For more information, visit www.pieris.com.

Forward Looking Statement:

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the expected timing of the filing of our Annual Report on Form 10-K including our audited financials, 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 or making IND filings related to our programs, and partnering prospects for any such programs. 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 FDA; competition in the industry in which we operate 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 SEC available at www.sec.gov, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and the Company's Quarterly Reports on Form 10-Q.

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