

**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): August 1, 2019

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

Nevada
(State or other jurisdiction of
Incorporation)

001-37471
(Commission
File Number)

EIN 30-0784346
(IRS Employer
Identification No.)

225 State Street, 9th Floor
Boston, MA
(Address of principal executive offices)

02109
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 2.02 Results of Operations and Financial Condition.

On August 1, 2019, Pieris Pharmaceuticals, Inc. (the “Company”) issued a press release announcing certain financial results for the fiscal quarter ended June 30, 2019. 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 financial results for the quarter ended June 30, 2019, dated August 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: August 1, 2019

/s/ Allan Reine

Allan Reine

Chief Financial Officer

PIERIS PHARMACEUTICALS REPORTS SECOND QUARTER 2019 CASH POSITION AND PROVIDES CORPORATE UPDATE

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON
THURSDAY, AUGUST 1, 2019 AT 8:00 AM EDT

BOSTON, MA, August 1, 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 second quarter of 2019 ended June 30, 2019, and provided an update on the Company's recent and future developments.

"In the first half of 2019, we made significant progress on our clinical milestones, and we expect that momentum to build into the end of the year," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "Last quarter, we presented two clinical data sets, including data from the phase 1 single ascending dose study of PRS-060, an inhaled IL-4 receptor alpha antagonist for moderate-to-severe asthma that was found to be safe and well-tolerated in the study and demonstrated favorable pharmacokinetics and robust target engagement. Looking ahead, we are pleased to announce that we will present data from the phase 1 multiple ascending dose study of that candidate, including the drug's FeNO-reducing potential versus placebo, at the European Respiratory Society International Congress this fall. We are also pleased to announce that we plan to present data from the phase 1 dose-escalation study of PRS-343, a 4-1BB/HER2 bispecific for HER2-positive solid tumors, at a medical meeting later this year."

- **PRS-060:** Pieris will present detailed data from the ongoing phase 1 multiple ascending dose study of PRS-060, an inhaled IL-4 receptor alpha antagonist for moderate-to-severe asthma, at the 2019 European Respiratory Society International Congress on October 1, 2019. This study is evaluating the safety, tolerability, and potential of PRS-060 to reduce fractional exhaled nitric oxide (FeNO) versus placebo in patients with mild asthma and elevated levels of FeNO. The Company presented data from the phase 1 single ascending dose study of PRS-060 at the 2019 American Thoracic Society International Conference earlier this year. In that study, PRS-060 was found to be safe and well-tolerated in 54 healthy volunteers, in addition to demonstrating favorable pharmacokinetics and robust target engagement. Upon completion of a phase 2a study sponsored and funded by AstraZeneca, Pieris will have separate options to co-develop and, subsequently, to co-commercialize the drug candidate. PRS-060 is the lead candidate in Pieris' five-program respiratory collaboration with AstraZeneca.
- **Respiratory Pipeline:** Pieris initiated an additional discovery-stage respiratory program in its alliance with AstraZeneca, bringing the total number of active programs to four; AstraZeneca may initiate one additional program within the alliance. Pieris also initiated an additional proprietary respiratory discovery-stage program and continues to advance the two proprietary discovery-stage programs it initiated last year.
- **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 plans to report comprehensive data from the study at a medical meeting 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 the study later this year.

- **Immuno-Oncology Pipeline:** Pieris plans to file an IND application for PRS-344, a 4-1BB/PD-L1 bispecific the Company is developing as part of its immuno-oncology collaboration with Servier, later this year. Pieris holds exclusive commercialization rights in the U.S. for PRS-344 and will receive royalties on ex-U.S. sales for this program.
- **PRS-080:** Pieris presented data from the phase 2a study of PRS-080, a half-life-optimized hepcidin antagonist for anemia, at the 24th European Hematology Association Congress. In that study, PRS-080 was safe and well-tolerated, potently inhibited hepcidin, yielded robust iron mobilization, and increased transferrin saturation. At 8mg/kg, there was preliminary evidence of hemoglobin increase in patients treated with PRS-080. ASKA Pharmaceutical Co. currently has an exclusive option for PRS-080 for Japan and other Asian territories. Following delivery of a final study report, ASKA will decide whether to exercise its option to develop and commercialize PRS-080 in those territories.
- **Board Appointments:** Pieris appointed Dr. Maya Said to the Company's Board of Directors. Dr. Said is the founder and Chief Executive Officer of Outcomes4Me, a health technology company focused on providing patients diagnosed with cancer and other chronic life altering diseases with personalized treatment options as well as outcomes information. Her prior experience includes positions at Novartis, where she served as Senior Vice President, Global Head of Oncology Policy & Market Access, and at Sanofi, where she served as Vice President, Head of Strategy, Science Policy & External Innovation, Global R&D.
- **Cash Position:** Cash, cash equivalents and investments totaled \$99.7 million as of June 30, 2019, compared to a cash, cash equivalents and investments balance of \$128.1 million as of December 31, 2018.
- **Additional Financials:** Our second quarter 2019 financials will be released with our 10-Q, expected to be filed by Friday, August 9, 2019.

Conference Call:

Pieris management will host a conference call beginning at 8:00 AM Eastern Daylight Time on Thursday, August 1, 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

trademark of P1010. For more information, visit www.p1010.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, 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, the expected timing of filing of our Quarterly Report on Form 10-Q, including our unaudited 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, 2018 and the Company's Quarterly Reports on Form 10-Q.

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