# 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): May 10, 2018

# 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)

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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.  $\Box$ 

#### Item 2.02 Results of Operations and Financial Condition.

On May 10, 2018, Pieris Pharmaceuticals, Inc. (the "Company") issued a press release announcing certain financial results for the fiscal quarter ended March 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 financial results for the quarter ended March 31, 2018, dated May 10, 2018.

#### 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: May 10, 2018

/s/ Allan Reine

Allan Reine Chief Financial Officer

#### PRESS RELEASE

#### PIERIS PHARMACEUTICALS REPORTS FIRST QUARTER 2018 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

#### COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON THURSDAY, MAY 10, 2018 AT 8:00 AM EDT

BOSTON, MA, May 10, 2018 – Pieris Pharmaceuticals, Inc. (NASDAQ:PIRS), a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin<sup>®</sup> technology platform for cancer, respiratory and other diseases, today reported financial results for the first quarter of 2018 ended March 31, 2018, and provided an update on the Company's recent and future developments.

"The first quarter of 2018 was an instrumental one for Pieris, both in advancing our clinical programs and in laying the groundwork for future company growth," said Stephen S. Yoder, President and CEO of Pieris. "We announced a collaboration with Seattle Genetics, strengthening our commitment to building a strong oncology portfolio and forging alliances with other companies on the cutting-edge of cancer research. We also completed an equity raise totaling \$47.2 million in net proceeds, allowing for continued value creation through the expansion of our product pipeline and acceleration of IND filings within our immuno-oncology franchise. We are pleased to report that the pace of enrollment for the PRS-343, PRS-060 and PRS-080 trials is healthy, and we are looking forward to reporting data for all three programs in the second half of this year."

- PRS-343: Enrollment is progressing on schedule in the Phase I open-label dose-escalation study for PRS-343, a tumor-targeted 4-1BB-based immuno-oncology (IO) bispecific, which the Company initiated in 2017. This program represents the first bispecific T cell costimulatory agonist to enter clinical development. The Company intends to report initial safety, tolerability, pharmacokinetic and pharmacodynamic data from this study in the second half of 2018.
  - Pieris recently signed an agreement with Roche granting the Company access to atezolizumab (Tecentriq), an approved PD-L1 inhibitor. The plan is to initiate a combination study of PRS-343 plus atezolizumab (Tecentriq) in HER2-positive cancer patients during the second half of 2018.
- PRS-060: Pieris continues to enroll healthy subjects in a Phase I first-in-human study for PRS-060, an IL-4
  receptor alpha antagonist, which the Company initiated in 2017. PRS-060 is the lead product in the
  Company's respiratory alliance with AstraZeneca. Pieris is sponsoring the Phase I clinical program while
  AstraZeneca is responsible for funding its costs. The Company intends to report initial data from the Phase
  la trial in the fourth quarter of 2018. AstraZeneca will sponsor and continue to fund the development of
  PRS-060 after completion of a Phase Ib study. Upon completion of a Phase IIa study, Pieris will have
  separate options to co-develop and co-commercialize PRS-060 with AstraZeneca in the U.S., including the
  right to field a sales force.
- PRS-080: Pieris continues to enroll and treat dialysis-dependent patients with functional iron deficiency
  anemia in a Phase IIa study for PRS-080, which the Company initiated in 2017. The Company intends to
  report safety and pharmacodynamic data from this study, including the change in hemoglobin levels after
  five weekly doses of PRS-080, in the second half of 2018. If data are positive, the Company will seek to
  partner PRS-080 in territories outside of Japan and other Asian territories for which ASKA Pharmaceutical
  Co. has an exclusive option.
- Board Appointment: In April 2018, Pieris appointed Ann Barbier, M.D., Ph.D., to the Company's Board of Directors. Dr. Barbier is currently the Chief Medical Officer of Translate Bio.

First Quarter Financial Update:

<u>Cash Position</u> - Cash, cash equivalents and investments totaled \$162.2 million as of March 31, 2018, compared to a cash 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. The increase was partially offset by \$11.7 million of operating cash expenditures during the year.

<u>R&D Expense</u> - R&D expenses were \$7.9 million for the quarter ended March 31, 2018, compared to \$5.4 million for the quarter ended March 31, 2017. The Company's increase in R&D expenses reflects advancement across its pipeline of programs as well as preparation for and advancement of clinical studies. The increase was partially offset by decreases in our preclinical and manufacturing costs.

<u>G&A Expense</u> - G&A expenses were \$4.4 million for the quarter ended March 31, 2018, compared to \$4.0 million for the quarter ended March 31, 2017. The Company's increase in G&A expenses reflects higher personnel, recruiting, and professional services costs. The increase was partially offset by transaction fees for our license and collaboration agreements recorded in the first quarter of 2017.

<u>Net Loss</u> - Net loss was \$8.7 million or \$(0.17) per share for the quarter ended March 31, 2018, compared to a net loss of \$8.0 million or \$(0.19) per share for the quarter ended March 31, 2017.

#### Conference Call:

Pieris management will host a conference call beginning at 8:00 AM Eastern Daylight Time on Thursday, May 10, 2018, to discuss the first quarter of 2018 financial results and provide a corporate update. You 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 immuno-oncology multi-specifics tailored for the tumor microenvironment, an inhaled Anticalin protein to treat uncontrolled asthma 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<sup>®</sup> is a registered trademark of Pieris. For more information, visit www.pieris.com.

TECENTRIQ® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

#### Forward Looking Statements

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, 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 related to our 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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# PIERIS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited, in thousands)

	March 31, 2018		December 31, 2017	
Assets:				
Cash and cash equivalents	\$	109,521	\$	37,878
Short term investments		50,061		34,751
Accounts receivable		3,309		15,546
Prepaid expenses and other current assets		3,190	122	1,615
Total current assets	30	166,081		89,790
Property and equipment, net		4,445		4,034
Long term investments		2,583		9,922
Other non-current assets		130		130
Total Assets	\$	173,239	\$	103,876
Liabilities and stockholders' equity:	()			
Accounts payable	\$	1,934	\$	2,452
Accrued expenses		6,578		6,170
Deferred revenue, current portion		50,851	122	37,153
Total current liabilities		59,363		45,775
Deferred revenue, net of current portion		63,146		46,542
Other long-term liabilities		37		37
Total Liabilities		122,546		92,354
Total stockholders' equity		50,693		11,522
Total liabilities and stockholders' equity	\$	173,239	\$	103,876

## PIERIS PHARMACEUTICALS, INC CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited, in thousands, except per share data)

	Three months ended March 31,			
		2018	90.0803 (BS 90) 990	2017
Revenues	\$	4,152	\$	1,343
Operating expenses				
Research and development		7,936		5,360
General and administrative		4,352		3,989
Total operating expenses		12,288		9,349
Loss from operations		(8,136)		(8,006)
Interest income, net		325		_
Other (expense) income, net		(903)		12
Loss before income taxes		(8,714)		(7,994)
Provision for income tax	22.2	—		—
Net loss	\$	(8,714)	\$	(7,994)
Basic and diluted net loss per share	\$	(0.17)	\$	(0.19)
Basic and diluted weighted average shares outstanding		50,046		43,064