

**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, 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 May 10, 2019, Pieris Pharmaceuticals, Inc. (the “Company”) issued a press release announcing certain financial results for the fiscal quarter ended March 31, 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 March 31, 2019, dated May 10, 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: May 10, 2019

/s/ Allan Reine

Allan Reine

Chief Financial Officer

May 10, 2019



Pieris Pharmaceuticals Reports First Quarter 2019 Financial Results and Provides Corporate Update

Company To Host An Investor Conference Call On Friday, May 10, 2019 At 8:00 AM EDT

BOSTON, MA / ACCESSWIRE / May 10, 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 financial results for the first quarter of 2019 ended March 31, 2019, and provided an update on the Company's recent and future developments.

"We are looking forward to reporting detailed data from the phase 1 single ascending dose study of PRS-060, an inhaled IL-4 receptor alpha antagonist for asthma, at the 2019 American Thoracic Society International Conference later this month," said Stephen S. Yoder, President and CEO of Pieris. "We are also looking forward to presenting data from the currently-enrolling phase 1 multiple ascending dose study of that candidate, including the drug's FeNO-reducing potential versus placebo, at an upcoming medical meeting. Beyond PRS-060, we continue to advance multiple respiratory discovery programs, both proprietary and in collaboration with AstraZeneca, driving value across our expanding respiratory franchise. We also continue to make headway in our immuno-oncology programs. We plan to report comprehensive data from the phase 1 dose-escalation study of PRS-343, a 4-1BB/HER2 bispecific for HER2-positive solid tumors later this year. We also plan to report data from the phase 1 combination study of PRS-343 with atezolizumab later this year. Additionally, we expect to file an IND application for PRS-344, a PD-L1/4-1BB bispecific drug candidate we are co-developing with Servier, by year-end. We continue to work hard on execution over the last year and are pleased to be able to share the resulting fruits of our labor with our shareholders over the coming months."

- **PRS-060:** Pieris will present detailed data from the phase 1 single ascending dose study of PRS-060, an inhaled IL-4 receptor alpha antagonist for asthma, at the 2019 American Thoracic Society (ATS) International Conference later this month. The Company previously announced topline data from this study, reporting that PRS-060 was found to be safe and well-tolerated in healthy volunteers. Pieris also plans to present data from the multiple ascending dose phase 1 study of PRS-060 in patients with mild asthma and elevated levels of fractional exhaled nitric oxide (FeNO), a validated biomarker of lung inflammation, at an upcoming medical meeting. This study evaluates the safety, tolerability and FeNO-reducing potential of inhaled PRS-060 versus placebo. PRS-060 is the lead candidate in Pieris' respiratory collaboration with AstraZeneca. Pieris is sponsoring the single and multiple ascending dose phase 1 studies and AstraZeneca is funding the costs. Assuming successful completion of the ongoing multiple ascending dose phase 1 study, AstraZeneca would sponsor and fund the phase 2a study. Upon completion of that study, Pieris may exercise options to co-develop and, later, co-commercialize PRS-060.
- **Respiratory Pipeline:** Pieris continues to advance two discovery-stage programs as part of its respiratory alliance with AstraZeneca, under which AstraZeneca may initiate up to two additional programs. 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.
- **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.
- **PRS-080:** Pieris will present data from the phase 2a study of PRS-080, a half-life-optimized hepcidin

- **FRS-006.** Fiens will present data from the phase 2a study of FRS-006, a next-generation hepcidin antagonist for anemia, at the 24th European Hematology Association Congress on June 16, 2019.
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First Quarter Financial Update:

Cash Position - Cash, cash equivalents and investments totaled \$110.8 million as of March 31, 2019, compared to a cash, cash equivalents and investments balance of \$128.1 million as of December 31, 2018. The decrease was due to operating cash expense, annual bonus payments, and timing of receivables collection from our strategic partners.

R&D Expense - R&D expenses were \$14.3 million for the three months ended March 31, 2019, compared to \$7.9 million for the three months ended March 31, 2018. The increase in research and development expenses reflects increases in clinical, drug supply and manufacturing, and salaries and benefit costs associated with the advancement of our clinical and preclinical programs.

G&A Expense - G&A expenses were \$4.9 million for the three months ended March 31, 2019, compared to \$4.4 million for the three months ended March 31, 2018. The increase in G&A expenses reflects higher personnel costs and audit and tax professional fees.

Interest Income - Interest income was \$0.5 million for the three months ended March 31, 2019, compared to \$0.3 million in interest income earned in the comparable 2018 period. The Company earned higher rates of interest despite having lower overall investment amounts compared to the first quarter of 2018.

Other Expense - Other expense was \$0.2 million for the three months ended March 31, 2019, compared to other expense of \$0.9 million for the three months ended March 31, 2018. The decrease in other expense was the result of a strengthening of the U.S. dollar against the euro, positively impacting the remeasurement of U.S. dollar denominated monetary assets held in Germany, combined with lower foreign denominated balances.

Net Loss - Net loss was \$10.3 million or \$(0.20) per share for the three months ended March 31, 2019, compared to a net loss of \$8.7 million or \$(0.17) per share for the three months ended March 31, 2018.

Conference Call:

Pieris management will host a conference call beginning at 8:00 AM Eastern Daylight Time on Friday, May 10, 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

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.

Company Contact: **Investor Relations Contact:**

Pieris Pharmaceuticals, Inc. Pieris Pharmaceuticals, Inc.

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PIERIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	March 31, 2019	December 31, 2018
Assets:		
Cash and cash equivalents	\$ 52,094	\$ 74,867
Short term investments	58,685	53,240
Accounts receivable	7,128	2,701
Prepaid expenses and other current assets	6,379	4,574
Total current assets	<u>124,286</u>	<u>135,382</u>
Property and equipment, net	4,893	5,049
Other non-current assets	1,869	910
Total Assets	<u>\$ 131,048</u>	<u>\$ 141,341</u>
Liabilities and stockholders' equity:		
Accounts payable	\$ 3,728	\$ 3,350
Accrued expenses	9,216	9,114
Deferred revenue, current portion	28,181	35,612
Total current liabilities	<u>41,125</u>	<u>48,076</u>
Deferred revenue, net of current portion	59,734	53,303
Other long-term liabilities	27	27
Total Liabilities	<u>100,886</u>	<u>101,406</u>
Total stockholders' equity	30,162	39,935
Total liabilities and stockholders' equity	<u>\$ 131,048</u>	<u>\$ 141,341</u>

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

	Three months ended March 31,	
	2019	2018
Revenues	\$ 8,545	\$ 4,152

Operating expenses

Research and development

14,296

7,936

General and administrative	4,932	4,352
Total operating expenses	<u>19,228</u>	<u>12,288</u>
Loss from operations	(10,683)	(8,136)
Interest income	506	325
Other income (expense), net	<u>(171)</u>	<u>(903)</u>
Loss before income taxes	(10,348)	(8,714)
Provision for income tax	<u>—</u>	<u>—</u>
Net loss	<u>\$ (10,348)</u>	<u>\$ (8,714)</u>
Basic and diluted net loss per share	<u>\$ (0.20)</u>	<u>\$ (0.17)</u>
Basic and diluted weighted average shares outstanding	<u>50,873</u>	<u>50,046</u>

SOURCE: Pieris Pharmaceuticals, Inc.
