

**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, 2020

PIERIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of
incorporation)

255 State Street, 9th Floor
Boston, MA

(Address of principal executive offices)

001-37471

(Commission
File Number)

30-0784346

(IRS Employer
Identification No.)

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))

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, 2020, Pieris Pharmaceuticals, Inc. (the “Company”) issued a press release announcing certain financial results for the fiscal year ended December 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 year ended December 31, 2019, dated March 12, 2020](#)

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, 2020

/s/ Tom Bures

Tom Bures

Vice President, Finance

March 12, 2020



Pieris Pharmaceuticals Reports Full-Year 2019 Financial Results And Provides Corporate Update

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON THURSDAY, MARCH 12, 2020 AT 8:00 AM EDT

BOSTON, MA / ACCESSWIRE / March 12, 2020 / Pieris Pharmaceuticals, Inc. (NASDAQ:PIRS), a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin[®] technology platform for respiratory, cancer, and other diseases, today reported financial results for its fiscal year ended December 31, 2019 and provided an update on the Company's recent and future developments.

"2019 was a milestone year for Pieris as we reported two positive clinical data sets, one from each of our core focus areas of respiratory diseases and immuno-oncology," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "PRS-060, an inhaled IL-4 receptor alpha antagonist for moderate-to-severe asthma that we are developing with AstraZeneca, demonstrated robust fractional exhaled nitric oxide, or FeNO, reduction in mild asthmatics in a phase 1 multiple-ascending dose study. We are very pleased with the data and are currently enrolling the final cohorts in that study to help inform the phase 2a study, which we anticipate will begin in the second half of this year. Additionally, PRS-343, a 4-1BB/HER2 bispecific for HER2-positive solid tumors, demonstrated both single-agent and checkpoint-combination anti-tumor activity, including partial responses, in heavily pre-treated patients across multiple HER2-positive tumors with correlative biomarker data indicative of 4-1BB agonism on T cells in phase 1 dose-escalation studies. These data strengthen our conviction in a 4-1BB-targeted immuno-oncology approach, and we look forward to completing the ongoing dose-escalation studies and moving this program into the next phase of development in gastric cancer. Finally, we look forward to advancing PRS-344, a 4-1BB/PD-L1 bispecific that is partnered with Servier, into the clinic."

- **PRS-060:** In October, Pieris presented data from the phase 1b placebo-controlled multiple ascending dose study of PRS-060/AZD1402, an inhaled IL-4 receptor alpha antagonist for moderate-to-severe asthma, at the 2019 European Respiratory Society International Congress. In that analysis, PRS-060/AZD1402 was found to be safe and well tolerated at all doses, led to a statistically-significant reduction in FeNO (a marker of airway inflammation) relative to placebo, and showed dose-dependent systemic target engagement in patients with mild asthma and elevated levels of FeNO (≥ 35 ppb). Dosing of additional cohorts by Pieris is ongoing and will inform the phase 2a study; AstraZeneca and Pieris plan to initiate the phase 2a study in moderate-to-severe asthmatics in the second half of 2020. The study will be sponsored, funded, and delivered by AstraZeneca and upon completion of that study, Pieris will have the options to co-develop and, subsequently, co-commercialize PRS-060/AZD1402 in the United States.
- **PRS-343:** In November, Pieris presented data from its phase 1 dose-escalation monotherapy study of PRS-343, a 4-1BB/HER2 bispecific for HER2-positive solid tumors, at the Society for Immunotherapy of Cancer's 34th Annual Meeting. PRS-343 was safe and well tolerated at all doses and schedules tested, demonstrated anti-tumor activity in a heavily pre-treated patient population across multiple tumor types, and showed a marked increase in CD8+ T cell numbers in the tumor microenvironment of responders, indicative of 4-1BB agonism on T cells. The Company also presented emerging data from the dose-escalation phase 1 study of PRS-343 in combination with atezolizumab at the Company's R&D day in November, showing clinical responses and correlative increases in CD8+ T cells in responding patients. Pieris plans to present detailed data from both studies at a medical meeting in the second half of this year. Based on emerging data from the ongoing clinical studies, the Company expects to initiate the next phase of PRS-343's development in gastric cancer this year.
- **Preclinical Respiratory Pipeline:** Beyond PRS-060, Pieris continues to advance three of four discovery programs in its five-program respiratory collaboration with AstraZeneca. AstraZeneca will have the option to initiate the fourth discovery program in the collaboration this year. The Company also continues to advance several proprietary discovery-stage respiratory programs. Pieris expects to share data and rationale for advancement of one of its proprietary programs at a medical meeting in the second half of this year.

- **Asthma Research Collaboration with the University of Pittsburgh:**As part of the Company's commitment to building a novel respiratory pipeline, in the fourth quarter, Pieris entered into research collaboration with the
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laboratories of University of Pittsburgh Professors Sally Wenzel, MD, and Anuradha Ray, PhD, focused on comprehensive immune phenotyping of severe asthmatic patients. Key objectives of the multi-year collaboration include patient stratification strategies for more streamlined development of therapeutic interventions as well as identifying and validating novel asthma targets.

- **Immuno-oncology Pipeline:** Pieris plans to file an IND application for PRS-344, a 4-1BB/PD-L1 bispecific that the Company is developing as part of its collaboration with Servier, in the first half of this year. Pieris holds exclusive commercialization rights for PRS-344 in the United States and will receive royalties on ex-U.S. sales for this program. The Company's immuno-oncology collaboration with Seattle Genetics continues to progress on schedule.
- **Private Placement:** In the fourth quarter, the Company completed a \$32 million private placement with new and existing healthcare-focused institutional investors that resulted in a year-end cash and investment position exceeding \$100 million.

Fiscal Year Financial Update:

Cash Position - Cash, cash equivalents, and investments totaled \$104.2 million for the year ended December 31, 2019, compared to a cash, cash equivalents, and investments balance of \$128.1 million for the year ended December 31, 2018. The decrease in cash, cash equivalents, and investments was primarily due to the Company's operational needs during 2019, offset by proceeds from the private placement financing completed in November 2019.

R&D Expense - R&D expenses were \$55.0 million for the year ended December 31, 2019, compared to \$41.5 million for the year ended December 31, 2018. The increase in R&D expenses was primarily due to higher manufacturing costs supporting planned and ongoing clinical studies as well as higher personnel, facility, and IT costs supporting the ongoing advancement of the Company's pipeline. The increase was offset by a decline in royalty expenses due to lower upfront and milestone payments compared to 2018.

G&A Expense - G&A expenses remained flat at \$18.4 million for both years ended December 31, 2019 and December 31, 2018. The Company incurred higher hardware and software costs to support operations growth and efficiency, and higher audit and tax fees due to new accounting regulations and internal control requirements. These costs were offset by both lower professional service fees as the Company better leveraged internal resources in 2019 and lower facilities and IT costs attributed to G&A functions.

Interest Income - Interest income was \$1.7 million for the year ended December 31, 2019, compared to \$2.0 million earned for the year ended December 31, 2018. The decrease was due to lower average cash amounts invested during the year and declining interest rates on investments in 2019.

Net Loss Attributable to Common Stockholders - Net loss attributable to common stockholders was \$28.3 million or \$(0.56) per share for the year ended December 31, 2019, compared to a net loss of \$26.8 million or \$(0.50) per share for the year ended December 31, 2018.

Conference Call:

Pieris management will host a conference call beginning at 8:00 AM Eastern Daylight Time on Thursday, March 12, 2020, to discuss the full year financial results and 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 and immuno-oncology multi-specifics tailored for the tumor microenvironment. 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 Statements:

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, Pieris' plans for a phase 2a study of PRS-060/AZD1402; the expected timing and potential outcomes of the reporting by the Company of key clinical data from its lead programs, 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, including PRS-343 and PRS-344 and the expected timing of the initiation of the next stage of PRS-343's development in gastric cancer. 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; delays or disruptions due to the coronavirus; 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.

CONTACT:

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

	<u>December 31, 2019</u>	<u>December 31, 2018</u>
Assets:		
Cash and cash equivalents	\$ 62,260	\$ 74,867
Short term investments	41,894	53,240
Accounts receivable	6,787	2,701
Prepaid expenses and other current assets	4,072	4,574
Total current assets	<u>115,013</u>	<u>135,382</u>
Property and equipment, net	19,502	5,049
Operating lease right-of-use assets	3,436	-
Other non-current assets	3,146	910
Total Assets	<u>\$ 141,097</u>	<u>\$ 141,341</u>
Liabilities and stockholders' equity:		
Accounts payable	\$ 5,803	\$ 3,350
Accrued expenses	9,944	9,114
Deferred revenue, current portion	11,256	35,612
Total current liabilities	<u>27,003</u>	<u>48,076</u>
Deferred revenue, net of current portion	47,258	53,303
Operating lease liabilities	15,484	-
Other long-term liabilities	-	27
	<u> </u>	<u> </u>

Total Liabilities	<u>89,745</u>	<u>101,406</u>
Total stockholders' equity	<u>51,352</u>	<u>39,935</u>
Total liabilities and stockholders' equity	<u>\$ 141,097</u>	<u>\$ 141,341</u>

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

	Twelve months ended December 31,	
	2019	2018
Revenues	\$ 46,279	\$ 29,101
Operating expenses		
Research and development	54,996	41,490
General and administrative	18,440	18,442
Total operating expenses	73,436	59,932
Loss from operations	(27,157)	(30,831)
Interest income	1,714	1,962
Other (expense) income, net	(26)	1,803
Loss before income taxes	(25,469)	(27,066)
Provision for income tax	-	(312)
Net loss	\$ (25,469)	\$ (26,754)
Preferred stock dividends	(2,830)	-
Net loss attributable to common stockholders	\$ (28,299)	\$ (26,754)
Basic and diluted net loss per share	\$ (0.56)	\$ (0.50)
Basic and diluted weighted average shares outstanding	50,625	53,081
SOURCE: Pieris Pharmaceuticals, Inc		

View source version on accesswire.com:

<https://www.accesswire.com/580386/Pieris-Pharmaceuticals-Reports-Full-Year-2019-Financial-Results-And-Provides-Corporate-Update>
