# 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): November 9, 2016

# 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
United States
(Address of principal executive offices, including zip code)

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

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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))							

# Item 2.02 Results of Operations and Financial Condition.

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.

Attached as Exhibit 99.1 is a copy of a press release of Pieris Pharmaceuticals, Inc. (the "Company"), dated November 9, 2016, announcing certain financial results for the third quarter ended September 30, 2016.

# **Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

99.1 Press release announcing financial results for the third quarter ended September 30, 2016, dated November 9, 2016.

# **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.

Dated: November 10, 2016 PIERIS PHARMACEUTICALS, INC.

By: /s/ Darlene Deptula-Hicks

Name: Darlene Deptula-Hicks

Title: SVP & Chief Financial Officer

# EXHIBIT INDEX

# Exhibit No. Description

Press release announcing financial results for the third quarter ended September 30, 2016, dated November 9, 2016.



# PRESS RELEASE

# PIERIS PHARMACEUTICALS REPORTS FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE FOR THE THIRD QUARTER ENDED SEPTEMBER 30, 2016

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON THURSDAY, NOVEMBER 10, 2016 AT 10:00 AM ET

**BOSTON, MA, November 9, 2016 – Pieris Pharmaceuticals, Inc.** (NASDAQ:<u>PIRS</u>), a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform for cancer and other diseases, today reported financial results for the third quarter of 2016 and provided an update on the Company's recent developments.

"I am pleased to report that during the third quarter, we built on the progress we made in the prior quarter, with continued advancement of both our pipeline and partnerships. Our most advanced Anticalin® program, PRS-080, for anemia of chronic disease, remains on track to complete dosing in our Phase 1b single ascending dose study by year end and to complete the multiple ascending dose phase in mid-2017. At the CRI-CIMT-AACR International Cancer Immunotherapy Conference, we presented preclinical data demonstrating a differentiated mode of action for PRS-343, our lead 4-1BB (CD137)-based bispecific immuno-oncology program, which is poised to enter clinical development in the first half of 2017," said Stephen Yoder, President and CEO. "Our inhaled asthma program, PRS-060, is differentiated from systemically administered competitor mAb efforts targeting the same pathway, and it remains on track for the initiation of a Phase 1 study in the first half of 2017. Beyond PRS-343, we continue to advance a next generation immuno-oncology portfolio of multispecific therapeutic proteins, as well as our partnerships with Roche, Sanofi and Daiichi-Sankyo, including the achievement last month of a significant preclinical milestone in our second program with Daiichi-Sankyo, while continuing to explore additional collaborations. Finally, we ended the third quarter in a solid financial position with sufficient capital to fund us through multiple milestones."

# Recent Highlights:

- Advancing PRS-080 through an ongoing Phase 1 single ascending dose study in anemia of chronic disease, with an expected completion of dosing by year end
- Presented new preclinical data demonstrating in vivo efficacy and a differentiated mode of action for our lead 4-1BB (CD137)-based bispecific cancer immunotherapeutic drug candidate, PRS-343, at the 2016 CRI-CIMT-AACR International Cancer

Immunotherapy Conference. The data demonstrated the potential benefits of tumor microenvironment-localized costimulatory T cell activation for both reduced systemic toxicity and higher efficacy in comparison to conventional agonistic anti-4-1BB antibodies, as well as a positive manufacturability profile

- Advancing PRS-343 through IND-enabling studies and towards a first-in-patient study for a range of HER-2 positive cancers, expected to commence in the first half of 2017
- Advancing PRS-060 through IND-enabling studies for moderate to severe asthma as an inhaled therapeutic, and towards a first-in-human study, expected to commence in the first half of 2017
- Continued preclinical development of a novel multi-checkpoint blockade bispecific, PRS-332, comprised of an anti-PD-1 antibody
  genetically linked to an existing Anticalin against an undisclosed checkpoint
- Appointed Julian Adams, Ph.D. to Pieris' Board of Directors. Dr. Adams is the President of Research & Development at Infinity
  Pharmaceuticals and leads the full spectrum of Infinity's drug discovery, preclinical and clinical development, and regulatory affairs
  activities
- Appointed Christopher Kiritsy to Pieris' Board of Directors. Mr. Kiritsy is the Chief Executive Officer of Arisaph Pharmaceuticals and
  was previously the Chief Financial Officer of Kos Pharmaceuticals, which was acquired by Abbott
- Achieved a preclinical milestone in October with our second partnered program with Daiichi

#### Third Quarter Financial Update:

<u>Cash Position</u> - Cash and cash equivalents totalled \$36.6 million at September 30, 2016, compared to \$29.3 million at December 31, 2015. The increase in cash was driven primarily by the \$16.5 million gross private placement financing completed in June 2016.

**R&D Expense** - Research and development expenses were \$4.6 million for the quarter ended September 30, 2016, compared to \$2.0 million for the quarter ended September 30, 2015. The \$2.6 million increase was due primarily to a \$1.6 million increase in pre-clinical development and CMC costs for PRS-343 as we carry out IND enabling studies and increased development costs for our other PRS-300 series programs, a \$0.2 million increase for our PRS-080 program due to the initiation of the Phase Ib clinical trial in the first quarter 2016, and a \$0.2 million increase in CMC and other preclinical costs associated with PRS-060 as we carry out IND enabling studies. Other R&D expenses also increased by \$0.6 million primarily due to a \$0.5 million increase in personnel related expenses, including stock-based compensation expense, an increase of \$0.1 million for legal and patent fees, and \$0.1 million increase for general lab costs. These increases were offset by a decrease of \$0.1 million in recruiting and other costs.

<u>G&A Expense</u> - General and administrative expenses for the quarter ended September 30, 2016 were \$2.3 million, compared to \$2.2 million for the quarter ended September 30, 2015. The \$0.1 million increase in G&A expenses was primarily due to \$0.3 million in higher personnel related costs, including stock compensation, and \$0.2 million increase for recruiting and rent expense, offset by \$0.4 million in lower legal, consulting, and other costs.

<u>Net Loss</u> - Net loss was \$6.2 million or (\$0.14) per share for the quarter ended September 30, 2016, compared to a net loss \$3.9 million or (\$0.10) per share for the quarter ended September 30, 2015.

#### Conference Call

Pieris management will host a conference call beginning at 10:00 AM Eastern Time on Thursday, November 10, 2016, to discuss the third quarter financial results and provide a corporate update. To access the call, participants may dial 877-407-8920 (US & Canada) or 1-412-902-1010 (International) at least 10 minutes prior to the start of the call. An archived replay of the call will be available by dialling 877-660-6853 (US & Canada) or 1-201-612-7415 (International) and providing the Conference ID # 13603006.

#### About Pieris

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® is a registered trademark of Pieris. For more information, visit www.pieris.com.

### Company Contact:

### **Investor Relations Contact:**

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### 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; our business and product development plans and timelines; the timing and progress of our studies, our

liquidity and ability to fund our future operations; our ability to achieve certain milestones and receive future milestone or royalty payments; current or future partnerships; or market information. 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; 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, 2015 and the Company's Quarterly Reports on Form 10-Q.

(tables to follow)

# PIERIS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2016 (Unaudited)	December 31, 2015
Assets:		
Cash and cash equivalents	\$36,557,701	\$29,349,124
Prepaid expenses and other current assets	4,579,659	2,311,385
Total current assets	41,137,360	31,660,509
Property and equipment, net	2,447,733	2,162,771
Other noncurrent assets	127,626	126,781
Total Assets	\$43,712,719	\$33,950,061
Liabilities and stockholders' equity:		
Accounts payable	\$ 4,523,798	\$ 1,058,536
Accrued expenses	2,898,388	1,739,380
Deferred revenue, current portion	2,529,661	
Total current liabilities	9,951,847	2,797,916
Deferred revenue, net of current portion	2,233,834	_
Other long-term liabilities	44,565	23,852
Total Liabilities	12,230,246	2,821,768
Total stockholders' equity	31,482,473	31,128,293
Total liabilities and stockholders' equity	\$43,712,719	\$33,950,061

# PIERIS PHARMACEUTICALS, INC CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30, 2016 2015			Nine Months Ended September 30, 2016 2015					
		(Unaudited)				(Unaudited)			
Revenues		785,007	\$	414,610	\$	3,104,513	\$	792,474	
Operating expenses									
Research and development		(4,621,957)		(2,051,688)		(12,781,489)		(5,301,911)	
General and administrative		(2,341,010)		(2,242,804)		(6,677,110)		(6,606,209)	
Total operating expenses		(6,962,967)		(4,294,492)		(19,458,599)		(11,908,120)	
Loss from operations		(6,177,960)		(3,879,882)		(16,354,086)		(11,115,645)	
Interest expense, net		_		_		_		(4,223)	
Other income, net		(18,243)		(1,929)		113,575		3,325	
Loss before income taxes		(6,196,203)		(3,881,811)		(16,240,511)		(11,116,544)	
Provision (benefit) for income tax				(40,441)				(40,441)	
Net loss		(6,196,203)	\$	(3,922,252)	\$	(16,240,511)	\$	(11,156,985)	
Basic and diluted net loss per share	\$	(0.14)	\$	(0.10)	\$	(0.39)	\$	(0.34)	
Basic and diluted weighted average shares outstanding		43,063,790		38,890,546		41,259,749		32,584,354	