

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 22, 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: 857-246-8794

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))
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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 March 22, 2016, announcing certain financial results for the year ended December 31, 2015.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits.*

99.1 Press release announcing financial results for the year-ended December 31, 2015, dated March 22, 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.

PIERIS PHARMACEUTICALS, INC.

Dated: March 23, 2016

By: /s/ Darlene Deptula-Hicks

Name: Darlene Deptula-Hicks

Title: Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release announcing financial results for the year-ended December 31, 2015, dated March 22, 2016.

March 22, 2016



Pieris Pharmaceuticals Reports Full-Year 2015 Financial Results and Corporate Update

Company to Host an Investor Conference Call on Wednesday, March 23, 2016 at 10:00 AM ET

BOSTON, MA — (Marketwired) — 03/22/16 — **Pieris Pharmaceuticals, Inc.** (NASDAQ: PIRS), a biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform, announced today 2015 corporate highlights, a clinical development overview and financial results for the fiscal year ending December 31, 2015.

“I’m pleased to report that 2015, and particularly the fourth quarter, was a period of significant progress for Pieris Pharmaceuticals, both financially and in terms of program and partner development. In the fourth quarter, we announced a major oncology collaboration agreement with Roche, received development milestone payments from collaborators Daiichi-Sankyo and Sanofi and initiated IND-enabling activities for PRS-343, our lead immuno-oncology bispecific drug candidate targeting CD137 and HER2,” commented Pieris’ President and Chief Executive Officer, Stephen Yoder. “Earlier in the year, we completed a public offering of common stock raising \$25.8M in total net proceeds, we completed a successful Phase I clinical trial for PRS-080, our anti-hepcidin Anticalin® therapeutic protein designed to treat anemic patients, and we initiated IND-enabling activities for PRS-060, a potential first-in-class inhaled biologic targeting IL4Ra to address asthma patients, collectively setting the stage for an eventful 2016.”

2015 Corporate Highlights:

- Announced the Company’s first immuno-oncology research collaboration and license agreement with world leading oncology company, Roche, with an approximately \$6.5 million upfront payment which was received in January 2016 and the potential to receive approximately \$415 million in milestones
- Presented data from a Phase I clinical study with PRS-080, an Anticalin hepcidin antagonist, in healthy male volunteers at the 57th Annual Meeting of the American Society of Hematology (ASH), demonstrating safety, tolerability and desired half-life, while confirming the mode of action (iron mobilization)
- Appointed significant key personnel — Dr. Jean-Pierre Bizzari, formerly of Celgene Corporation and Sanofi-Aventis, to our board of directors, Dr. Louis A. Matis as SVP & Chief Development Officer, Dr. Mary Fitzgerald as VP of Respiratory Medicine, and Darlene Deptula-Hicks as SVP and Chief Financial Officer
- Established US headquarters in Boston, MA
- Achieved a third payment-based milestone in our R&D collaboration with Sanofi, who continues advancing the tetraspecific Anticalin-based program in preclinical studies for *pseudomonas*-related illness
- Dosed the first subject in a Phase I clinical study with collaboration partner Daiichi Sankyo for the parties’ lead partnered Anticalin program, also triggering a milestone payment, the eighth milestone payment overall under the collaboration agreement

- Presented preclinical data for PRS-343, the Company's Anticalin-based CD137/HER2 bispecific and lead immuno-oncology program, demonstrating superior drug-like properties and tumor-targeted immune responses distinct from conventional anti-CD137 monoclonal antibodies, triggering development candidate nomination and initiation of IND-enabling activities
- Announced a \$AUS 500,000 research grant to the University of Melbourne to further develop PRS-060 in immunological diseases
- Completed a successful public offering of common stock, including the overallotment, raising \$25.8M in total net proceeds

Pipeline Update:

PRS-080

Pieris completed a Phase I clinical trial for PRS-080, an anti-hepcidin Anticalin therapeutic protein designed to treat anemia in chronic kidney disease patients suffering from functional iron deficiency (FID). The clinical data were presented at the 2015 American Society of Hematology (ASH) in an oral presentation that discussed the favorable safety profile of the drug and demonstrable proof of mechanism. PRS-080 was well tolerated by the 48 healthy male subjects with no serious adverse events. Among all subjects receiving the PRS-080 doses of 1.2 mg/ml or higher in the six dose study, ranging from 0.08 to 16 mg/kg, statistically significant increases in total serum iron mobilization were observed relative to the placebo (p=0.005). PRS-080 currently is undergoing a first-in-patient study in end-stage renal disease (ESRD) patients exhibiting FID anemia.

PRS-060

PRS-060 is a potent antagonist of IL4Ra and is being developed for pulmonary delivery to treat asthma. With direct delivery into the lungs, PRS-060 may allow for low doses compared to subcutaneously administered antibody approaches, while offering a more convenient administration regimen and a potentially superior therapeutic index. The Company has shown proof of concept in animal models of lung inflammation, as well as feasibility of pulmonary delivery in multiple formulations. PRS-060 currently is in IND-enabling studies and has the potential to be a first-in-class inhaled biologic. PRS-060 is currently undergoing IND-enabling activities, and we expect to begin a Phase I clinical trial with PRS-060 in 2017.

PRS-343

PRS-343 is a bivalent, bispecific fusion protein targeting CD137 (4-1BB) and HER2 comprising an agonistic CD137-targeting Anticalin genetically linked to a HER2-targeting antibody. CD137 is a key costimulatory immunoreceptor and a member of the TNF-receptor (TNFR) superfamily. While multiple lines of evidence show that CD137 is a highly promising therapeutic target in cancer, current mAb approaches are not designed to achieve a tumor-mediated activation and, therefore, may display toxicity and a limited therapeutic window due to peripheral T cell and NK cell activation. To overcome this limitation, PRS-343 has been designed to promote CD137 clustering by bridging CD137-positive T cells with HER2-positive tumor cells, thereby providing a potent costimulatory signal to tumor antigen-specific T cells. Data from ex vivo T cell assays and a humanized mouse model of cancer support the intended mode of action of tumor-localized costimulatory T cell activation with an enhanced therapeutic index compared to anti-CD137 antibody approaches. PRS-343 currently is in IND-enabling studies.

Financial Update:

Cash Position—Cash and cash equivalents totaled \$29.3 million at December 31, 2015, compared to \$18.5 million at December 31, 2014. The increase was driven primarily by the company's common offering completed in July 2015.

R&D Expenses—Research and development expenses were \$8.2 million for the year ended December 31, 2015, compared to \$5.6 million for the year ended December 31, 2014. The \$2.6 million increase was primarily attributable to \$2.3 million and \$0.4 million in pre-clinical development for our PRS-300 series and PRS-060 programs respectively, \$0.2 million in initial clinical development activities for our PRS-080 program, offset by a \$0.3 million decrease in other R&D activities.

G&A Expenses—General and administrative expenses for the year ended December 31, 2015 were \$8.4 million, compared to \$7.0 million for the year ended December 31, 2014. The \$1.4 million increase in G&A expenses are due primarily to costs incurred for operating as a public Company such as investor relations costs and D&O insurance premiums, increased personnel-related expenses including approximately \$0.8 million in non-cash stock based compensation expense.

Net Loss—Net loss was \$14.1 million or (\$0.41) per share for the year ended December 31, 2015, compared to a net loss \$9.8 million or (\$0.71) per share for the year ended December 31, 2014.

Conference Call:

Pieris management will host a conference call beginning at 10:00 AM Eastern Time on Wednesday, March 23, 2016, to discuss the full year 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) and providing the conference ID: 13603006. An archived replay of the call will be available by dialing +1-877-660-6853 (US & Canada) or +1-201-612-7415 (International).

About Pieris

Pieris Pharmaceuticals is a clinical-stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immuno-oncology multi-specifics tailored for the tumor micro-environment, an inhaled Anticalin to treat uncontrolled asthma and a half-life-optimized Anticalin to treat anemia. Proprietary to Pieris, Anticalins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin®, Anticalins® are registered trademarks of Pieris. For more information visit www.pieris.com.

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; our liquidity and ability to fund our future operations; 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, 2014 and the Company's Quarterly Reports on Form 10-Q.

(tables to follow)

PIERIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2015	December 31, 2014
Assets:		
Cash and cash equivalents	\$29,349,124	\$18,474,211
Prepaid expenses and other current assets	2,311,385	1,331,214
Total current assets	<u>31,660,509</u>	<u>19,805,425</u>
Property and equipment, net	2,162,771	2,052,221
Other noncurrent assets	126,781	—
Total Assets	<u>\$33,950,061</u>	<u>\$21,857,646</u>
Liabilities and stockholders' equity:		
Accounts payable	\$ 1,058,536	\$ 1,260,015
Accrued expenses	1,739,380	986,620
Bank loan, including accrued interest	—	1,270,605
Total current liabilities	<u>2,797,916</u>	<u>3,517,240</u>
Other long-term liabilities	23,852	333,988
Total Liabilities	<u>2,821,768</u>	<u>3,851,228</u>
Total stockholders' equity	<u>31,128,293</u>	<u>18,006,418</u>
Total liabilities and stockholders' equity	<u>\$33,950,061</u>	<u>\$21,857,646</u>

PIERIS PHARMACEUTICALS, INC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
	(Unaudited)			
Revenues	\$ 2,139,457	\$ 3,275,223	\$ 2,931,931	\$ 5,365,054
Operating expenses				
Research and development	2,942,840	2,332,159	8,244,751	5,600,421
General and administrative	1,762,006	2,859,086	8,368,215	6,962,891
Total operating expenses	4,704,846	5,191,245	16,612,966	12,563,312
Loss from operations	(2,565,389)	(1,916,022)	(13,681,035)	(7,198,258)
Interest expense, net	(184,091)	(2,250,439)	(184,645)	(2,654,727)
Other income, net	10,754	190	10,905	3,003
Loss before income taxes	(2,738,726)	(4,166,271)	(13,854,775)	(9,849,982)
Provision (benefit) for income tax	163,425	—	203,866	(18)
Net loss	<u>\$ (2,902,151)</u>	<u>\$ (4,166,271)</u>	<u>\$ (14,058,641)</u>	<u>\$ (9,849,964)</u>
Basic and diluted net loss per share	<u>\$ (0.07)</u>	<u>\$ (0.21)</u>	<u>\$ (0.41)</u>	<u>\$ (0.71)</u>
Basic and diluted weighted average shares outstanding	<u>39,792,809</u>	<u>19,936,001</u>	<u>34,392,636</u>	<u>13,872,390</u>

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