

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 11, 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 May 11, 2016, announcing certain financial results for the first quarter ended March 31, 2016.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits.*

99.1 Press release announcing financial results for the first quarter ended March 31, 2016, dated May 11, 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: May 12, 2016

PIERIS PHARMACEUTICALS, INC.

By: /s/ Darlene Deptula-Hicks

Name: Darlene Deptula-Hicks

Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.

Description

99.1

Press release announcing financial results for the first quarter ended March 31, 2016, dated May 11, 2016.

May 11, 2016



Pieris Pharmaceuticals Reports Financial Results and Corporate Update for the First Quarter Ended March 31, 2016

Company to Host an Investor Conference Call on Thursday, May 12, 2016 at 10:00 AM ET

BOSTON, MA — (Marketwired) — 05/11/16 — Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS), 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 first quarter of 2016 and provided an update on the Company's recent developments.

“During the first quarter, we made substantial progress across both our pipeline and partnerships, in our continued efforts to build a world class protein biotherapeutic company with a balanced business model offering diversification of assets and risk mitigation. Our continued progress with our most advanced Anticalin® program, PRS-080, for anemia of chronic disease, ensures that we are on track to complete the ongoing Phase 1b single ascending dose study in anemia patients by year end. We also advanced according to plan our asthma program, PRS-060, which targets the clinically validated IL-4 receptor (IL-4Ra), as well as our lead immuno-oncology (IO) bispecific program, PRS-343, which targets CD137 and HER-2, with each of these programs remaining on track for first-in-human study initiation in the first half of 2017. We are also advancing our earlier immuno-oncology portfolio, while advancing our partnerships with Roche, Sanofi and Daiichi-Sankyo,” said Stephen Yoder, President and CEO. “Looking ahead to the rest of 2016, we expect the advancement of our IO multi-specifics franchise to further validate the repeatability of our Anticalin®-based approach, with the objective of seeking corporate partnerships in IO beyond our Roche collaboration. Our commitment to novel IO multispecifics remains strong, and our recent PD-1 antibody license agreement with Enumeral Biomedical, which gives Pieris the ability to generate novel multispecifics for cancer involving a fusion of a novel PD-1 antibody with our proprietary Anticalins®, affords us an opportunity to build an independent and highly competitive position around an established core component of the current IO treatment paradigm.”

First Quarter Highlights:

- Advancing PRS-080 into an ongoing Phase 1 single ascending dose study in anemia of chronic disease, with expected completion by year end
- Advancing PRS-060 towards IND-enabling studies for moderate to severe asthma, and towards a first-in-human study, expected to commence in 1H17
- Advancing PRS-343 towards IND-enabling studies and a first-in-patient study for HER-2 positive cancers, expected to commence in 1H17

- Advancing PRS-342, a potential first-in-class bispecific targeting CD137 and GPC3, through preclinical studies
- Received a \$6.5 million upfront payment from Roche
- Furthered our corporate collaborations with Roche, Sanofi and Daiichi Sankyo through lead identification, preclinical development and clinical development, respectively

Financial Update:

Cash Position - Cash and cash equivalents totalled \$31.2 million at March 31, 2016, compared to \$29.3 million at December 31, 2015. The increase was driven primarily by the receipt of the \$6.5 million up-front payment from Roche, offset by operating expenses for the quarter.

R&D Expenses - Research and development expenses were \$3.7 million for the quarter ended March 31, 2016, compared to \$1.5 million for the quarter ended March 31, 2015. The \$2.2 million increase was primarily attributable to a \$0.7 million and \$0.3 million increase in pre-clinical development costs for our PRS-300 series and PRS-060 programs respectively, and a \$1.4 million increase in other research and development activities primarily due to additional personnel-related costs and the 5% license fee due to TUM pertaining to the Roche agreement. These were offset by a decrease in the PRS-080 program of \$0.2 million as the Phase 1a trial has been completed.

G&A Expenses—General and administrative expenses for the quarter ended March 31, 2016 were \$2.0 million, compared to \$2.4 million for the quarter ended March 31, 2015. The \$0.4 million decrease in G&A expenses was due to a reduction of professional fees of \$0.8 million offset by a \$0.3 million increase in personnel-related expenses, including stock-based compensation expense and increased investor relation expenses of \$0.1 million.

Net Loss - Net loss was \$4.2 million or (\$0.10) per share for the quarter ended March 31, 2016, compared to a net loss \$3.7 million or (\$0.13) per share for the quarter ended March 31, 2015.

Conference Call:

Pieris management will host a conference call beginning at 10:00 AM Eastern Time on Thursday, May 12, 2016, to discuss the first quarter 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 dialling +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; projected timing and outcomes of clinical trials; our liquidity and ability to fund our future operations; our ability to achieve certain milestones and receive future milestone or royalty payments; 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

PIERIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	<u>March 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Assets:		
Cash and cash equivalents	\$31,188,527	\$29,349,124
Accounts receivable, net	70,259	—
Prepaid expenses and other current assets	3,608,102	2,311,385
Total current assets	<u>34,866,888</u>	<u>31,660,509</u>
Property and equipment, net	2,210,389	2,162,771
Other noncurrent assets	128,020	126,781
Total Assets	<u>\$37,205,297</u>	<u>\$33,950,061</u>
Liabilities and stockholders' equity:		
Accounts payable	\$ 1,711,028	\$ 1,058,536
Accrued expenses	2,322,044	1,739,380
Deferred revenue, current portion	2,464,722	—
Total current liabilities	<u>6,497,794</u>	<u>2,797,916</u>
Deferred revenue, net of current portion	3,491,690	—
Other long-term liabilities	39,742	23,852
Total Liabilities	10,029,226	2,821,768
Total stockholders' equity	<u>27,176,071</u>	<u>31,128,293</u>
Total liabilities and stockholders' equity	<u>\$37,205,297</u>	<u>\$33,950,061</u>

PIERIS PHARMACEUTICALS, INC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2016	2015
	(Unaudited)	
Revenues	\$ 1,246,644	\$ 217,621
Operating expenses		
Research and development	3,659,435	1,524,631
General and administrative	1,967,883	2,394,323
Total operating expenses	5,627,318	3,918,954
Loss from operations	(4,380,674)	(3,701,333)
Interest expense, net	—	(4,170)
Other income, net	219,620	769
Loss before income taxes	(4,161,054)	(3,704,734)
Provision (benefit) for income tax	—	—
Net loss	<u>\$ (4,161,054)</u>	<u>\$ (3,704,734)</u>
Basic and diluted net loss per share	<u>\$ (0.10)</u>	<u>\$ (0.13)</u>
Basic and diluted weighted average shares outstanding	<u>39,833,023</u>	<u>29,292,855</u>

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Source: Pieris Pharmaceuticals, Inc.