

**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): August 9, 2018

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 August 9, 2018, Pieris Pharmaceuticals, Inc. (the “Company”) issued a press release announcing certain financial results for the fiscal quarter ended June 30, 2018. A copy of the press release issued by the Company is furnished as Exhibit 99.1 to this report.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

99.1 [Press release announcing financial results for the quarter ended June 30, 2018, dated August 9, 2018.](#)

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: August 9, 2018

/s/ Allan Reine

Allan Reine

Chief Financial Officer

PRESS RELEASE

**PIERIS PHARMACEUTICALS REPORTS SECOND QUARTER 2018
FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE**

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON
THURSDAY, AUGUST 9, 2018 AT 8:00 AM EDT

BOSTON, MA, August 9, 2018 - Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS), a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin[®] technology platform for cancer, respiratory and other diseases, today reported financial results for the second quarter of 2018 ended June 30, 2018, and provided an update on the Company's recent and future developments.

"The second quarter of 2018 was characterized by intense focus on execution of our clinical programs. We remain on track to update investors with data from all three programs before year end. Our lead IO program, PRS-343, continues to advance apace in a dose-escalation study, and we expect to initiate a trial in combination with atezolizumab (Tecentriq[®]) later this year. For PRS-060, our inhaled IL-4 receptor alpha antagonist program, we successfully completed the single-ascending dose inhalation phase in healthy volunteers and recently initiated a multiple-ascending dose study in subjects with mild asthma to test for early proof of concept via biomarkers. Our anchor alliances with AstraZeneca for respiratory diseases and with Servier and Seattle Genetics for immuno-oncology, which account for more than five active programs within our pipeline and represent a cornerstone of our strategy of managing risk through diversification and shared investments, are also progressing well," said Stephen S. Yoder, President and CEO of Pieris. "With our team's clinical execution performance and our commitment to further mature our immuno-oncology franchise with two expected IND filings next year, we believe we are well-positioned to deliver on our milestones and create long-term value for our shareholders."

- **PRS-343:** Pieris intends to report initial pharmacokinetic, safety, tolerability and biomarker data for its PRS-343 Phase I study for the treatment of HER2+ solid tumors in the fourth quarter of 2018. PRS-343, the first bispecific costimulatory T-cell agonist to enter the clinic, is a fully-proprietary immuno-oncology drug candidate composed of Anticalin proteins targeting 4-1BB genetically fused to an antibody targeting HER2. Pieris also intends to initiate a PRS-343 combination trial with atezolizumab during the second half of 2018 to interrogate the synergistic potential of 4-1BB agonism and PD-L1 blockade.
- **PRS-060:** Pieris intends to report initial data for its PRS-060 single-ascending dose study in healthy volunteers during the fourth quarter of 2018. PRS-060, the lead candidate in Pieris' respiratory collaboration with AstraZeneca, is an IL-4 receptor alpha antagonist in development for the treatment of moderate-to-severe asthma. The Company rapidly enrolled the inhaled cohorts of the single-ascending dose study in healthy volunteers and has initiated a multiple-ascending dose study in subjects with mild asthma and elevated levels of fractional exhaled nitric oxide (FeNO). The study will evaluate the safety, tolerability and FeNO-reducing potential of PRS-060 versus placebo. Although Pieris is sponsoring the Phase I trial, AstraZeneca is funding its costs. AstraZeneca will conduct and fund the Phase IIa study, after which Pieris will have separate options to co-develop and co-commercialize the drug candidate.
- **PRS-080:** Pieris intends to report, by year end, pharmacokinetic, safety, tolerability and pharmacodynamic data for its PRS-080 Phase IIa study for the treatment of dialysis-dependent patients with functional iron deficiency anemia, including changes in hemoglobin levels after five weekly doses of PRS-080. ASKA Pharmaceutical Co. currently has an exclusive option for PRS-080 for Japan and other Asian territories, and Pieris will seek to partner the asset outside of those territories if data are positive.
- **AstraZeneca Collaboration:** Pieris recently initiated an additional program on an undisclosed respiratory target as part of its collaboration with AstraZeneca. The collaboration was signed in 2017 and covers the development of PRS-060 and four additional inhalable novel Anticalin proteins against undisclosed targets for respiratory diseases. As part of the collaboration, Pieris has separate co-development and co-commercialization options for PRS-060 and two of the four additional programs.
- **Servier Collaboration:** Pieris continues to work closely with Servier on the development of several bispecific candidates as part of an immuno-oncology collaboration the companies signed in 2017 and anticipates filing the first IND under the collaboration in 2019 for a program for which Pieris retains the option to full U.S. rights.

- **Seattle Genetics Collaboration:** Pieris has initiated work under its collaboration with Seattle Genetics, signed earlier this year, and has generated multiple functionally characterized bispecific antibody-Anticalin fusion proteins for the first program. Under the terms of the collaboration, the companies will pursue the development of three bispecific therapeutics programs assembled from Pieris' suite of costim-engaging Anticalin proteins and Seattle Genetics' substantial tumor-targeted antibody portfolio. Pieris may opt into global co-development and U.S. commercialization of one program and share in global costs and profits on a 50/50 basis.
- **Roche Collaboration:** Pieris recently received notification of Roche's intent to discontinue the companies' research collaboration and license agreement, effective August 21, 2018. The Roche collaboration, signed in 2015, pursued the discovery of Anticalin proteins specific for an exploratory immuno-oncology target selected by Roche. Pieris received an upfront payment of approximately \$6.4M for the collaboration. Anticalin proteins generated under the collaboration will be wholly owned by the Company; Pieris is currently reviewing the data generated under this collaboration and will consider its strategic options thereafter.
- **Sanofi Collaboration:** Pieris recently received notification of Sanofi's intent to return to Pieris all rights to the tetraspecific Anticalin program targeting *P. aeruginosa*, effective August 23, 2018. The program originated from a 2010 collaboration from which Pieris received an upfront payment of €3.5M and three milestone payments totaling €1.2M. Sanofi will transfer all related materials, data, and reports to Pieris, who will gain full control over the program. Pieris intends to review this data package and consider its strategic options thereafter.
- **Early Stage Pipeline:** Pieris remains committed to advancing several early stage programs into the clinic and is on track to file two immuno-oncology INDs, one proprietary and one as part of its collaboration with Servier, in 2019. The Company has also initiated two proprietary respiratory programs.

Second Quarter Financial Update:

Cash Position - Cash, cash equivalents and investments totaled \$151.7 million as of June 30, 2018, compared to a cash, cash equivalents and investments balance of \$82.6 million as of December 31, 2017. The increase was driven primarily by the \$47.2 million in net proceeds from the Company's February 2018 equity financing, the \$30.0 million in upfront payments received as part of the Seattle Genetics immuno-oncology collaboration, and the \$12.5 million milestone payment from AstraZeneca that was triggered during the fourth quarter of 2017 and received during the first quarter of 2018. The increase was partially offset by \$22.2 million of operating cash expenditures during the year.

R&D Expense - R&D expenses were \$9.2 million for the three months ended June 30, 2018, compared to \$5.4 million for the three months ended June 30, 2017. R&D expenses were \$17.1 million for the six months ended June 30, 2018, compared to \$10.8 million for the six months ended June 30, 2017. The Company's increase in R&D expenses reflects advancement across its pipeline of programs as well as preparation for and advancement of clinical studies.

G&A Expense - G&A expenses were \$4.8 million for the three months ended June 30, 2018, compared to \$4.3 million for the three months ended June 30, 2017. G&A expenses were \$9.1 million for the six months ended June 30, 2018, compared to \$8.3 million for the six months ended June 30, 2017. The Company's increase in G&A expenses reflects higher personnel costs, professional services costs for audit and legal, as well as an increase in general administrative costs to support the growing business of the Company. The increase was partially offset by lower transaction fees for license and collaboration agreements compared to amounts recorded in the first half of 2017.

Net Loss - Net loss was \$0.2 million or \$0.00 per share for the three months ended June 30, 2018, compared to a net loss of \$10.1 million or \$(0.23) per share for the three months ended June 30, 2017. Net loss was \$8.9 million or \$(0.17) per share for the six months ended June 30, 2018, compared to a net loss of \$18.1 million or \$(0.42) per share for the six months ended June 30, 2017.

Conference Call:

Pieris management will host a conference call beginning at 8:00 AM Eastern Daylight Time on Thursday, August 9, 2018, to discuss the first quarter of 2018 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). 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 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.

Tecentriq® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

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 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 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, 2017 and the Company's Quarterly Reports on Form 10-Q.

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

	<u>June 30, 2018</u>	<u>December 31, 2017</u>
Assets:		
Cash and cash equivalents	\$ 50,576	\$ 37,878
Short term investments	100,399	34,751
Accounts receivable	2,559	15,546
Prepaid expenses and other current assets	3,065	1,615
Total current assets	<u>156,599</u>	<u>89,790</u>
Property and equipment, net	4,597	4,034
Long term investments	700	9,922
Other non-current assets	<u>129</u>	<u>130</u>

Total Assets	\$ 162,025	\$ 103,876
Liabilities and stockholders' equity:		
Accounts payable	\$ 3,174	\$ 2,452
Accrued expenses	4,562	6,170
Deferred revenue, current portion	44,598	37,153
Total current liabilities	52,334	45,775
Deferred revenue, net of current portion	54,336	46,542
Other long-term liabilities	37	37
Total Liabilities	106,707	92,354
Total stockholders' equity	55,318	11,522
Total liabilities and stockholders' equity	\$ 162,025	\$ 103,876

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

	Three months ended June		Six months ended June 30,	
	2018	2017	2018	2017
Revenues	\$ 11,691	\$ 1,853	\$ 15,843	\$ 3,196
Operating expenses				
Research and development	9,155	5,396	17,091	10,756
General and administrative	4,779	4,348	9,131	8,337
Total operating expenses	13,934	9,744	26,222	19,093
Loss from operations	(2,243)	(7,891)	(10,379)	(15,897)
Interest income, net	662	—	987	—
Other income (expense), net	1,230	(1,380)	327	(1,368)
Loss before income taxes	(351)	(9,271)	(9,065)	(17,265)
Provision for income tax	(148)	814	(148)	814
Net loss	\$ (203)	\$ (10,085)	\$ (8,917)	\$ (18,079)
Basic and diluted net loss per share	\$ —	\$ (0.23)	\$ (0.17)	\$ (0.42)
Basic and diluted weighted average shares outstanding	53,983	43,408	52,025	43,237