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 10, 2020

PIERIS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Nevada	**001-37471**	**30-0784346**
(State or other jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

225 State Street, 9th Floor	**02109**
Boston, MA	
(Address of principal executive offices)	**(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**PIRS**	**The Nasdaq Capital Market**

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 10, 2020, Pieris Pharmaceuticals, Inc. (the "Company") issued a press release announcing certain financial results for the fiscal quarter ended June 30, 2020. 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 Dated August 10, 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: August 10, 2020

/s/ Tom Bures

Tom Bures

Vice President, Finance

PRESS RELEASE

PIERIS PHARMACEUTICALS REPORTS
SECOND QUARTER 2020 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON
MONDAY, AUGUST 10, 2020 AT 8:00 AM EDT

- **PRS-060/AZD1402 phase 2a trial in asthma to start in fourth quarter**
- **Signed clinical trial collaboration agreement with Lilly for supply of ramucirumab for phase 2 trial of PRS-343**
- **PRS-343 phase 2 trial in gastric cancer to start this year**
- **PRS-343 phase 1 data to be presented in oral presentation session at ESMO**
- **Achievement of preclinical milestone for first program in Seattle Genetics collaboration**

BOSTON, MA, August 10, 2020 - ***Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS)***, a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform for respiratory diseases, cancer, and other indications, today reported financial results for the second quarter of 2020 ended June 30, 2020 and provided an update on the Company's recent and future developments.

"We look forward to beginning the phase 2 trials of our lead clinical programs, PRS-343 and PRS-060, later this year. In preparation for the phase 2 trial of PRS-343 with ramucirumab and paclitaxel, we have signed a clinical trial collaboration agreement for supply of ramucirumab with Lilly, which will give us the ability to explore the potential merits of this combination regimen while managing costs efficiently," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "We also have made measurable progress in our collaboration with Seattle Genetics, achieving a key preclinical milestone for the first of up to three bispecific programs we are developing as part of that alliance."

- **PRS-060:** Pieris and AstraZeneca are preparing to initiate the phase 2a study of PRS-060/AZD1402 in in the fourth quarter of 2020. The study of PRS-060/AZD1402, which is being developed for the treatment of moderate-to-severe asthma, will be sponsored, funded, and delivered by AstraZeneca. 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:** Pieris is working towards the initiation of a phase 2 single-arm study of PRS-343, a 4-1BB/HER2 bispecific for HER2-positive tumors, in combination with ramucirumab and paclitaxel in the second line of treatment of HER2-positive gastric cancer later this year. The U.S. Food and Drug Administration (FDA) has provided input on the design of the planned proof-of-concept study, and, pending the successful completion of an additional in-use and compatibility study in connection with the partial clinical hold placed on the phase 1 studies of the drug candidate, which the company is designing with input from FDA and plans to initiate later this month, the Company expects to initiate a phase 2 study in second-line gastric cancer in combination with the standard of care this year. Although Pieris cannot enroll new patients into the phase 1 studies of PRS-343 until resolution of this partial hold, currently-enrolled patients may continue to receive treatment. Additionally, Pieris will present phase 1 dose-escalation monotherapy and combination with atezolizumab data for PRS-343 in an oral presentation session at the European Society for Medical Oncology (ESMO) Virtual Congress 2020.

- **Ramucirumab Drug Supply Agreement:** Pieris has entered into a clinical trial collaboration agreement with Eli Lilly and Company to evaluate the safety and efficacy of combining Pieris' PRS-343 with Lilly's ramucirumab, a VEGFR2 antagonist FDA-approved for multiple types of solid tumors, and paclitaxel in second-line treatment of HER2-positive gastric cancer in a phase 2 study. Under the terms of the agreement, Lilly will supply Pieris with ramucirumab, as well as collaborate on data from the trial.

- **Seattle Genetics Collaboration:** Pieris achieved a key preclinical milestone for one of the programs in the collaboration, a bispecific tumor-targeted costimulatory agonist, triggering a $5 million milestone payment. The program is one of up to three potential programs in the Seattle Genetics alliance, and the achieved milestone further validates Pieris' approach and leadership in immuno-oncology bispecifics, complementing the encouraging clinical data seen with PRS-343. Pieris has handed the program over to Seattle Genetics, who is responsible for further advancement and funding of the asset.

- **Servier Collaboration:** Pieris and Servier continue development of PRS-344 and PRS-352. Pieris anticipates filing an IND application for PRS-344, a 4-1BB/PD-L1 bispecific, next year. The Company holds exclusive commercialization rights for PRS-344 in the United States and will receive royalties on ex-U.S. sales by Servier for this program. Pieris is also focused on completing the non-GLP preclinical work for PRS-352, a preclinical-stage program addressing undisclosed targets, and expects to hand it over to Servier in the fourth quarter of this year.

- **Preclinical Respiratory Pipeline:** Beyond PRS-060, Pieris continues to advance three discovery programs in its five-program respiratory collaboration with AstraZeneca. Pieris expects AstraZeneca will initiate the fourth discovery program in the collaboration later 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 in later this year.

Fiscal Year Financial Update:

Cash Position - Cash, cash equivalents, and investments totaled $77.2 million for the quarter ended June 30, 2020, compared to a cash, cash equivalents, and investments balance of $104.2 million for the quarter ended December 31, 2019. The decrease was due primarily to operating cash expenses and capital as well as one-time expenditures associated with the move to a new R&D facility in Hallbergmoos, Germany in the first quarter of 2020.

R&D Expense - R&D expenses were $11.3 million for the quarter ended June 30, 2020, compared to $13.4 million for the quarter ended June 30, 2019. The decrease in R&D expenses was due primarily to lower manufacturing spending on PRS-344, PRS-060, and other preclinical programs, lower costs on non-core programs, and lower travel-related expenditures due to COVID-19 restrictions, all partially offset by an increase in allocated IT and facility costs due to the move to the new facility and higher personnel costs.

G&A Expense - G&A expenses were $4.6 million for the quarter ended June 30, 2020, compared to $4.2 million for the quarter ended June 30, 2019. The increase in G&A expenses was due primarily to higher legal expense, audit expense, and allocated IT and facility costs due to the move to the new facility. These increases were partially offset by lower personnel costs, professional services, and travel-related expenditures due to COVID-19 restrictions.

Net Loss - Net loss was $5.0 million or $(0.09) per share for the quarter ended June 30, 2020, compared to a net loss of $11.8 million or $(0.24) per share for the quarter ended June 30, 2019.

Conference Call*:*

Pieris management will host a conference call beginning at 8:00 AM EDT on Monday, August 10, 2020, to discuss the first quarter 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**:*

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, the timing for, and outcome of, the additional in-use and compatibility study for PRS-343 as requested by the FDA; whether data from patients enrolled to date will be sufficient to inform the recommended phase 2 dose for the Company's planned proof of concept study of PRS-343 in gastric cancer; the expected timing and potential outcomes of the reporting by the Company of key clinical data from its 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, making IND filings or achieving other milestones related to our programs, including PRS-060/AZD1402, PRS-343, PRS-344, and PRS-352 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, including with respect to the additional in-use and compatibility study for PRS-343, and the resolution of the partial clinical hold relating to that drug candidate; competition in the industry in which we operate; delays or disruptions due to COVID-19; 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, 2019 and the Company's Quarterly Reports on Form 10-Q.

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CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	June 30, 2020	December 31, 2019
Assets:		
Cash and cash equivalents	$ 44,302	$ 62,260
Short term investments	32,912	41,894
Accounts receivable	10,712	6,787
Prepaid expenses and other current assets	4,102	4,072
Total current assets	92,028	115,013
Property and equipment, net	20,506	19,502
Operating lease right-of-use assets	3,274	3,436
Other non-current assets	1,975	3,146
Total Assets	$ 117,783	$ 141,097
Liabilities and stockholders' equity:		
Accounts payable	$ 4,406	$ 5,803
Accrued expenses	5,942	9,944
Deferred revenue, current portion	7,912	11,256
Total current liabilities	18,260	27,003
Deferred revenue, net of current portion	37,845	47,258
Operating lease liabilities	15,006	15,484
Total Liabilities	71,111	89,745
Total stockholders' equity	46,672	51,352
Total liabilities and stockholders' equity	$ 117,783	$ 141,097

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

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Revenues	$ 11,246	$ 5,332	$ 24,507	$13,877
Operating expenses				
Research and development	11,333	13,373	24,091	27,669
General and administrative	4,568	4,189	8,927	9,121
Total operating expenses	15,901	17,562	33,018	36,790
Loss from operations	(4,655)	(12,230)	(8,511)	(22,913)
Interest income	129	449	448	955
Other income (expense), net	(424)	23	(484)	(148)
Loss before income taxes	(4,950)	(11,758)	(8,547)	(22,106)
Provision for income tax	—	—	—	—
Net loss	$ (4,950)	$ (11,758)	$ (8,547)	$ (22,106)
Basic and diluted net loss per share	$ (0.09)	$ (0.24)	$ (0.16)	$ (0.44)
Basic and diluted weighted average shares outstanding	52,371	49,204	53,792	50,034