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 4, 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 Boston, MA	**02109**
(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 November 4, 2020, Pieris Pharmaceuticals, Inc. (the "Company") issued a press release announcing certain financial results for the fiscal quarter ended September 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 November 4, 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: November 4, 2020

/s/ Tom Bures
Tom Bures
Vice President, Finance

PRESS RELEASE

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

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON
WEDNESDAY, NOVEMBER 4, 2020 AT 8:00 AM EST

- **PRS-060/AZD1402 first regulatory submission for global phase 2a study has been made; site initiation and patient screening expected this year**
- **PRS-343 in-use studies requested by FDA are completed; forthcoming meeting with FDA to align on path for continued development**
- **PRS-343 phase 1 monotherapy and atezolizumab combination data at ESMO demonstrated clinical benefit in both studies, including a confirmed complete response in the mono-therapy study, durable benefit, and biomarker data suggesting 4-1BB-driven activity**
- **$9.7M in net proceeds through strategic use of ATM facility**

BOSTON, MA, November 4, 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 third quarter of 2020 ended September 30, 2020 and provided an update on the Company's recent and anticipated future developments.

"Within our respiratory franchise, we are pleased with AstraZeneca's commitment to the continued clinical development of PRS-060/AZD1402 and are happy to announce that preparations for a global phase 2a study of that program are complete. The study will be performed using a dry powder formulation in moderate asthmatics and will assess FEV1 improvement," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "In immuno-oncology, we presented additional data from our phase 1 studies of PRS-343 at ESMO, which showed single-agent clinical benefit, including a confirmed complete response, robust durability of response, and biomarker data suggesting 4-1BB-driven activity. Further, I am proud of the diligence of our team in completing the in-use studies to address the partial clinical hold of PRS-343. In a planned upcoming meeting with FDA, we intend to confirm the sufficiency of these data to remove the hold and align on the path to initiate our planned proof of concept study in gastric cancer."

- **PRS-060:** AstraZeneca submitted the first Clinical Trial Application for a global phase 2a study of PRS-060/AZD1402. Dependent on regulatory approval, site initiation and patient screening are expected to begin this year. The first patients will be dosed thereafter, which we anticipate will be in the first quarter of next year, triggering a milestone payment from AstraZeneca. The phase 2a study will be performed using a dry powder formulation and will evaluate the efficacy, safety, and pharmacokinetics of PRS-060/AZD1402 in moderate uncontrolled asthmatics over four weeks with FEV1 improvement as the primary endpoint, following a four-week dosing arm in moderate controlled asthmatics to establish the safety and pharmacokinetics of the dry powder formulation. The study of PRS-060/AZD1402, which is being developed for the treatment of moderate-to-severe asthma, is being 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 presented a clinical data update from the phase 1 monotherapy and atezolizumab combination studies of PRS-343, a 4-1BB/HER2 bispecific for the treatment of HER2-positive solid tumors, in an oral presentation at the European Society for Medical Oncology (ESMO) Virtual Congress 2020. In that presentation, PRS-343 demonstrated durable clinical benefit in the active

dose cohorts, including a confirmed complete response, in heavily pre-treated patients across multiple HER2-positive tumor types. Additionally, a significant expansion of CD8+ T cells in the

tumor microenvironment of responders and a substantial increase of soluble 4-1BB were observed in the active dose cohorts, suggesting 4-1BB-mediated target engagement driving clinical benefit. The Company has completed the in-use studies it deems necessary to remove the previously announced partial clinical hold. As part of the completed in-use studies, Pieris has optimized the level of an existing excipient to enhance the stability of PRS-343 in preparation for administration. The Company will shortly submit the data from these studies to FDA as part of a Type A meeting request to align on the next phase of development for PRS-343. As a result of this more thorough engagement with FDA, Pieris now expects to initiate the phase 2 study of PRS-343 in combination with ramucirumab and paclitaxel in the second line of treatment of HER2-positive gastric cancer next year.

- **Servier Collaboration:** Pieris and Servier remain on track to file 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 intends to complete non-GLP preclinical work for PRS-352 this year before handing the program over to Servier, who would be fully responsible for further development. PRS-352 is a preclinical-stage program within the Servier alliance addressing undisclosed targets for immuno-oncology.

- **Preclinical Respiratory Pipeline:** AstraZeneca initiated the fourth program in the collaboration in the third quarter, taking full advantage of all available potential new project starts envisioned in the alliance. Pieris continues to advance several proprietary discovery-stage respiratory programs and now expects to share data and rationale for advancement of one of its proprietary programs next year.

- **ATM Deployment:** The Company raised $9.7 million in net proceeds from investment fund Pontifax through its at-the-market (ATM) equity facility. This transaction provides a meaningful yet focused amount of working capital to advance the pipeline, while further strengthening the Company's shareholder base.

Fiscal Year Financial Update:

Cash Position - Cash, cash equivalents, and investments totaled $82.6 million for the quarter ended September 30, 2020, compared to a cash, cash equivalents, and investments balances of $77.2 million and $104.2 million for the quarters ended June 30, 2020 and December 31, 2019, respectively. The decrease since year end was primarily due 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, partially offset by third quarter 2020 cash inflows of $9.7 million in net proceeds from an ATM offering and $5.0 million collected for the prior achievement of a milestone.

R&D Expense - R&D expenses were $11.8 million for the quarter ended September 30, 2020, compared to $13.2 million for the quarter ended September 30, 2019. The decrease in R&D expenses was primarily due to lower manufacturing and clinical spending on PRS-060, lower preclinical and manufacturing costs, and lower travel-related expenditures due to COVID-19 restrictions. The overall decrease was partially offset by an increase in allocated IT and facility costs due to the move to the new facility, higher consulting spend, and higher license costs.

G&A Expense - G&A expenses were $4.1 million for the quarter ended September 30, 2020, compared to $4.8 million for the quarter ended September 30, 2019. The decrease in G&A expenses was primarily due to lower personnel costs, lower audit and professional fees, and lower travel-related expenditures due to COVID-19 restrictions. These decreases were partially offset by higher allocated IT and facility costs due to the move to the new facility.

Net Loss - Net loss was $14.3 million or $(0.26) per share for the quarter ended September 30, 2020, compared to a net loss of $2.6 million or $(0.05) per share for the quarter ended September 30, 2019.

***Conference Call**:*

Pieris management will host a conference call beginning at 8:00 AM EST on Wednesday, November 4, 2020, to discuss the third 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, including AstraZeneca, Seagen, and Servier. 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 FDA's views as to, 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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PIERIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	September 30, 2020	December 31, 2019
Assets:		
Cash and cash equivalents	$ 66,890	$ 62,260
Short term investments	15,750	41,894
Accounts receivable	2,944	6,787
Prepaid expenses and other current assets	3,074	4,072
Total current assets	88,658	115,013
Property and equipment, net	21,395	19,502
Operating lease right-of-use assets	3,678	3,436
Other non-current assets	1,993	3,146
Total Assets	$ 115,724	$ 141,097
Liabilities and stockholders' equity:		
Accounts payable	$ 2,154	$ 5,803
Accrued expenses	7,488	9,944
Deferred revenue, current portion	10,045	11,256
Total current liabilities	19,687	27,003
Deferred revenue, net of current portion	36,919	47,258
Operating lease liabilities	15,427	15,484
Total Liabilities	72,033	89,745
Total stockholders' equity	43,691	51,352
Total liabilities and stockholders' equity	$ 115,724	$ 141,097

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

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Revenues	$ 2,939	$ 15,132	$ 27,446	$ 29,009
Operating expenses				
Research and development	11,822	13,211	35,913	40,880
General and administrative	4,116	4,835	13,043	13,956
Total operating expenses	15,938	18,046	48,956	54,836
Loss from operations	(12,999)	(2,914)	(21,510)	(25,827)
Interest income	55	377	503	1,332
Other expense	(1,339)	(55)	(1,823)	(203)
Loss before income taxes	(14,283)	(2,592)	(22,830)	(24,698)
Net loss	$ (14,283)	$ (2,592)	$ (22,830)	$ (24,698)
Basic and diluted net loss per share	$ (0.26)	$ (0.05)	$ (0.42)	$ (0.50)
Basic and diluted weighted average shares outstanding	54,340	49,353	53,976	49,805