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 2, 2021

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 2, 2021, Pieris Pharmaceuticals, Inc. (the "Company") issued a press release announcing certain financial results for the quarter ended September 30, 2021. 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 Exhibit 99.1 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 2, 2021.

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 2, 2021

/s/ Tom Bures
Tom Bures
Chief Financial Officer

PRESS RELEASE

PIERIS PHARMACEUTICALS REPORTS
THIRD QUARTER 2021 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON
TUESDAY, NOVEMBER 2, 2021 AT 8:00 AM EDT

- **Dosing completed in part 1a of phase 2a study of PRS-060/AZD1402**
- **Dosing to begin this quarter in phase 2 study of cinrebafusp alfa**
- **Received regulatory approval from multiple countries for phase 1/2 study of PRS-344/ S095012**
- **Presented preclinical data for PRS-220 at ERS; on track for 2022 clinical initiation**
- **Initiated respiratory and ophthalmology programs with Genentech**
- **Promoted Thomas Bures to CFO and Ahmed Mousa to CBO**

BOSTON, MA, November 2, 2021 - ***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 2021 ended September 30, 2021 and provided an update on the Company's recent and anticipated future developments.

"I am pleased to report that AstraZeneca has completed dosing in part 1a of the phase 2a study of PRS-060/AZD1402. We look forward to announcing the completion of the safety review by AstraZeneca before initiating the second part of that study and presenting topline data informing our co-development opt-in decision next year. Also within our respiratory franchise, we are progressing PRS-220 toward the clinic next year, and we recently presented preclinical data for that program, reinforcing our enthusiasm about it. Additionally, we have made important strides in getting the next phase of clinical trials for our immuno-oncology programs cinrebafusp alfa and PRS-344 activated, and we are excited to see those trials progress," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "We have a solid balance sheet of over $125 million as we continue to advance a diverse and rich pipeline of fully proprietary and co-developed assets into and through the clinic this year and anticipate several key inflection points in 2022."

- **PRS-060/AZD1402 and AstraZeneca Collaboration:** Dosing has been completed in part 1a (safety) of the global phase 2a study of PRS-060/AZD1402, an inhaled IL-4 receptor alpha inhibitor under development in collaboration with AstraZeneca for the treatment of moderate-to-severe asthma. Data unblinding and review will now follow, the outcome of which the Company will publicly disclose, gating progression to the second part of the study, where efficacy will be assessed in moderate, uncontrolled asthmatics. Pieris and AstraZeneca expect to announce topline data from the entire phase 2a study next year. Upon completion of the study, which is being sponsored and funded by AstraZeneca, Pieris will have the options to co-develop and, separately, co-commercialize PRS-060/AZD1402 in the United States. Pieris and AstraZeneca continue to advance each of the four programs in the collaboration beyond PRS-060/AZD1402.

- **Cinrebafusp Alfa (PRS-343):** Pieris plans to dose the first patient in a two-arm phase 2 study for cinrebafusp alfa, a 4-1BB/HER2 bispecific for the treatment of HER2-expressing solid tumors, in gastric cancer this quarter and reconfirms its plan to report initial data from the arm evaluating cinrebafusp alfa in combination with tucatinib in HER2-low gastric cancer next year. The Company has decided to focus enrollment on second line patients and now expects to report data from the arm evaluating cinrebafusp alfa in combination with ramucirumab and paclitaxel in HER2-high

gastric cancer in 2023.

- **PRS-344/S095012 and Servier Collaboration:** Regulatory approval for the phase 1/2 study of PRS-344/S095012, a 4-1BB/PD-L1 bispecific, has been granted by multiple countries. Pieris holds exclusive commercialization rights for PRS-344/S095012 in the United States and will receive royalties on ex-U.S. sales for this program, should it receive regulatory approval. Additionally, Servier is continuing development of PRS-352, an undisclosed Anticalin-based bispecific beyond 4-1BB.

- **PRS-220:** Pieris presented initial preclinical data for PRS-220, a proprietary inhaled Anticalin protein targeting connective tissue growth factor (CTGF) for the treatment of idiopathic pulmonary fibrosis (IPF), at the European Respiratory Society International Congress 2021 (ERS) demonstrating a more potent and durable target engagement profile compared to a clinical-stage, systemically delivered anti-CTGF antibody benchmark. Additionally, the targeting of CTGF locally in the lung showed increased attenuation of fibrotic lung remodeling *in vivo* compared to the systemically delivered antibody. This outcome correlates with superior lung tissue exposure of PRS-220 compared to that of the systemically administered antibody in head-to-head studies, where intratracheally administered PRS-220 efficiently penetrates the fibrotic, interstitial lung tissue of mice. Clinical development for the program in IPF and post-COVID pulmonary fibrosis, as supported by a grant from the Bavarian government, is expected to begin next year.

- **Genentech Collaboration:** Pieris and Genentech initiated joint discovery activities for the two committed programs, one in respiratory and one in ophthalmology, as part of their research collaboration and license agreement to discover, develop, and commercialize locally delivered therapies that leverage Pieris' proprietary Anticalin technology.

- **Executive Leadership:** Pieris announced the promotion of Thomas Bures to Senior Vice President and Chief Financial Officer. Mr. Bures oversees all financial matters at the company, including treasury, tax, financial planning, procurement and investor relations. Pieris additionally announced the promotion of Ahmed Mousa to Senior Vice President and Chief Business Officer. In his new role, Mr. Mousa heads business development and portfolio strategy, in addition to serving as General Counsel and Boston site head.

First Quarter Financial Update:

Cash Position – Cash and cash equivalents totaled $125.1 million for the quarter ended September 30, 2021, compared to a cash and cash equivalents balance of $70.4 million for the year ended December 31, 2020. The increase since December 2020 is due to cash received from new and existing collaboration agreements, including milestone achievements and use of the Company's ATM program. This increase was partially offset by cash used to fund operations for the first nine months of 2021. The September 30th cash position does not include the impact of the Bavarian government grant, as those proceeds will be reimbursed for qualifying program costs incurred over the PRS-220 development period. In the third quarter ended September 30, 2021, the Company raised more than $23 million in cash through the use of the ATM program.

R&D Expense - R&D expenses were $18.9 million for the quarter ended September 30, 2021, compared to $11.8 million for the quarter ended September 30, 2020. The increase reflects higher spending on preclinical and manufacturing activities for PRS-220, an increase in manufacturing costs across multiple immuno-oncology programs, higher clinical costs on cinrebafusp alfa and higher employee related costs. These increases were partially offset by lower manufacturing costs on PRS-060, which are fully reimbursable.

G&A Expense - G&A expenses were $4.1 million for the quarter ended September 30, 2021, compared to $4.1 million for the quarter ended September 30, 2020. There were no significant changes in categories of spending as G&A departments continue to efficiently leverage spending to support the Company's overall

spending as Gartner departments continue to efficiently leverage spending to support the Company's overall needs.

Other Income - For the quarter ended September 30, 2021, $1.8 million of other income was recorded for PRS-220 program costs that qualified for reimbursement under the Bavarian grant that was announced in June 2021.

Net Loss - Net loss was $16.5 million or $(0.24) per share for the quarter ended September 30, 2021, compared to a net loss of $14.3 million or $(0.26) per share for the quarter ended September 30, 2020.

Conference Call:

Pieris management will host a conference call beginning at 8:00 AM EDT on Tuesday, November 2, 2021, to discuss finance results for the third quarter of 2021 and provide a corporate update. Individuals can join the call by dialing +1-877-407-8920 (US & Canada) or +1-412-902-1010 (International). Alternatively, a listen-only audio webcast of the call can be accessed here.

For those unable to participate in the conference call or listen to the webcast, a replay will be available on the Investors section of the Company's website, www.pieris.com.

About Pieris Pharmaceuticals:

Pieris is a clinical-stage biotechnology company that combines leading protein engineering capabilities and deep understanding into molecular drivers of disease to develop medicines that drive local biology to produce superior clinical outcomes for patients. Our pipeline includes inhalable Anticalin proteins to treat respiratory diseases and locally-activated bispecifics for immuno-oncology. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by respiratory and immuno-oncology focused partnerships with leading pharmaceutical companies. 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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the potential for Pieris' development programs such as PRS-060/AZD1402, cinrebafusp alfa, PRS-344/S095012 and PRS-220 to address our core focus areas such as respiratory diseases and immuno-oncology; 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, cinrebafusp alfa, PRS-344/S095012 and PRS-220; the therapeutic potential of our Anticalin platform; our continued progress in the areas of co-stim bispecifics and inhaled therapeutics; and the advancement of our developmental programs generally. 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 U.S. Food and Drug Administration; 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 Securities and Exchange Commission available at www.sec.gov, including, without limitation,

file with the Securities and Exchange Commission available at www.sec.gov, including, without limitation, the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and the Company's Quarterly Reports on Form 10-Q.

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

	June 30, 2021	December 31, 2020
Assets:		
Cash and cash equivalents	$ 125,052	$ 70,436
Short term investments	—	—
Accounts receivable	6,646	1,706
Prepaid expenses and other current assets	5,949	3,579
Total current assets	137,647	75,721
Property and equipment, net	19,613	22,046
Operating lease right-of-use assets	3,974	3,934
Other non-current assets	2,950	3,309
Total Assets	$ 164,184	$ 105,010
Liabilities and stockholders' equity:		
Accounts payable	$ 3,562	$ 1,787
Accrued expenses	19,685	7,731
Deferred revenue, current portion	26,449	12,627
Total current liabilities	49,696	22,145
Deferred revenue, net of current portion	46,190	35,900
Operating lease liabilities	14,445	15,932
Other long-term liabilities	—	6
Total Liabilities	110,331	73,983
Total stockholders' equity	53,853	31,027
Total liabilities and stockholders' equity	$ 164,184	$ 105,010

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,	
	2021	2020	2021	2020
Revenues	$ 4,057	$ 2,939	$ 22,975	$ 27,446
Operating expenses				
Research and development	18,937	11,822	51,299	35,913
General and administrative	4,132	4,116	12,508	13,043
Total operating expenses	23,069	15,938	63,807	48,956
Loss from operations	(19,012)	(12,999)	(40,832)	(21,510)
Interest income	4	55	10	503
Grant income	1,794	—	2,590	—
Other income (expense), net	678	(1,339)	2,026	(1,823)
Loss before income taxes	(16,536)	(14,283)	(36,206)	(22,830)
Provision for income tax	—	—	—	—
Net loss	$ (16,536)	$ (14,283)	$ (36,206)	$ (22,830)
Basic and diluted net loss per share	$ (0.24)	$ (0.26)	$ (0.58)	$ (0.42)
Basic and diluted weighted average shares outstanding	67,730	54,340	62,019	53,976