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 7, 2018

PIERIS PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Nevada	**001-37471**	**EIN 30-0784346**
(State of Incorporation)	**(Commission File Number)**	**(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 November 7, 2018, Pieris Pharmaceuticals, Inc. (the "Company") issued a press release announcing certain financial results for the fiscal quarter ended September 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 September 30, 2018, dated November 7, 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: November 7, 2018

/s/ Allan Reine

Allan Reine

Chief Financial Officer

PRESS RELEASE

PIERIS PHARMACEUTICALS REPORTS THIRD QUARTER 2018 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

COMPANY TO HOST AN INVESTOR CONFERENCE CALL ON WEDNESDAY, NOVEMBER 7, 2018 AT 8:00 AM EST

BOSTON, MA, November 7, 2018 - ***Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS)***, a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform for respiratory, cancer and other diseases, today reported financial results for the third quarter of 2018 ended September 30, 2018 and provided an update on the Company's recent and future developments.

"We are pleased to announce that PRS-060, an IL-4 receptor alpha antagonist for moderate-to-severe asthma, was safe and well-tolerated by healthy volunteers in a single ascending dose Phase I study. This is the first clinical use of an inhaled Anticalin protein and marks an important development milestone for the Company. We continue to enroll subjects with mild asthma in a multiple ascending dose Phase I study. Along with our partner AstraZeneca, we anticipate reporting the data from the Phase I studies at an upcoming medical meeting. For PRS-343, our 4-1BB/HER2 bispecific, we now intend to report initial data from a Phase I study in the first half of next year, after completing the dose escalation, to provide a more comprehensive data set," said Stephen S. Yoder, President and CEO of Pieris. "We look forward to providing updates on our progress as we head into 2019."

- **PRS-060:** PRS-060, an inhaled IL-4 receptor alpha antagonist for moderate-to-severe asthma, was tested in 48 healthy volunteers at dose levels ranging from 0.25 mg to 400 mg in a single ascending dose Phase I study. The drug candidate was safe and well-tolerated in this study. Pieris continues to enroll subjects with mild asthma and elevated levels of fractional exhaled nitric oxide (FeNO) in a multiple ascending dose Phase I study. This study will evaluate the safety, tolerability and FeNO-reducing potential of PRS-060 versus placebo. The data from the PRS-060 Phase I studies will be presented at an upcoming medical meeting. PRS-060 is the lead candidate in Pieris' respiratory collaboration with AstraZeneca. Pieris is sponsoring the Phase I studies and AstraZeneca is funding the 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-343:** The Company continues to enroll and treat patients in a Phase I dose-escalation study of PRS-343, a 4-1BB/HER2 bispecific for HER2-positive solid tumors, and now intends to report initial data from the study in the first half of 2019, after completing the dose escalation, in order to provide a more comprehensive data set. Our objective for the remaining enrollment will be to favor patient selection across a range of immunotherapy-responsive tumor types. The Company is screening patients for the 11th cohort of the study, a dose level comparable to approved dose levels of trastuzumab. In August, Pieris initiated a trial with PRS-343 in combination with atezolizumab, and the Company intends to report data from this trial in 2019.

- **PRS-080:** Pieris is planning to enroll and complete dosing of the final patient in its Phase IIa multiple ascending dose study of PRS-080, a half-life-optimized hepcidin antagonist for anemia, by year end. In the ongoing trial, PRS-080 at both doses (4mg/kg and 8mg/kg) has not generated any observed drug-related serious adverse events and has demonstrated substantial iron mobilization and transferrin saturation (TSAT) increases versus placebo. To date, there has been no conclusive change in hemoglobin at either dose versus placebo. We remain committed to completing the study and sharing the data with ASKA and other potential partners for continued development. We intend to report the full data set from the study in the first half of 2019.

- **PRS-344:** Pieris will present preclinical data for PRS-344, a PD-L1/4-1BB antibody-Anticalin bispecific in IND-enabling studies, at the Society for Immunotherapy of Cancer (SITC) 2018 Annual Meeting in Washington, D.C. The poster, P375, will be presented on November 9–10, 2018. PRS-344 is one of five development programs in Pieris' immuno-oncology alliance with Servier.

- **Board Appointments:** In September 2018, Pieris appointed Peter Kiener, D.Phil. to the Company's Board of Directors. Dr. Kiener served in several executive roles, most recently as the Chief Scientific Officer at Sucampo. In October 2018, Pieris also appointed Matthew L. Sherman, M.D. to the Company's Board of Directors. Dr. Sherman most recently served as Executive Vice President and Chief Medical Officer at Acceleron Pharma.

- **Preclinical Pipeline:** Pieris remains committed to advancing several early-stage programs into the clinic and is on track to file two immuno-oncology INDs, one for a proprietary drug candidate and one as part of its collaboration with Servier, in 2019. The Company has also initiated two proprietary respiratory programs.

Third Quarter Financial Update:

Cash Position - Cash, cash equivalents and investments totaled $137.3 million as of September 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 $35.7 million of operating cash expenditures during the year.

R&D Expense - R&D expenses were $11.4 million for the three months ended September 30, 2018, compared to $6.3 million for the three months ended September 30, 2017. R&D expenses were $28.5 million for the nine months ended September 30, 2018, compared to $17.0 million for the nine months ended September 30, 2017. The Company's increase in R&D expenses reflects preparation for and advancement of clinical studies as well as advancement across its pipeline of preclinical programs.

G&A Expense - G&A expenses were $4.7 million for the three months ended September 30, 2018, compared to $2.9 million for the three months ended September 30, 2017. G&A expenses were $13.9 million for the nine months ended September 30, 2018, compared to $11.2 million for the nine months ended September 30, 2017. The Company's increase in G&A expenses reflects higher personnel costs and professional services costs for audit and legal, as well as an increase in general administrative costs to support the growing business of the Company. On a nine-month basis, the increase was partially offset by lower transaction fees for license and collaboration agreements compared to amounts recorded in the first half of 2017.

Interest Income - Interest income was $0.5 million and $1.5 million for the three and nine months ended September 30, 2018, respectively, compared to no interest income earned in the comparable 2017 periods. The Company began investing cash received from the collaboration agreements signed in 2017 in the fourth quarter of 2017.

Other Income - Other income was $1.1 million and $1.5 million for the three and nine months ended September 30, 2018, respectively, compared to other expense of $1.7 million and $3.1 million for the three and nine months ended September 30, 2017, respectively. The Company began investing cash received from the collaboration agreements signed in 2017 in the fourth quarter of 2017. The increase in income for the three- and nine- month periods is a result of net foreign currency transaction gains due to the strengthening of the U.S. dollar against the euro, positively impacting the remeasurement of U.S. dollar denominated monetary assets held in Germany.

Net Loss - Net loss was $6.2 million or $(0.11) per share for the three months ended September 30, 2018, compared to a net loss of $7.1 million or $(0.16) per share for the three months ended September 30, 2017. Net loss was $15.1 million or $(0.29) per share for the nine months ended September 30, 2018, compared to a net loss of $25.1 million or $(0.58) per share for the nine months ended September 30, 2017.

Conference Call:

Pieris management will host a conference call beginning at 8:00 AM Eastern Standard Time on Wednesday, November 7, 2018, to discuss the third quarter of 2018 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 immuno-oncology multi-specifics tailored for the tumor microenvironment, inhalable Anticalin proteins to treat respiratory diseases 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.

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)

	September 30, 2018	December 31, 2017
Assets:		
Cash and cash equivalents	$ 89,482	$ 37,878
Short term investments	47,822	34,751
Accounts receivable	5,338	15,546
Prepaid expenses and other current assets	4,207	1,615
Total current assets	146,849	89,790
Property and equipment, net	4,687	4,034
Long term investments	—	9,922
Other non-current assets	121	130
Total Assets	$ 151,657	$ 103,876
Liabilities and stockholders' equity:		
Accounts payable	$ 2,693	$ 2,452
Accrued expenses	5,981	6,170
Deferred revenue, current portion	31,920	37,153
Total current liabilities	40,594	45,775
Deferred revenue, net of current portion	60,770	46,542
Other long-term liabilities	32	37
Total Liabilities	101,396	92,354
Total stockholders' equity	50,261	11,522
Total liabilities and stockholders' equity	$ 151,657	$ 103,876

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,	
	2018	2017	2018	2017
Revenues	$ 8,345	$ 3,927	$ 24,187	$ 7,123
Operating expenses				
Research and development	11,401	6,259	28,492	17,015
General and administrative	4,748	2,852	13,878	11,190
Total operating expenses	16,149	9,111	42,370	28,205
Loss from operations	(7,804)	(5,184)	(18,183)	(21,082)
Interest income	504	—	1,491	—
Other income (expense), net	1,147	(1,729)	1,472	(3,097)
Loss before income taxes	(6,153)	(6,913)	(15,220)	(24,179)
Provision for income tax	—	146	(148)	959
Net loss	$ (6,153)	$ (7,059)	$ (15,072)	$ (25,138)
Basic and diluted net loss per share	$ (0.11)	$ (0.16)	$ (0.29)	$ (0.58)
Basic and diluted weighted average shares outstanding	54,089	44,387	52,721	43,624