UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

DIVISION OF
CORPORATION FINANCE

September 6, 2024

Stephen Yoder
Chief Executive Officer
Pieris Pharmaceuticals, Inc.
225 Franklin Street, 26th Floor
Boston, MA 02110

Re: Pieris Pharmaceuticals, Inc.
Registration Statement on Form S-4
Filed August 9, 2024
File No. 333-281459

Dear Stephen Yoder:

We have reviewed your registration statement and have the following comments.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe a comment applies to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to this letter, we may have additional comments.

Registration Statement on Form S-4

Questions and Answers About the Merger, page 1

1. Please revise your Q&A disclosure, where appropriate, as follows:
   - Clarify the material terms of the CVR Agreement, your intentions with respect to Pieris' pre-merger assets and describe any material assets that either have been divested or may be divested by Pieris pursuant to the CVR Agreement.
   - With reference to your disclosure on pages 9 and 215, please revise the Q&A and Summary to highlight, if true, that if the merger is completed, the combined company will focus on developing Palvella's product candidates, and it is anticipated that the combined company will not continue to develop any of Pieris' legacy product candidates.
   - Also, revise the Q&A to explain what Pieris' stockholders will receive in the merger to provide context for your disclosure on page 8 discussing the tax treatment of the CVRs.

What is the PIPE Financing?, page 2

2. We note your disclosure that the PIPE Investors have agreed to subscribe for and purchase (in cash or by cancellation of convertible notes) either shares of Pieris common stock or pre-funded warrants to purchase shares of the combined company common stock. Here and throughout where appropriate, please revise to quantify the amount of the expected $78.9 million gross PIPE proceeds to be received in cash versus the amount expected to be attributed to the conversion of outstanding Palvella convertible notes.

How many votes can be cast by all stockholders?, page 4

3. We note your disclosure that on the record date the holder of one outstanding share of Series F Preferred Stock will be entitled to be entitled 25,000,000 votes only on Proposal No. 2 related to increasing the number of authorized shares of Pieris common stock, to be voted together with the holders of Pieris common stock as a single class.
   - Consistent with your disclosure page 57 and in your 8-K dated August 8, 2024 incorporated by reference, please revise the Q&A to disclose that on August 7, 2024, Pieris entered into a Subscription and Investor Representation Agreement with James Geraghty, the chairman of the Pieris board of directors, pursuant to which he purchased one share of Pieris' Series F Preferred Stock for $1.00 cash.
   - Consistent with your disclosure on page 206, explicitly state that the issuance of the Series F Preferred Stock, with its attendant voting rights, was issued by the Company solely to affect the passage of Proposal 2, which is a condition to the completion of the Merger. Explain the reason(s) why the Board determined that such issuance was necessary in this case.

4. Please revise your disclosure to explicitly describe the impact of the outsized voting rights the holder of the Series F Preferred share will have on Proposal 2 relative to holders of common stock. In this regard:
   - Please consider including an illustrative example of the effects the super voting rights of the Series F Preferred Stock will have on reaching the voting threshold necessary to approve Proposal 2. Based on the number of Pieris common shares reported outstanding in the proxy statement and assuming (1) the common shares subject to the Pieris Support Agreement and (2) the Series F Preferred share are each voted as described in the proxy statement, please clarify the number of votes that will need to be cast (i.e., the number of common shares that will need to be voted) to approve Proposal 2.
   - If true, please revise to clearly explain that the mirrored voting mechanism of the Series F Preferred Stock will have a significant impact on the vote needed to pass Proposal 2. For example, assuming the minimum quorum is met with no additional shares of common stock appearing in person or by proxy, disclose whether and if so how the mirrored voting mechanism of the Series F Preferred Stock will operate with respect to the percentage of the common shares outstanding required to vote to pass Proposal 2.
   - Clearly explain the consequence to holders of Pieris' common stock of not casting a vote on a common share for or against the proposal in person or by proxy. In this

regard, please state the likelihood that even if a Pieris' common shareholder does not vote on the proposals, Pieris will reach or exceed the voting threshold required for approval of Proposal 2.

Palvella Therapeutics, Inc., page 9

5. Please revise the Summary and throughout where appropriate to clarify the status of Palvella's ongoing and planned clinical trials. In this regard:
   - Clarify if references on page 10 and elsewhere to Palvella's "planned" Phase 2 baseline-controlled trial of QTORIN Rapamycin for the treatment of CVM expected to start in Q4 2024 are separate from references to the Phase 2 baseline-controlled trial Palvella "is conducting," with top-line data expected in Q4 2025. Also revise to clarify when you submitted, or plan to submit, an IND for the planned trial for the CVM indication.
   - Similarly, reconcile your disclosure on page 10 and elsewhere that "Palvella currently has one ongoing clinical trial and one clinical trial planned to start" with disclosure on page 226 that "QTORIN rapamycin is currently being evaluated in three ongoing clinical trials."
   - In light of your risk factor disclosure on page 73, also disclose the location(s) of Palvellas completed, ongoing and planned clinical trials.

6. Please revise the Summary and throughout where appropriate to eliminate any implication that Palvella's product candidates have been or will ultimately be determined safe and/or effective or have demonstrated safety and/or efficacy for purposes of approval by the FDA or comparable regulatory agency. Where you deem appropriate, you may present objective data without including your conclusions related to safety or efficacy. By way of example and not limitation, refer to the following:
   - Statements that Palvella has announced "positive" or "encouraging" topline Phase 2 clinical trial results. (pages 10, 221, 229 and 264)
   - Statements that "Palvella is developing the first approved therapy" for microcystic LM and CVM. (pages 226 and 233)

7. Please revise the Summary and Palvella's Business section to provide context and balance to the discussion of Palvella's proprietary QTORIN platform. To the extent that you highlight Palvella's intention to leverage its "versatile" QTORIN platform to expand its pipeline to treat a "broad spectrum" of rare, genetic skin diseases, please include equally prominent disclosure highlighting, if true:
   - that Palvella has limited experience in therapeutic discovery and development;
   - Palvella's platform is novel and unproven, and that clinical evidence to support the two current clinical-stage QTORIN product candidates is preliminary and limited at this time;
   - prior candidates developed using the QTORIN platform targeting different indications have failed to meet their respective primary endpoints, which may affect Palvella's ability to conduct clinical programs for other QTORIN-based product candidates; and
   - the platform may never result in the regulatory approval of any product candidate.

8. Please revise your disclosure regarding Palvella's product candidates to clarify discuss the material factors that could delay or prevent Palvella's ability to receive marketing approval. Highlight the novel and/or subjective clinical endpoints and the "baseline control" Palvella has established in connection with its Phase 3 trial design in microcystic LM, and disclose that the FDA has made comments to Palvella indicating it could request a placebo-controlled trial or additional trials to assess different clinical endpoints. In this regard, we refer to your disclosure on pages 62, 66 and 71.

9. Please revise the Summary and Business sections to explicitly disclose that Palvella currently plans to pursue marketing approval for QTORIN rapamycin for microcystic LM and other indications through the FDA's Section 505(b)(2) pathway. Briefly explain the steps necessary to achieve FDA approval using this process, and highlight those steps that still remain to be completed.

Prospectus Summary
Pieris Pharmaceuticals, Inc., page 9

10. Please revise to disclose the remaining portion of the $7.5 million of severance costs that Pieris expects to be paid through the end of 2024.

PIPE Financing, page 11

11. It appears that the shares to be sold in the PIPE Financing are included in the shares to be registered on this registration statement. You disclose in the second paragraph of this section and elsewhere that the investors in the PIPE Financing made their investment decision in a private offering; therefore, the sale must close privately.
    - With reference to Exhibit 107 (Filing Fee Table), please remove from this registration statement the (1) 3,154,241 of shares of Pieris common stock and (2) up to 2,592,585 shares of Pieris common stock issuable upon the exercise of Pre-Funded Warrants to the PIPE Investors in connection with the PIPE Financing, or otherwise advise.
    - Disclosure in the penultimate sentence in the second paragraph should seemingly refer to a resale registration statement on Form S-1 to be consistent with the Registration Rights Agreement included in Annex L. Please review and reconcile as appropriate.

Support Agreements, page 16

12. With respect to your discussion of the support agreements on pages 17 and 175, you state that the Palvella stockholders that are party to a support agreement with Pieris "include" all executive officers and directors of Palvella and "certain other stockholders owning 5% or more of the outstanding shares of Palvella capital stock." In this regard, please show us how the percentages of securities owned by the Petrichor Opportunities Fund I LP, Petrichor Opportunities Fund I Intermediate LP, and Agent Capital Fund I, LP. are reconcilable to the principal stockholder table on page 321. Otherwise confirm, if true, that only Palvella executive officers, directors, affiliates, founders and their family members, and holders of 5% or more of Palvella voting equity securities are subject to the support agreement.

Pieris may be treated as a "public shell" company..., page 32

13. Please revise this risk factor to remove the qualifying phrase "may be treated" and instead disclose the risks attendant to the conclusion, disclosed on pages 20 and elsewhere throughout, that Pieris was "determined to be a shell company in that it did not meet the GAAP definition of a business, did not have more than nominal assets, and does not have more than nominal operations at the time of the merger," or otherwise advise. Similarly, revise the following sentence in risk factor disclosure on page 36: "Furthermore, if Pieris is deemed to be a shell company, the baby shelf rules, and therefore its Form S-3, would not be available to Pieris." Refer to footnote 943 of the Special Purpose Acquisition Companies, Shell Companies, and Projection adopting release (Release Nos. 33-11265; 34-99418; IC-35096), available at https://www.sec.gov/files/rules/final/2024/33-11265.pdf.

Risks Related to Palvella, page 58

14. Please tell us your consideration of including risk factor disclosure concerning the clinical trial risks associated with pediatric trials. We note that based on your disclosure on page 235, Palvella intends to enroll patients aged 6 years or older in its planned Phase 2 clinical trial of QTORIN rapamycin in cutaneous venous malformations in the 4th quarter of 2024. We also note your disclosure on page 229 that toxicities have limited the use of oral rapamycin for the treatment of LM patients, particularly for pediatric and adolescent patients.

The articles of incorporation of the combined company will generally provide..., page 109

15. We note that the articles of incorporation of the combined company will identify the Eighth Judicial District Court of Clark County, Nevada as the exclusive forum for certain litigation, including any derivative action. Please disclose whether this provision will apply to actions arising under the Securities Act or Exchange Act and, if so, make conforming revisions in your related risk factor disclosure. In this regard, we note that Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, and Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. If the provision applies to Securities Act claims, please also revise your disclosure to state that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. If this provision does not apply to actions arising under the Securities Act or Exchange Act, please ensure that the exclusive forum provision in your bylaws states this clearly, or tell us how you will inform investors in future filings that the provision does not apply to any actions arising under the Securities Act or Exchange Act.

The Merger
Background of the Merger, page 119

16. Please revise throughout this section to disclose when and why any potential reverse merger candidate was eliminated from consideration. By way of example only, we note that the September 5, 2023 entry does not explain Pieris' reason(s) for reversing its prior determination on August 24, 2024 to advance one candidate. Similarly, to the extent

known, revise throughout to disclose any material reason(s) why any potential reverse merger candidate withdrew itself from consideration.

17. You disclose that on October 2, 2023, Pieris' Board decided to advance three candidates, one of which was Company A, into the third and final round of diligence. You also disclose that on October 4, 2023, one of the third-round candidates withdrew from the process. Notwithstanding, we note that certain subsequent entries, such as those dated October 31, 2023 and November 9, 2023, refer to "the remaining three candidates" as of those dates. Please reconcile or advise.

18. Please revise your disclosure throughout this section to provide greater detail as to how the material terms of the transaction structure and consideration evolved during the negotiations between Pieris and Palvella through proposals and counter-proposals.The disclosure should provide shareholders with an understanding of how, when, and why the material terms of your proposed transaction evolved and why this transaction is being recommended as opposed to any alternatives. Please specifically address :
    - the acceleration of Pieris options and restricted stock units;
    - contingent value rights to be issued to pre-merger Pieris stockholders;
    - the valuations of the parties, including any amount ascribed by Palvella to Pieris in excess of its ending net cash position and the reason(s) therefor;
    - the equity allocations in the combined company via the contemplated exchange ratio;
    - the structure of the combined company's board of directors and management;
    - support and lockup agreements; and
    - the PIPE financing.

19. We note your disclosure regarding discussions between Pieris and Palvella regarding Palvella’s clinical trial design for QTORIN rapamycin. In this regard:
    - Please revise the April 3, 2024 entry to explain in greater detail the questions Pieris' Board posed to Palvella's management "on the valuation analysis and matters related to Palvellas's clinical development plan." Disclose the substance of any subsequent discussions after Palvella's presentation at that meeting.
    - Similarly, revise the entries between May 3 and May 14, 2024 to explain the additional information that Pieris' management "was continuing to request...regarding the Phase 3 clinical trial design for [Palvella's] QTORIN rapamycin in microcystic LM" and why, including with respect to how any information provided in response was considered.
    - Describe any material discussion related to "the FDA and S&T committee feedback on Palvella's planned Phase 3 clinical trial design for QTORIN rapamycin," including whether and if so how such discussions impacted the proposed terms of the LOI or the Transaction Committee's decisions to authorize Pieris management to enter into the LOI with Palvella.

Summary of Material Financial Analyses, page 139

20. Please revise this section as follows:
    - Briefly explain why oncology and platform companies, and IPOs of such companies otherwise meeting the comparable public company selection criteria were excluded from the analysis.
    - Disclose the underlying judgments and assumptions Stifel made in conducting its various analyses and the conclusions of its analyses relative to Palvella, including how the results of each analysis formed the basis for selecting an implied enterprise value reference range for Palvella.

Certain Unaudited Financial Projections of Palvella, page 142

21. You disclose on page 141 that Stifel used financial forecasts of Palvella for the second half of calendar year 2024 through calendar year 2040 to perform its analyses. As such, please revise the Palvella Projections summary table on page 144 to include the complete projections as prepared by Palvella management through that date.

22. We note the disclosure on page 142 that the projections prepared by Palvella management pertained to the "business, operations, earnings, cash flow, assets, liabilities and prospects of Palvella." You also state on page 144 that the Palvella Projections include financial measures including EBIT, yet there is no such corresponding line item in the summary table. To the extent not already disclosed, please revise to include all material information that was provided to and considered by the Pieris board of directors in connection with its evaluation of the Merger and used or relied upon by Stifel in rendering its fairness opinion.

23. Please disclose the nature of, and the bases for, any material assumptions that underlie the line items presented, or to be presented, in the summary table on page 144. Ensure the level of detail provided is sufficient for investors to evaluate and understand the reasonableness of the assumptions, uncertainties and/or contingencies underlying the projections as well as the inherent limitations on the reliability of projections.

24. You note on page 143 that the financial projections cover multiple years, and that this information by its nature becomes subject to greater uncertainty with each successive year. With respect to the length of the projections, please:
    - Disclose the basis for projections beyond year five, including if the forecasts reflect more than simple assumptions about growth rates.
    - Where appropriate, explain how Pieris management and the Board considered the financial projections and how, if at all, they determined that they are reasonable, particularly in light of the extensive length of the forecasts and since Palvella is a clinical stage company with limited operations and no approved products.

Interests of Pieris Directors and Executive Officers in the Merger, page 144

25. We note your disclosure regarding the calculation of Pieris' net cash beginning on page 149 and your disclosures throughout that under certain circumstances the ownership percentages in the combined company may be adjusted up or down depending on the amount of Pieris net cash as of closing. Please revise this section and elsewhere as appropriate to explain any material payments to Pieris' executives, such as

"golden parachute" compensation that is based on or otherwise relates to the Merger, that will be excluded from the calculation of "net cash" at the determination time. Disclose the types and aggregate amounts of such payments and explain the impact to other Pieris stockholders.

Intellectual Property, page 218

26. We note your disclosure on page 218 relating to Pieris' patent portfolio. On an individual or patent family basis, please revise to clearly disclose:
    - the number of patents and patent applications, separately;
    - whether each is owned or licensed;
    - the specific products, product groups and technologies to which such patents or patent applications relate;
    - the type of patent protection grated or sought;
    - the expiration date; and
    - the jurisdiction covered by each patent.

    In this regard, it may be useful to provide this disclosure in tabular form to support the narrative already included. Please also make similar revisions in the section related to Palvella's intellectual property on page 239.

Pieris' Business
Strategic Partnerships, page 219

27. You disclose that Pieris may continue to explore other partnerships or arrangements to license out its legacy assets and intellectual property, including PRS-400 and PRS-220. Here, in the Q&A, and elsewhere throughout if true, please clearly state that Pieris has not identified third party partners or arrangements for these assets, has not set any milestones for such legacy assets, and that it is uncertain whether it will do so. Please also clearly state that Pieris shareholders will not be able to determine the value of the CVRs, if any, prior to voting on the Merger since a portion of the consideration will be contingent upon the occurrence of future events.

Strategic Partnerships, page 219

28. Please revise your disclosure to include a discussion of all material terms of Pieris' license and collaboration agreements, including but not limited to:
    - Nature and scope of intellectual property transferred;
    - Each parties' rights and obligations;
    - Duration of agreement and royalty term;
    - Term and termination provisions; and
    - Payment terms. In this regard, quantify any upfront fees, amounts paid to date, aggregate potential milestone payments segregated by development and commercial milestone payments, and the applicable royalty rates to be paid by each party. In the event a range is provided in place of the actual royalty rate, such range should be within ten percentage points.

Palvella's QTORIN Platform, page 223

29. We note that a key element of Palvella's strategy is to leverage its QTORIN platform to generate additional product candidates that target rare genetic skin diseases. Please briefly describe the proprietary processes that you collectively refer to as Palvella's "platform." Explain how it was developed by Palvella's research team and how Palvella has utilized and plans to utilize this platform to execute its strategy.

30. In light of Palvella's development stage, revise to qualify and/or explain the basis for the following statements that the QTORIN platform:
    - "will enable [Palvella] to generate new product candidates while minimizing the challenges and timelines typically associated with formulation development activities;" and
    - "would expand the range of indications for which novel, life-changing therapies may be created...to address the needs of hundreds of thousands of patients with genetic skin diseases who have no FDA approved therapies for their disease."

    Additionally, please address the numerous references to the “scalable” nature of Palvella's platform. If the scalability of the platform is currently aspirational, please so state.

QTORIN Rapamycin for the Treatment of Microcystic LM, page 226

31. We note your disclosure on page 229 that Palvella has initiated a "pivotal" Phase 3 trial to evaluate QTORIN rapamycin in patients with microcystic LM. In this regard:
    - Please revise to briefly describe what you mean by "pivotal," and explain the Company's strategy to use such a pivotal study to seek regulatory approval in the context of the Section 505(b)(2) regulatory pathway. Explain the basis for Palvella's belief, if any, that the FDA has agreed or will agree that the pivotal study may be sufficient for the approval of the commercialization of QTORIN rapamycin for microcystic LM.
    - In light of your risk factor disclosure on page 70, explain the basis for Palvella's belief, if any, that the FDA has agreed or will agree that its Phase 3 pivotal study may be sufficient for the approval of the commercialization of QTORIN rapamycin for microcystic LM. Explain Palvella's rationale for planning to bridge QTORIN rapamycin and the approved oral rapamycin product based on crosstudy comparison between pharmacokinetic data from the prescribing information for the approved product. As applicable, explain whether and if so why Palvella's bridging strategy may be susceptible to objection.
    - Your revisions should make clear what further trials or testing is or may be required. To the extent that the FDA could require additional bridging studies, please explain what a "relative bioavailability study" is and how one differs from traditional efficacy trials.

32. Similarly, in light of your risk factor disclosure on pages 62 and 66, please revise Palvella's business section in the appropriate place(s) to disclose prior comments or recommendations the FDA has provided to Palvella with respect to key clinical trial design features of the Phase 3 trial of QTORIN rapamycin for the treatment of microcystic LM, including with respect to its selection of novel endpoints and choice of control, and when such feedback was provided. Also explain Palvella's rationale

for employing a dynamic assessment that uses a comparative rating scale as the primary endpoint and selecting a baseline control rather than a placebo control, as well as the potential outcomes if the FDA ultimately disagrees with Palvella's trial design or interpretation of trial results.

33. You disclose on page 226 that Palvella intends to rely on the FDA's conclusions of safety and efficacy from its review of the reference sponsor's studies of reference drug RAPAMUNE, along with Palvella generated data, to support approval. In this regard, please identify and describe the reference studies and results you intend to rely on, including the identification of the parties that performed the studies.

34. We note that Palvella commissioned a primary market research study in May 2024 that surveyed 52 dermatologists and hematologists with respect to the potential market opportunity for QTORIN rapamycin in microcystic LM. Please revise Figure 7 to summarize only objective data from that study, and remove the subjective, unattributed quotes in the rightmost column.

PALV-06 Phase 2 Pharmacokinetic and Safety/Tolerability Results, page 232

35. You state as follows on page 232: "Safety data obtained in the PALV-06 [Phase 2] trial was similar to that observed in larger clinical studies of QTORIN rapamycin." Please revise to clarify which larger clinical studies you refer to.

Potential Market Opportunity and Market Research, page 232

36. You disclose Palvella's belief that QTORIN repamycin, if approved, has significant commercial potential for microcystic LM "in the U.S. and other markets." Please revise to disclose whether the estimate that the total addressable market opportunity on an annualized basis is greater than $1 billion is based on the estimated U.S. prevalence of over 30,000 diagnosed patients.

General

37. Please provide the opinion of counsel as to:
    - Whether the vote taken including votes represented by the Series F Preferred will be valid under Nevada law; and
    - The legality under Nevada law of the redemption of the share of Series F Preferred by Pieris upon the earlier to occur of: (i) the order of the Pieris board of directors in its sole discretion and (ii) automatically and effective immediately after the effectiveness of the increase in the number of authorized shares of Pieris common stock proposed in Proposal No. 2.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

Please contact Gary Newberry at 202-551-3761 or Vanessa Robertson at 202-551-3649 if you have questions regarding comments on the financial statements and related matters. Please contact Lauren Hamill at 303-844-1008 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Joseph Walsh