



DIVISION OF  
CORPORATION FINANCE

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

October 25, 2024

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

**Re: Pieris Pharmaceuticals, Inc.  
Amendment No. 2 to Registration Statement on Form S-4  
Filed October 15, 2024  
File No. 333-281459**

Dear Stephen Yoder:

We have reviewed your amended 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. Unless we note otherwise, any references to prior comments are to comments in our October 8, 2024 letter.

Amendment No. 2 to Registration Statement on Form S-4

The Companies

Palvella Therapeutics, Inc., page 11

1. We note your response to prior comment 1. In this regard, we note seemingly inconsistent risk factor disclosure on page 69, which states: "Negative results in the development of QTORIN rapamycin for either the treatment of microcystic LM or cutaneous venous malformations may also impact [Palvella's] ability to obtain regulatory approval for other product candidates which Palvella expects to develop based on its QTORIN platform, either at all or within anticipated timeframes because, although Palvella may be targeting different indications, the underlying technology platform is the same for each product candidate and there may be commonalities in the manufacturing and development processes. Accordingly, a failure in any one

QTORIN-based program may decrease trust in its technology and affect its ability to conduct clinical programs for other QTORIN-based product candidates." Please tell us how your response reconciles with this disclosure, or otherwise revise your registration statement as requested in the third bullet of prior comment 7 of our letter dated September 6, 2024.

Support Agreements, page 18

2. We note your response to prior comment 3. You now state on pages 18 and 179 that the Palvella stockholders that are party to a support agreement with Pieris include the "Agent Capital Fund I, LP, owning approximately 2.7% of the outstanding shares of Palvella capital stock." Please consider Securities Act Sections Compliance and Disclosure Interpretation 239.13 and explain why you believe it is appropriate to register the issuance of Pieris' shares on this Form S-4 at this time.

Risk Factors

The articles of incorporation of the combined company will generally provide...., page 112

3. We note your response to prior comment 4. Please further revise your disclosure here and elsewhere, where appropriate, to clarify what you mean by the following: "the choice-of-forum provision does not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act...".

Certain Unaudited Projections of Palvella, page 146

4. You now state on page 147 that Palvella provided U.S. revenue projections for QTORIN rapamycin for treatment of cutaneous venous malformations starting in 2029, and that "Pieris fully disregarded the venous malformations (VM) indication in connection with the evaluation of the Merger." In this regard:
  - Please further revise to explain the reason(s) why Pieris disregarded the CVM indication when evaluating the Merger.
  - In light of the foregoing, expressly state whether or not the Palvella Projections table presented on page 148 includes projections for both the microcystic LM and CVM indications during the period presented. If both, revise to disclose the date you assume Palvella will be granted regulatory approval for, and commercially launch, QTORIN rapamycin for the CVM indication. Further, with respect to line items such as total net sales, please specifically identify the material product revenue stream(s) underlying the projections.
5. You now disclose that Palvella arrived at the probability of regulatory approval for QTORIN rapamycin for the treatment of microcystic LM based on a joint research report published in 2021 that estimated success rates for each phase of clinical development for "other" therapeutic areas including but not limited to dermatology, and adjusting the ultimate probability of regulatory approval upwards. In this regard:
  - Please revise to disclose the success rate cited in the named research report for completion of Phase 3 studies in the therapeutic area group titled "Others" that includes dermatology.
  - Disclose Palvella's assumed adjusted probability of regulatory approval for

QTORIN rapamycin for microcystic LM, and any other indication reflected in the Palvella Projections.

- Disclose how Palvella determined that the upward adjustment to the therapeutic area group average rate for successful completion of Phase 3 was reasonable. Explain any specific material factor(s) pertaining to Palvella's "Phase 2 clinical study results, safety profile, and FDA Breakthrough Therapy Designation" that formed the basis for Palvella's conclusion that its product candidate has a greater likelihood of regulatory approval compared to the therapeutic area group average.
- Please also revise to discuss the risk that the assumed probabilities of successful completion may be unrealistic given the unpredictability of drug development.

#### Palvella's Business

#### Phase 3 trial - PALV-09 (SELVA) and Anticipated pre-NDA Meeting, page 237

6. Please revise this section to disclose when Palvella received the FDA Orphan Drug Clinical Trial Grant to support the Phase 3 trial of QTORIN rapamycin for the treatment of microcystic LM. Please also revise to disclose the total number of grants under this program since inception and to explicitly state that the receipt of the grant does not guarantee FDA approval of QTORIN rapamycin for the treatment of microcystic LM or any other indication.

#### Exhibits

7. Please revise your exhibits and exhibit index to accurately reflect the status of any redactions. In this regard:
  - We note your statement at the top of the first page of Exhibits 10.18 and 10.20 stating that certain information has been redacted because it is both not material and the type of information that the company treats as private or confidential. If accurate, please revise your exhibit index to disclose that certain portions of such exhibits have been omitted pursuant to Item 601 of Regulation S-K. Refer to Item 601(b)(10)(iv) of Regulation S-K.
  - We note your statement at the top of the first page of Exhibit 10.19 that certain personal information has been excluded from the exhibit pursuant to Item 601(a)(6) of Regulation S-K. As appropriate, please: (1) mark the exhibit to indicate where information has been omitted and (2) revise the exhibit index to disclose that certain portions of such exhibit have been omitted pursuant to this provision of Regulation S-K.

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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 Sprague 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