

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

May 2, 2022

John Ballard Chief Financial Officer Qualis Innovations, Inc. 225 Wilmington West Chester Pike Suite 200 #145 Chadds Ford, PA 19317

> Re: Qualis Innovations, Inc. Amendment No. 2 to Registration Statement on Form S-1 Filed April 20, 2022 File No. 333-260982

Dear Mr. Ballard:

We have reviewed your amended registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe our comments apply 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 these comments, we may have additional comments. Unless we note otherwise, our references to prior comments are to comments in our February 2, 2022 letter.

Amended Registration Statement on Form S-1 filed April 20, 2022

#### Cover Page

1. Revise the prospectus cover page to disclose, if true, that the selling shareholder offering will commence upon the termination of the primary offering by the Company. Also revise to clarify when the secondary offering will terminate. Refer to Item 501(b)(8) of Regulation S-K.

**Prospectus Summary** 

Corporate Background, page 2

2. Please disclose here, as you have on page 30, that you have not finalized development of

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your planned SOLACE device and that you have not yet generated any cash flow from operations.

## If we fail to comply with FDA regulations, our business could suffer, page 15

3. We note your response to prior comment 10 and reissue it. Please further revise this risk factor to remove the duplicative information that now appears under the Business subsection captioned "Government Regulation".

## Government Regulation, page 46

4. We note your disclosure on page 44 stating that you are still finalizing your SOLACE product design and have not yet filed a 510(k) application with the FDA. However, much of this section remains in the present tense, instead of in the future tense, and could be read to imply that your product is further along in the development process than it actually is. Please further revise this section to better reflect the current development status of your product.

#### Directors, Executive Officers, Promoters, and Control Persons, page 47

- 5. We note your response to prior comment 28 and reissue it in part. Please revise the disclosure pertaining to your management and board of directors to include applicable dates or ranges from which investors can discern the principal occupations and business experience of each individual from the past five years. Refer to Item 401(e) of Regulation S-K.
- 6. Please revise both your Directors and Officers table and the narrative disclosure following it to remove Mr. Bingol, as disclosure on page 27 indicates that he is no longer involved with the company as of April 15, 2022.

#### Executive Compensation, page 50

7. We note your response to prior comment 29 and reissue it in part. Please revise the Director Compensation table to remove President from John Ballard's principal position.

#### 16. Exhibits

# Exhibit 23.1, page 61

8. Please request Paris, Kreit & Chiu CPA LLP to revise their consent for their report with respect to your financial statements as of December 31, 2020 and December 31, 2019 to correct the dual date for those items affected by the restatement discussed in Note 11.

#### **Exhibits**

9. Please move the filing fee-related information from the cover page of your prospectus to a separate exhibit document. Refer to Item 601(b)(107) of Regulation S-K.

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## General

10. We reissue prior comment 42. Please further revise your prospectus to remove any plural references to your "products," "proposed products," and "product candidates" as disclosure on page 3 indicates that SOLACE is your sole product.

You may contact Tracey Houser at 202-551-3736 or Jeanne Baker at 202-551-3691 if you have questions regarding comments on the financial statements and related matters. Please contact Tyler Howes at 202-551-3370 or Christopher Edwards at 202-551-6761 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Lance Brunson