



DIVISION OF  
CORPORATION FINANCE

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

December 9, 2021

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

**Re: Qualis Innovations, Inc.**  
**Registration Statement on Form S-1**  
**Filed November 12, 2021**  
**File No. 333-260982**

Dear Mr. Ballard:

We have reviewed your 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.

Form S-1 filed November 12, 2021

Cover Page

1. Please disclose on the prospectus cover page the price to the public of the securities, the net proceeds you receive, and the selling shareholders' net proceeds. Please show this information on both a per share basis and for the total amount of the offering and show this information based on the total minimum and total maximum amount of the offering.
2. We note numerous references to your common stock being quoted on the "OTC Link" ATS throughout the registration statement. Given that OTC Markets Group Inc. operates OTC Link to organize securities into three tiers (i.e., OTCQX, OTCQB, and Pink), please revise your disclosures throughout the registration statement, including the

prospectus cover page, offering summary, and risk factors, to specify that your common stock is quoted in the OTC Pink marketplace as you have on page 20.

License Agreement, page 2

3. Here in the prospectus summary and in other places where the LCMD license agreement is discussed, please revise to clarify when you provided the cash and equity consideration in exchange for the license and when you obtained access to the referenced licensed intellectual property. Please also disclose whether any royalty payments have been incurred under the agreement and when the agreement terminates.
4. We note your disclosure on pages 2, 24-25, and 32 that you will lose your rights to the intellectual property you have licensed from LCMD, which includes patents covering your lead SOLACE device that has received 501(K) clearance from the FDA for certain indications, if LCMD does not fully satisfy its payment obligation of \$2.4 million to the original owners of the underlying IP (i.e., the "Marchitto Entities") on or before April 24, 2022 and you are then unable to license such IP directly from the Marchitto Entities. Please revise your risk factor disclosure to discuss the risk of loss of this IP and any potential material impact to your business and to investors should such loss occur.
5. Please disclose whether LCMD has the ability to satisfy its payment obligations to the Marchitto Entities and what the Company intends to do if LCMD is unable to do so. Please include a discussion of any representations you have obtained from LCMD regarding its ability to meet its obligation to the Marchitto Entities and disclose the portion of the \$2.4 million it has paid as of the date of the prospectus, if any, and discuss the potential impact to your operations if LCMD does not meet its obligation. Please clarify whether the proceeds of this offering may be used to satisfy the obligations of LCMD under the court order between LCMD and the Marchitto Entities. Please include similar revisions on page 23.

Prospectus Summary

Corporate Background, page 2

6. By way of example and not limitation, we note that you refer to "CNS-based solutions" and "CNS solutions" on pages 2 and 23 without definition. Here and throughout your registration statement, please revise to define shorthand designations, acronyms, and other material terms at first use.
7. Please revise your disclosure to expand your description of your "modality-agnostic, virtual operating model" on pages 2 and 23. In describing your model, also include the basis for the following statements:
  - The modality-agnostic framework allows you "to pursue meaningful pain management, other CNS solutions, regardless of their platform (i.e., devices, pharmaceuticals and technology enabled products)."
  - The virtual operating model allows you "to pursue a broad range of product opportunities without the cost and risk of having to significantly invest in research

and development function or headcount for sales and promotional efforts." Also in this regard, we note that this statement may be read to conflict with other statements in your prospectus. By way of example and not limitation, we refer you to risk factor disclosure on page 6 indicating that you expect to incur research and development and sales and marketing expenses, and that such amounts have recently increased in connection with your "efforts to expand [your] sales force," and disclosure on pages 8 and 10 indicating that in order to successfully compete and commercialize your products, you will "need to establish and maintain sophisticated sales and marketing teams." Please reconcile.

8. We note your statements on pages 2 and 23 that you are developing "best in class products." Given the start-up nature of your company and the current development status of your lead SOLACE device as described in your disclosures, this statement is seemingly premature. Further, the use of the phrase may inappropriately imply 1) that you currently have multiple product candidates in development and 2) that the updated version of the SOLACE device you are developing design improvements for will be approved for FDA clearance. As such, please remove these references.
9. You note on page 2 and elsewhere that your "lead product is the SOLACE device." However, we also note the varied use of phrases throughout the prospectus such as "some of our products," "our proposed products," or "product candidates" in the plural versus phrases such as "our product" in the singular. Please revise as appropriate to address these apparent inconsistencies. Further, to help investors better understand your business, please revise your prospectus summary and other discussions of your business to clarify the following:
  - Whether the extent of your current product lineup is limited to the SOLACE device. If not, revise to describe any other material product(s) in your pipeline.
  - With respect to the SOLACE device, revise to distinguish between any existing versions of the product from versions of the product you aspire to sell in the future. To the extent versions of the device are currently in development, please clarify the development stage.
10. We note the following statement on pages 2 and 23 of the prospectus: "We believe that our products will provide clinicians and patients with new and differentiated set of pain management tools to meet the diversity of patient needs, providing safe and effective pain relief for everyone." As safety and efficacy determinations are solely within the authority of the FDA and comparable regulatory bodies, it is inappropriate to state or imply that your product candidates are, or will be, safe or effective. Please revise this statement and any similar statements throughout your prospectus that suggest the safety and efficacy of your candidates. Where you deem appropriate, you may present objective data without including your conclusions related to safety or efficacy.
11. We note the disclosure that the SOLACE product was originally cleared by the FDA in 2014. Please disclose, if true, that you are not currently selling the device and that you

have not generated any revenues.

Summary of the Offering, page 3

12. We note that page 3 indicates that the Selling Security Holders will be offering 4,500,000 shares of common stock in the secondary offering; however, disclosure elsewhere in the prospectus, such as on the cover page and page 18, indicates that 500,000 shares are being registered by the Selling Security Holders. Please reconcile.

Risk Factors

Failure to keep pace with the latest technological changes could result in decreased revenues..., page 5

13. Please provide the basis for the following statement or otherwise revise: "We have derived, and we expect to continue to derive, a substantial portion of our revenues from the development and sale of products in the medical device industry." In this regard, we note the statement on page 39 that at least as of the six months ended June 30, 2021, you had earned no revenue since inception.

When we complete our audit, our auditors may issue a "going concern" audit opinion, page 7

14. We note that your auditor issued a going concern opinion upon completion of its audit of the both the Qualis and mPathix financials for the years ended December 31, 2020 and 2019, respectively. However, your risk factor disclosure on page 7, which is written largely in the future tense, states that your auditors "may issue" a going concern opinion and thus may imply that an opinion has not already been issued in an existing audit report. Please revise this risk factor to highlight mPathix' operating losses since inception, any expectation of incurring additional near-term losses, and your auditor's explanatory paragraph regarding your ability to continue as a going concern. Disclose whether your ability to continue as a going concern is contingent upon obtaining funding from sales of your securities in this offering, and describe the potential consequences to your business if you are unable to raise the additional financing sought. Disclose that if you cannot continue as a viable entity, your stockholders may lose some or all of their investment in your company.

We intend to rely on third parties to supply and manufacture our products..., page 8

15. Please explain the undefined reference to "WEMU" in this risk factor, or revise as appropriate.

Because the Selling Shareholders are selling their shares, we are less likely to sell all of the Primary Offering shares, page 18

16. Please clarify that the CEO of the company who will be offering the shares in the Primary Offering is also one of the selling shareholders who is offering shares in the Secondary Offering.

Dilution, page 21

17. Please revise the initial sentence to disclose your net tangible book value rather than the par value of your common stock. Ensure that your calculation of net tangible book value excludes intangible assets.
18. Please reconcile your statement on the top of page 22 that 7,843,300 shares were originally issued to the seventeen Selling Security Holders as consideration for the acquisition of mPathix Health, Inc. with your disclosures of the acquisition throughout the rest of the Form S-1 that state 6,988,300 shares were issued.

Selling Security Holders, page 21

19. Please identify the natural person or persons who have voting and investment control of the shares held by Echo Resources LLLP.

Management's Discussion and Analysis of Financial Condition and Results of Operations  
Intellectual Property, page 24

20. In relation to the Company's licensed material patents, please further revise your intellectual property disclosure to state:
  - Which patents are issued and which are pending; and
  - The expiration year of each pending or issued patent.

SOLACE Device, page 24

21. Please revise both the Summary and this discussion of your business to explain the SOLACE high frequency "Electromagnetic Induction ("EMI") technology platform, as referenced on page 24. Expand your discussion in the second and third paragraphs of this section to explain the operation of the SOLACE device, including how it uses EMI technology to "apply planar heat" as a method of treatment for the pain indications you are pursuing. Refer to Item 101(h)(4)(i) of Regulation S-K.
22. In the last paragraph in this section, you state that mPathix is currently developing an updated version of the SOLACE device for commercial launch, and that based on implementing a number of design improvements, you intend to seek FDA clearance for the redesigned SOLACE device within the next 12 months. Please expand this disclosure to:
  - Describe the nature, purpose, and current status of the design improvements to the redesigned product.
  - Disclose the indicated medical conditions for which you intend to seek market clearance for the redesigned SOLACE device.
  - Disclose the type of FDA device clearance you plan to seek for the redesigned product.
23. Revise pages 24 and 28 to provide the basis for the conclusion that your EMI technology "may provide for shorter duration of treatments and a more comfortable patient experience

vs. other energy-based technologies." Describe the "other energy-based technologies" to which you are comparing your SOLACE device, including whether such technologies are in development or already being marketed. So that investors may better evaluate your competitive claim, please further revise this disclosure to quantify the phrase "shorter duration of treatments" to the extent reasonably known. Refer to Item 101(h)(4)(iv) of Regulation S-K.

Market Dynamics, page 25

24. Please revise to specify how you face competition from the companies you reference on page 26 that are operating in the global pain management devices market, such as what their competing products are and whether they are in development or already being sold. Refer to Item 101(h)(4)(iv) of Regulation S-K.
25. We note your statement in the first paragraph of this section that you plan to market your "SOLACE device" for the treatment of selected medical conditions such as pain relief, muscle spasms, and joint contractures, but not for the treatment of malignancies. We further note that your "SOLACE 100" device, referenced on page 24, received 510(K) clearance from the FDA in March 2014 "to generate deep heat within body tissues for the treatment of medical conditions such as relief of pain, muscle spasms and joint contractures." However, you also state on page 24 that you do not market any previously cleared version of the device but are developing an updated version of the device that you have not yet sought FDA marketing clearance for. Please revise this section to clarify which version of the SOLACE device you intend to market for these selected medical conditions. To the extent you will continue not to market the cleared "SOLACE 100" device, please revise to describe why the Company is focusing its long-term business plans on the redesigned device.

Marketing, page 26

26. Please revise this section to provide the basis for the following statements:
- Page 27: We believe that our SOLACE device may offer a meaningful solution for the millions of patients suffering from low back pain for whom pharmaceuticals or interventional pain management are not considered safe, effective or desirable.
  - Page 27: We believe that our SOLACE device may fit well into the physical therapy treatment paradigm, adding significant value as a first line treatment.
  - Page 28: We believe the SOLACE device may become an integral tool within pain specialists' multidisciplinary protocols as part of a stepwise treatment approach of appropriate acute pain etiologies.

Potential Future Uses of the SOLACE Device, page 28

27. Please revise this section to provide the basis for the following statements:
- Page 28: We believe that our SOLACE device, which relies on electromagnetic induction therapy (EMI), may compare favorably to current [medical aesthetic

- device] competitors.
- Page 29: We believe that our SOLACE device may offer a non-invasive treatment option for women suffering from SUI.
  - Page 29: Based on our EMI technology, the SOLACE device may prove to be an effective treatment option for hyperhidrosis patients and may provide a more comfortable option vs. other energy-based devices.

Additionally, if accurate, revise this section to indicate that you will need additional FDA clearance to market the SOLACE device for these future additional applications. Make clear that without FDA clearance, the use of your device for other purposes besides approved pain management indications would be considered off-label use for which you could not market your product.

Consulting Agreement, page 31

28. On page 31 and in numerous other places throughout the registration statement, you indicate that in May 2021, you entered into a consulting agreement with a "related party" to provide advisory services to the Company until at least July 31, 2022. Please revise to name this party. Additionally, please file the consulting agreement as an exhibit or tell us why you do not believe you are required to file it. Refer to Item 601(b)(10) of Regulation S-K.

Results of Operations, page 33

29. We note for your analysis of operating expenses for each period presented, you attribute the increase to your anticipated business development. Please revise your disclosures to provide more company-specific analysis of the costs incurred for each period presented. For your research and development costs, please disclose and quantify the components of these costs and the specific activities generating these costs.

Description of Business, page 43

30. Please tell us your consideration of furnishing the information required by Item 11(a) of Form S-1 (that information required by Item 101 of Regulation S-K) in a discreet section under this heading, Description of Business, rather than including it under MD&A. Additionally, please expand your Business discussion to describe applicable government regulation of medical devices, including FDA oversight.

Description of Property, page 43

31. While you have indicated a mailing address for Qualis Innovations in Chadds Ford, Pennsylvania, it is not clear whether or to what extent Qualis or mPathix utilize any physical property in connection with its business operations. In your next amendment, please revise to provide the information required by Item 11(b) of Form S-1 (that information required by Item 102 of Regulation S-K) under this heading, Description of

Property, or advise.

Directors, Executive Officers, Promoters and Control Persons, page 43

32. Revise the disclosure pertaining to your management and board of directors beginning on page 44 to clearly indicate the business experience of each individual for the past five years, as required by Item 401(e) of Regulation S-K. In this regard, we note that you have not included applicable dates or ranges from which investors can discern these individuals' principal occupations and employment during such time period. Please also address the following:
- Revise A. Demir Bingol's biographical information to indicate that "EMF" is now known as mPathix for the avoidance of confusion. Indicate when Mr. Bingol joined the company and indicate all positions and offices he has held during his tenure.
  - Revise John Ballard's information, as it appears from your other disclosures that Mr. Ballard has not served as CEO since August 2019.
- In addition, the discussion regarding the experience of the Company's directors as a group on page 45 is too general. Please add detailed information regarding each director's specific qualifications that led to the conclusion that the person should serve as a director.

Advisory Board Members, page 45

33. We note your disclosure on page 45 providing biographical information for the members of your Advisory Board. Please expand your disclosure to describe the role of the board, how board members are selected, the term of service, and any compensation you pay to board members.

Executive Compensation, page 47

34. Your prospectus notes that Dr. Joseph V. Pergolizzi, Jr. is the acting Chief Executive Officer and Chairman of the Board as of October 2021, yet he is not included in either the executive Summary Compensation Table or the Director Compensation table covering the three years ended December 31, 2021 on page 47. Please revise accordingly. Refer to Item 402(a)(3) of Regulation S-K. Please additionally review and revise the tables and footnotes thereto to ensure that the principal positions of named individuals, and recent changes thereto during the period covered, are reflected. Refer to Item 402(c)(2)(i). Please supplementally confirm whether the amount of \$150,00 listed in the table for Demir Bingol reflects the entirety of the base salary earned by Mr. Bingol during 2021. In this regard, we note your disclosure on page 31 that pursuant to Mr. Bingol's initial employment agreement that was in effect for part of 2021, his base salary was \$250,000, which was later reduced to \$150,000 in an amended employment agreement effective October 1, 2021. Refer to Item 402(c)(2)(iii).



Index to Financial Statements, page F-1

35. Please revise your presentation to provide one index for all sets of financial statements included with one set of F pages. In addition, given that your Share Exchange Agreement with mPathix Health, Inc. was accounted for as a reverse merger, please clarify herein and elsewhere in the filing as appropriate, that your historical financial statements are the consolidated entity reflecting the continuation of the financial statements of the accounting acquirer (mPathix Health, Inc.). Also, please note that as a result of the Share Exchange Agreement, the audited financial statements for Qualis Innovations, Inc. for fiscal years 2020 and 2019 may also no longer be necessary pursuant to Rule 8-04 of Regulation S-X. However, if you continue to include these financial statements, they should be presented last.

Report of Independent Registered Public Accounting Firm (mPathix - Annual), page F-2

36. We note that you have not identified as an emerging growth company. As such, your auditor's report from Benjamin & Ko is missing the elements of paragraphs .11 - .17 of PCAOB AS 3101. Please consult with your auditors and include an audit opinion that complies with the all of the requirements of PCAOB AS 3101. Otherwise, provide us with your analysis of the requirements for qualifying as an emerging growth company as defined in the Securities Act, clearly identify as an emerging growth company, and provide all required disclosures throughout your Form S-1.
37. Please request Benjamin & Ko to revise the first paragraph under Basis for Opinion to clarify that they are registered with the PCAOB (United States). Refer to paragraph .09.g of AS 3101.

Statement of Operations (mPathix - Annual), page F-4

38. Please revise your presentation to include the amortization of the license agreement as research and development expense. Refer to ASC 730-10-25-2.c. for guidance. Address this comment in the interim financial statements.

Note 2 - Basis of Presentation (Qualis - Interim), page F-7

39. Please revise your financial statements and disclosures to address the following:
- Disclose that you are accounting for the Share Exchange Agreement between Qualis and mPathix as a reverse acquisition in accordance with the guidance in ASC 805-40.
  - Clarify that the historical financial statements presented reflect the transactions and operations of mPathix.
  - Revise the consolidated statements of changes in shareholders' equity to reflect the share activity prior to the transaction in a manner similar to the accounting for a stock split that results in the sum of the shares outstanding to reflect the 6,998,300 shares of Qualis common stock issued. Note that an exchange rate other than 1-for-1 will also

- impact the per share price in your corresponding disclosures.
- Revise the consolidated statements of changes in shareholders' equity to reflect Quails' outstanding shares as of June 29, 2021, as being issued by mPathix to acquire Qualis with Quails' net book value recognized as the value of these shares.
- Revise the presentation of loss per share to recalculate the weighted average shares outstanding for loss per share purposes.
- Retroactively reflect the above accounting implications to mPathix's audited financial statements as of and for the two years ended December 31, 2020. Please ensure Benjamin & Ko addresses the need to redate or dual-date their audit report to give effect to the additional work performed with respect to restating these financial statements.

Note 3 - Summary of Significant Accounting Policies (mPathix - Annual), page F-7

40. Please include your accounting policy for the recognition of research and development costs, including the types of costs included in line item and when these costs are recognized as an expense. Refer to ASC 730-10-25 for guidance.

Note 3 - Summary of Significant Accounting Policies

Basic and diluted earnings per share (Qualis - Interim), page F-10

41. Please revise your disclosure to correctly state that there were common stock equivalents outstanding as of June 30, 2021. Expand your disclosures in Note 8 to state the number of common stock equivalents by type of security issued that were excluded in the calculation of loss per share for the reason that they were anti-dilutive. Refer to ASC 260-10-50-1.c. for guidance.

Note 5 - Intellectual Property License Agreement (mPathix - Annual), page F-12

42. We note your disclosure that the effective date of a Preliminary Intellectual Property License Agreement with Life Care Medical Devices Limited (LCDM) is August 28, 2019 with a Binding Letter of Agreement entered into on June 3, 2021, or the consummation date. Please expand your disclosures to clarify what transpired on August 28, 2019 versus June 3, 2021, and how each of the transactions on these dates impacted the accounting for this agreement. As part of your disclosure, clarify when you provided the equity and the cash portions of the consideration and when you obtained access the licensed intellectual property.
43. Please expand your disclosure to clarify how you determined that the License Agreement should be capitalized rather than expensed when incurred. Refer to ASC 730-10-25-2.c. for guidance. To the extent that you continue to believe the License Agreement meets the requirements for capitalization, revise your tabular presentation for the estimated useful life of the License Agreement, which appears to be from August 28, 2019 through April 24, 2022.

Note 6 - Stockholders' Deficit

Common Stock (Qualis - Interim), page F-13

44. Please address the apparent discrepancies related to your common stock and options disclosures as compared to the transactions reflected in your Statement of Stockholders' Equity on page F-4. Ensure your revised disclosures discusses the issuance of common stock for \$1,150,000 and common stock for \$100,000 - related parties as reflected in your Statement of Stockholders' Equity.

General

45. To facilitate a better understanding of your company, as well as material risks attendant to an investment therein, please revise your references to the "SOLACE device" throughout the prospectus to either be used consistently or else to provide sufficient specificity and context to highlight and clarify any material distinctions between the versions of the device that investors may need to understand your current operations and business plans. In this regard, we note:
- References to your "SOLCACE device" used throughout the prospectus, including those to a "redesigned version" of the device that appears to be in development and which you intend to seek FDA approval to market;
  - References to a "licensed Life Care Magnetics product," used without definition or explanation, that begin on page 7 and appear to be used only throughout the risk factors section; and
  - A single reference to "the SOLACE 100 device" on page 24 in your MD&A, which appears to be the name of the first and current version of the SOLACE device that was cleared by the FDA in 2014 but which you do not presently market.
46. Please tell us how you will determine whether a particular sale of common stock will be made pursuant to the Primary Offering, in which the net proceeds will go to the company, or the Secondary Offering, in which proceeds will go to selling shareholders/affiliates of the company, including the Company's CEO who is selling the shares in the Primary Offering.
47. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications

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.

John Ballard  
Qualis Innovations, Inc.  
December 9, 2021  
Page 12

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 Lauren Hamill at 303-844-1008 or Christopher Edwards at 202-551-6761 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Lance Brunson