

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

Mail Stop 4546

January 25, 2017

Eugene Jiang Chief Executive Officer American BriVision (Holding) Corporation 11 Sawyers Peak Drive Goshen, NY 10924

Re: American BriVision (Holding) Corporation

Amendment No. 2 to Registration Statement on Form S-1

Filed January 19, 2017 File No. 333-213618

Dear Mr. Jiang:

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 December 2, 2016 letter.

Risk Factors

Our current products have certain side effects, page 9

- 1. We refer to your revised disclosure in response to prior comment 2. We note your references to clinicaltrials gov and to a medical journal for a discussion of adverse events. Please revise your risk factor and business section discussions to include a discussion of all material adverse events for each product candidate. Referring investors to sources outside your registration statement for material information is not sufficient to meet your disclosure obligation. Please revise your disclosure to ensure that all material information is included in your prospectus.
- 2. We note that your revised disclosure continues to include scientific terms throughout the risk factor. Please revise your risk factor to explain the risks in a manner that lay readers

- will understand. For example, your explanation of "eosinophilia" includes the terms "eosinophilic leukocytes" and "peripheral blood," which also require explanation.
- 3. You state that several serious adverse events were observed in 1 out of 21 participants. Please identify the product candidate associated with each event.
- 4. We note your disclosure in the first bullet under the table on page 10 that none of the adverse effects observed with respect to PDC-1421 were "clinically significant." Please explain the term "clinically significant."

Management's Discussion and Analysis . . ., page 22

5. Please revise your disclosure on page 24 to update the disclosure about the \$6.5 million payment due no later than December 15, 2016 and to indicate whether BioLite has submitted the corresponding IND package.

Business

Our Licensed Compound, page 31

- 6. We note your revised disclosure on page 31 stating that because of confidentiality obligations, you are not permitted to disclose the name of one of the cancer centers that is helping you to develop a Phase II clinical trial IND package for ABV-1502. Please revise your disclosure to eliminate "top" and "leading" to describe cancer centers and medical sites you are currently working with or negotiating with but are not able to identify.
- 7. We acknowledge your revised disclosure in response to comment 5. However, phase I/II clinical trials also test how well cancer or other disease responds to new treatment. Please explain how your Phase I/II clinical trial for ABV-1501 and ABV-1502 measured for such a response. If it did not include any endpoints relating to efficacy, please explain how this trial is considered a Phase I/II trial.
- 8. Please explain why 24 subjects enrolled in the study to see whether Maitake improves the neutrophil count and function in patients with MDA were not treated.
- 9. We acknowledge your revised disclosure in response to comment 9. Please further revise your disclosure on page 33 regarding the Phase I and the Phase II Part One trials for ABV-1504 and ABV-1505 to clearly explain whether the primary and secondary endpoints were met for each of the trials, and to discuss where the trials were conducted. In addition, we note your statement that the oral administration of PDC-1421 was "safe and well-tolerated" for certain doses. As previously noted, the FDA makes the determination that a drug is safe for use under prescribed conditions. Accordingly, please revise your disclosure to remove the suggestion that the FDA or any comparable regulatory authority has determined your product to be safe.

Market Opportunity and Growth Strategy/Business Plan, page 34

- 10. We note your revised disclosure in this section that one of your competitive advantages is the "intrinsic value" of your licensed compounds. Please expand your disclosure to describe this intrinsic value of the five compounds.
- 11. In response to our comment 14, you state that you will seek a qualified clinic to develop your product in the "unlikely event" that you are not able to co-develop your products with "leading big international pharmaceuticals." Since you currently do not have any co-development agreements with any leading pharmaceutical companies, please explain why it is unlikely that you may not enter into such an agreement, or delete the reference to the possibility being unlikely.
- 12. Please explain why you believe your business model provides you with a competitive advantage as the elements of your model are common in the industry.
- 13. We refer to your revised disclosure regarding the expressions of interest from pharmaceutical companies regarding certain of your licensed compounds. Please disclose whether any of these discussions have resulted in any type of term sheet or contractual arrangement. If not, please expand your disclosure to explain the possibility that you may not be able to reach any agreements on favorable terms.

Intellectual Property, page 35

14. Based on your revised disclosures, it appears that the last two patents appearing in the table on page 36 have expired. Please either delete them from the table or explain why it is appropriate to keep them.

Executive Compensation

Outstanding Equity Awards at Fiscal Year End, page 40

15. Please include the updated disclosures for your fiscal year ended September 30, 2016, as required by Item 402(p) of Regulation S-K.

Certain Relationships and Related Transactions, and Director Independence, page 41

16. Please provide the updated disclosures required by Item 404 of Regulation S-K.

Security Ownership of Certain Beneficial Owners and Management, page 43

17. Please update the table to reflect information as of the most recent practicable date as required by Item 403 of Regulation S-K.

<u>Financial Statements</u> Table of Contents, page F-1

- 18. Please address the following comments regarding your financial statements:
 - Provide your auditors' report that includes the fiscal 2016 financial statements. In this regard, the report on page F-17 only covers fiscal 2015.
 - Provide one set of audited comparable financial statements for fiscal 2016 and 2015. In this regard, it is unclear why you provide the fiscal 2015 standalone financial statements beginning on page F-18 when they are included in the financial statements beginning on page F-2.
 - When providing the financial statements in the preceding bullet, ensure that you remove the word "condensed" from each basic financial statements as condensed financial statements only apply to interim financial statements under Rule 8-03(a) of Regulation S-X.
- 19. We acknowledge your response to prior comment 20. As previously requested, please tell us about your \$300,000 "other payable." In this regard, tell us the following:
 - To whom you owed the \$300,000;
 - What you received in exchange for this payable (confirm whether or not you received \$300,000 in cash);
 - Assuming you received cash, why the creditor advanced you these funds (tell us whether this is some form of borrowing); and
 - How the cash flows associated with this obligation qualify as operating cash flows under ASC 230-10-45-16 an 45-17 instead of financing activities under ASC 230-10-45-14 and 45-15.

In addition, please revise your filing to provide the error correction disclosures required by ASC 250-10-50-7 and 50-8 for your reclassification of your "due to shareholder" obligation and any reclassification related to your "other payable," or explain to us why such disclosure is not warranted.

- 20. We acknowledge your response to prior comment 21. Please address the following comments:
 - Revise your statements of operations to present all your research and development expenses, including this upfront license fee, separately from your selling, general and administrative expenses. See ASC 730-10-50-1.
 - Tell us why you have not filed an Item 4.02 Form 8-K related to the financial statements included in your June 30, 2016 Form 10-Q and why you have not amended that interim report; and
 - Amend your September 30, 2016 Form 10-K and this filing for the revision in the first bullet of this comment and to provide the error correction disclosures required by ASC 250-10-50-7 and 50-8. When providing these disclosures, we remind you that although our comment may have prompted your reconsideration of your accounting, you must take responsibility for both your original and revised accounting.

Exhibit Index, page II-3

21. Please revise your exhibit index to identify the other parties to the agreements filed as exhibits 10.1 and 10.2.

Exhibit 23.1

22. We acknowledge your response to prior comment 22. As requested above, please include your auditor's report for the fiscal year 2016 in your filing. In addition, please ensure that the date of the report is appropriately referenced in their consent. In this regard, the current consent indicates that the date of their report is January 11, 2017 when the date of the report included in your September 30, 2016 Form 10-K is January 12, 2017.

You may contact Mark Brunhofer at 202-551-3638 or Lisa Vanjoske at 202-551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Dorrie Yale at 202-551-8776 or me at 202-551-3675 with any other questions.

Sincerely,

/s/ Suzanne Hayes Suzanne Hayes Assistant Director Office of Healthcare and Insurance

cc: Joan Wu, Esq. — Hunter Taubman Fischer & Li, LLC