

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

March 17, 2025

Bradley Burnam Chief Executive Officer Global Health Solutions, Inc. 250 N. Westlake Blvd. Westlake Village, CA 91362

Re: Global Health Solutions, Inc.
Amendment No. 1 to Offering Statement on Form 1-A
Filed March 6, 2025
File No. 024-12562

Dear Bradley Burnam:

We have reviewed your amended offering statement and have the following comments.

Please respond to this letter by amending your offering 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 offering 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 February 27, 2025 letter.

#### Amendment No. 1 to Offering Statement on Form 1-A

Risk Factors

Risks Related to The Pharmaceutical and Medical Device Business. Our business is dependent on the successful development..., page 4

- 1. In light of your revised disclosure on page 24, please revise here and throughout where appropriate to clarify, if true, that you are not currently conducting any human clinical trials and that you have not yet submitted an IND for your Hexagen drug product candidates. By way of example and not limitation:
  - Revise your statement that you have "two developed pharmaceutical/drug candidates at the clinical stage of development" on page 4.
  - Revise the reference to "ongoing clinical trials" on page 7.
  - Revise page 20 to clarify that your clinical development of the Hexagen formula

as new drug will require an IND in order to commence clinical trials. Similarly, revise the "clinical stage" column of the table on page 20 to indicate that the Hexagen product candidates for Moderate-Severe Eczema and for Onychomycosis are in the preclinical, IND-enabling stage.

## Use of Proceeds, page 18

- 2. We note your response to prior comment 2, which we reissue in part. With reference to your going concern disclosure in your financial statements, please disclose how long you expect the proceeds from this offering to fund your operations if you sell 100%, 75%, 50% or 25% of the total amount of shares offered.
- 3. We note you have added the following new footnote to the Use of Proceeds table on page 18: "(3) Does not include the full cost of the Phase 3 trial." In this regard, please revise to mark the table in the appropriate place(s) to identify the corresponding disclosure to which footnote 3 relates.

#### Our Business, page 19

- 4. We note your response to prior comment 4 which we reissue in part. Please revise to disclose when you received the following FDA 510(k) clearances:
  - K171191 (Hexagen as a medical device for the management of eczematous skin and the symptoms relating to eczema); and
  - K183681 ('Xeal' porous gauze combination product as a medical device for use on post-surgical wounds).
- 5. We note your response to prior comment 5 and revised disclosures and re-issue in part. Please revise to disclose whether, and if so when, you have applied for FDA clearance for Flex and the type of FDA medical device clearance you have sought or plan to seek.
- 6. We note your references to your agreement(s) with MiMedx. Please revise to describe the material terms of the MidMedx agreement(s) including the rights and obligations of the parties, term and termination provisions and payment terms, including applicable royalty rates or a range not to exceed 10 percentage points.

#### Government Regulation, page 21

7. We note your response to prior comment 8, which we reissue. Please expand your disclosure to briefly describe the FDA regulations and processes that apply or may apply to your development of each of medical device, drug and/or biologic product candidates. Your disclosure should describe the FDA review and approval procedures by material stage, as well as any material post-marketing requirements.

# Notes to Consolidated Financial Statements (Unaudited)

## 5. Licensing Agreements, page F-9

8. Please clarify your revised disclosure in this note and in the Liquidity and Capital Resources section on page 24 to explain what the next milestone relates to and the specific performance obligations. Also expand your disclosure to quantify the development and sales-based milestones related to the license agreement that you

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reference on page 20. Include a similar footnote in your notes to the audited financial statements.

### **Exhibits**

9. Please obtain and file an updated consent from your independent auditor.

Please contact Vanessa Robertson at 202-551-3649 or Sasha Parikh at 202-551-3627 if you have questions regarding comments on the financial statements and related matters. Please contact Lauren Sprague Hamill at 303-844-1008 or Alan Campbell at 202-551-4224 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Jeffrey S. Marks