



DIVISION OF
CORPORATION FINANCE

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

February 27, 2025

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

Re: Global Health Solutions, Inc.
Offering Statement on Form 1-A
Filed January 31, 2025
File No. 024-12562

Dear Bradley Burnam:

We have reviewed your 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.

Offering Statement on Form 1-A

Summary

The Company, page 1

1. Please provide the basis for your statement that Hexagen "has over 200,000 human applications." Please also clarify, if true, that your company has yet to recognize any revenues from its products.

Use of Proceeds, page 18

2. Please revise Use of Proceeds to disclose more specifically how proceeds from this offering will be applied, identifying the specific products and/or indications relating to the allocations for "research & development" and "marketing and sales." 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.

Our Business, page 19

3. Please revise this section, where appropriate, to disclose whether any of your products are currently sold commercially through partnerships or out-licensing arrangements. To the extent that Hexagen has received pre-market clearances but is not currently available for commercial sale, please briefly describe the reasons why. Please also revise to briefly describe your future business plan.

Hexagen, page 20

4. Please revise to briefly explain the 510(k) clearance process and to disclose when Hexagen received its 510(k) clearances.
5. We note your disclosure that your combination powder product utilizing Hexagen with animal collagen, known as "Flex," is pending FDA clearance for use on advanced wounds and burns. Please revise to disclose the type of FDA clearance you have sought for Flex and, to the extent known, when you expect to receive a decision from the FDA. Please also describe the material terms of the license agreement and file the agreement as an exhibit or otherwise advise. Refer to Item 17(6) of Part III of Form 1-A.
6. We note that you reference "ongoing clinical trials" and "ongoing clinical development efforts" on page 7, and on page 23 you state that during 2025, you plan to "complete phase 2 trials for [y]our eczema indications." Please revise this section to clarify whether these trials will be evaluating Hexagen as a medical device or as a pharmaceutical. Please also revise to disclose whether you have submitted INDs for your planned trials and whether you are currently conducting any clinical trials. To the extent you are currently conducting clinical trials, please briefly describe the parameters of each trial, including the jurisdiction of the trial and the indication being evaluated.

Thermostable Intranasal Vaccine, page 20

7. We note your disclosure that you have partnered with IAVI.org on a live intranasal vaccine candidate. Please revise to identify the indication(s) to be targeted, and disclose the current clinical development status of this vaccine candidate. Please also briefly describe the material terms of your partnership with IAVI and file the agreement as an exhibit.

Government Regulation, page 21

8. Please expand your disclosure to briefly describe the FDA regulations that apply or may apply to your development of each of medical device, drug and/or biologic product candidates.

Intellectual Property, page 21

9. In relation to the company's material patents, please revise your intellectual property disclosure to clearly describe on an individual or patent family basis whether such patent is owned or licensed, the product candidate or technology to which such patent relates, the expiration year of each patent and the jurisdiction, including any foreign jurisdiction, of each material pending or issued patent.

Management's Discussion and Analysis of Financial Condition and Results of Operation
Results of Operations, page 22

10. You disclose that the increase in research and development expenses during the 2024 Interim Period primarily resulted from a \$65,900 payment to your R&D vendor for clinical trials. Please clarify in revised disclosure which clinical trial(s) this payment was related to.

Directors and Executive Officers, page 23

11. Please revise the rightmost column of the table on page 23 to disclose the approximate average number of hours per week or month that your Chief Medical Officer is anticipated to work. Refer to Item 10(a)(2) of Part II of Form 1-A.

Liquidity and Capital Resources, page 23

12. You disclose in the notes to the financial statements that your cash and cash equivalents are less than a year's worth of cash reserves as of June 30, 2024. Please expand your discussion here to include a description and evaluation of your internal and external sources of liquidity (i.e. share purchase agreement with GEM, Crowdfunding Campaign) and include a brief discussion of any material unused sources of liquidity. If you have identified a material deficiency in liquidity, indicate the course of action that you have taken or propose to take to remedy the deficiency. Refer to Item 9(b) of Form 1-A.
13. You noted that deferred revenue for the periods presented is attributable to a license agreement for your FlexAM product. Please provide disclosure, where appropriate in the filing, of the material terms under the agreement. In your disclosure, also address the amount of funds received for each period presented and to date, as well as your accounting treatment, specifically when the deferred revenues will be recognized.

Plan of Operations, page 23

14. We note your disclosure on page 6 indicating that the regulatory process is lengthy, expensive, and inherently uncertain. As such, please remove the statements in this section that you plan to submit for FDA drug registration for eczema indications during 2027 and for the onychomycosis indication in 2028, as such statements appear to assume the successful completion of clinical trials for these indications.

Compensation, page 24

15. In your next filing, please update your executive compensation table for the fiscal year ended December 31, 2024. Refer to Item 11(a) of Part II of Form 1-A. Also, in a footnote or otherwise, please disclose if your Chief Medical Officer is not compensated for his service in this capacity.

Signatures, page 29

16. Please revise your signature page to include the signatures of your principal financial officer and principal accounting officer.

February 27, 2025

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Consolidated Financial Statements (Unaudited), page F-6

17. Regarding your unaudited interim financial statements, please provide disclosure on whether in the opinion of management all adjustments necessary to make the interim financial statements not misleading have been included. Refer to Part F/S(b)(5)(iii) of Form 1-A.

2. Summary of Significant Accounting Policies, page F-7

18. Please revise to disclose your research and development expense policy. Refer to ASC 730-10-50-1.

12. Subsequent Events, page F-12

19. You noted that since July 2024, the Company granted 110,075 options under the 2024 Stock Option Plan. Please explain how you determined the fair value of the common stock underlying these issuances. In addition, tell us the reasons for any significant differences between that fair value and the \$11.26 offering price.

We will consider qualifying your offering statement at your request. If a participant in your offering is required to clear its compensation arrangements with FINRA, please have FINRA advise us that it has no objections to the compensation arrangements prior to qualification.

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. We also remind you that, following qualification of your Form 1-A, Rule 257 of Regulation A requires you to file periodic and current reports, including a Form 1-K which will be due within 120 calendar days after the end of the fiscal year covered by the report.

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 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