



DIVISION OF
CORPORATION FINANCE

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

August 14, 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 Draft Registration Statement on Form S-1
Submitted July 30, 2025
CIK No. 0002023016**

Dear Bradley Burnam:

We have reviewed your amended draft registration statement and have the following comments.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement and non-public draft submissions on EDGAR. 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 the information you provide in response to this letter and your amended draft registration statement or filed registration statement, we may have additional comments. Unless we note otherwise, any references to prior comments are to comments in our July 17, 2025 letter.

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

Overview, page 2

1. We note that the first two paragraphs both highlight three FDA medical device clearances and their extensive use in humans. To the extent that you highlight these clearances and this history in the first two paragraphs, please revise to explain that these products are not presently on the market and/or that you are not currently generating revenues from these devices.

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Core Products and Programs, page 4

2. We note your revisions in response to prior comment 7. Please further revise disclosures concerning the first three medical devices to disclose the year of FDA clearance and to include the drug/program names that you utilize on pages 10-11 (*e.g.*, XEAL (K183681)). Disclose that the fourth medical device presented is out-licensed to MiMedx. For the GX-03 eczema drug candidate, please revise to indicate that the referenced human trials are Phase 2-equivalent.

GX-03 Development Roadmap: Eczema & Onychomycosis, page 5

3. We note your response to prior comment 9. As presented, the graphic appears to indicate that the Pivotal Phase 3 trials will start and end in Q4 2026. Please revise or advise. Also, revise to remove the NDA Submissions row given its speculative nature.

Immunomodulatory Activity Without the Cost and Risks of Biologics, page 7

4. Please revise to explain the term “cytokine modulation” and clarify whether this was demonstrated in pre-clinical work or in humans. Also, revise the Business section to present support for this claim or tell us where such support is presented.

Clinical Products, page 10

5. With reference to prior comment 16, please revise your disclosure to identify the two FDA-cleared products that you have packaged for out-licensing.
6. We note your disclosure on page 8 that you have historically licensed cleared medical device technologies—including wound dressings and antimicrobial platforms—to commercial partners. As applicable, please revise the disclosures on pages 10-11 to indicate whether any of the three FDA-cleared medical devices were out-licensed in the past. If so, please revise the Business section, or elsewhere as applicable, to identify each licensee and the date of each commercial partnership.

If we are unable to obtain, maintain and enforce patent protection for our current products....
page 35

7. We note your response to prior comment 25. Based on the inventions at issue, please revise the disclosure on page 37 to indicate whether any future licensing demands likely would pertain to one or all of your product candidates.

Liquidity and Capital Resources, page 63

8. With reference to your Development Roadmap on page 5, please revise your Liquidity and Capital Resources discussion and/or Business section disclosures to indicate how much funding you will require over the next twelve months as well as the amount needed to complete your planned pivotal Phase 3 trials for eczema and onychomycosis. Also explain your material funding needs in 2025 and 2026 for any other products candidates that you may be developing during this timeframe.

Business, page 69

9. We note your revisions in response to prior comment 3. Please revise the Business section, where appropriate, to present a detailed summary of the "*Diaper Dermatitis*" and "*Treatment of Phytophotodermatitis with Topical Antimicrobial: A Case Report*" case studies. Identify the providers and indicate when the case studies were performed. Disclose whether the providers are or were affiliated with you and whether you provided compensation for their efforts. Provide similar disclosures with respect to the "A Novel Approach to Polymicrobial Nail Infection" case study and include the patient results so it is clear how these results "suggested efficacy ranging from 70-85%."

Share Purchase Agreement, page 93

10. Your disclosure on page 94 indicates that you have contractual obligations under the agreement to file a resale registration statement concurrently with the filing of the registration statement covering this Direct Listing. With reference to Compliance Disclosure Interpretations, Securities Act Sections, Q. 139.13, please note that you would not be eligible to file a registration statement covering the equity line transaction until such time as there is an existing market for the securities. Accordingly, please advise us concerning your plans for registration of the equity line arrangement.

Sale Price History of Our Capital Stock, page 111

11. We note your revised disclosure in response to prior comment 30. Please revise to provide the disclosure specified in Regulation S-K, Item 201(a)(3) or explain why it is not applicable.

Notes to Consolidated Financial Statements

9. Licensing Agreements, page F-21

12. We note your response to prior comment 31. Please revise your disclosure to clarify the specific development and commercialization performance obligations.

General

13. Given Clear Street LLC's dual role as your financial advisor and a Registered Stockholder and the financial advisor's role under Nasdaq direct listing rules, please consider whether it is necessary to include a discussion of any material risk factors relating to potential conflicts of interest.
14. We note the disclosure on your cover page that "the Registered Stockholders will [not] be involved in Nasdaq's price-setting mechanism, including any decision to delay or proceed with trading, nor will . . . they control or influence the Advisor in carrying out its role as a financial adviser." Please revise this and any other similar statements for consistency given Clear Street LLC's current dual role as your financial advisor and a Registered Stockholder.
15. Please confirm that Clear Street LLC will not serve as the issuer's valuation agent for purposes of the Nasdaq direct listing rules.

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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 Joe McCann at 202-551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Stephen A. Byeff