

June 15, 2021

U.S. Securities and Exchange Commission Division of Corporation Finance Office of Life Sciences 100 F Street, N.E. Washington, D.C. 20549

Attn: Christine Torney Brian Cascio Abby Adams Laura Crotty

Re: HCW Biologics Inc. Registration Statement on Form S-1 Filed May 26, 2021 File No. 333-256510

## Ladies and Gentlemen:

On behalf of HCW Biologics Inc. ("*HCW*" or the "*Company*"), we submit this letter in response to comments received from the staff (the "*Staff*") of the Securities and Exchange Commission (the "*Commission*") by letter dated June 10, 2021 (the "*Comment Letter*") with respect to the Company's above referenced Registration Statement on Form S-1 (the "*Registration Statement*"). Concurrently with the submission of this response letter, the Company has revised the Registration Statement and is filing via EDGAR Amendment No. 1 to the Registration Statement (the "*Amended Registration Statement*"). In addition to addressing the comments raised by the Staff in its letter, the Company has revised the Amended Registration Statement to update other disclosures.

For the convenience of the Staff, the numbering of the paragraphs below corresponds to the numbering of the comment in the Comment Letter, the text of which we have incorporated into this response letter for convenience in italicized type and which is followed by the Company's response. In the responses below, page number references are to the Amended Registration Statement.

## Draft Registration Statement on Form S-1 General

## <u>Prospectus Summary</u> Overview

1. We note your response to our prior comment 1. To the extent your discussions with these seven potential partners are too preliminary to name them in the prospectus, please balance your disclosure by noting the uncertainty of whether you will be able to finalize agreements with any of these institutions and the implications thereof.

Orrick, Herrington & Sutcliffe LLP The Orrick Building 405 Howard Street San Francisco, CA 94105-2669 +1 415 773 5700 orrick.com June 15, 2021 Page Two

**Response**: The Company acknowledges the Staff's comment and has revised the disclosure on pages 2, 81, 101 and 106 of the Amended Registration Statement as requested.

2. We note your response to our prior comment 2 regarding your statements of safety and efficacy. However, as previously stated, safety and efficacy determinations are solely within the FDA's authority and they continue to be evaluated throughout all phases of clinical trials. Because the company's product candidates have not been evaluated by the FDA in clinical trials, please remove these and any such references in your prospectus. In the Business section, you may present objective data resulting from your animal models and research without including conclusions or speculation related to safety or efficacy.

**Response**: The Company acknowledges the Staff's comment and has revised the disclosure on pages 2, 3, 5, 75, 80, 81, 88, 99, 105, 106, 108, 109 and 112 of the Amended Registration Statement as requested.

3. We note your response to our prior comment 4. Please revise the disclosure to clarify, if true, that one of the institutions with whom you are in preliminary discussions regarding your clinical trials will also sponsor your IND, if those discussions are successful. If this is not the case, please identify the "investigator" who will sponsor your trials.

**Response**: The Company acknowledges the Staff's comment and has revised the disclosure on pages 2, 8, 81, 82, 99, 101, 104, 106, 108 and 110 of the Amended Registration Statement as requested.

4. We note your response to our prior comment 5 and we reissue the comment. Your response does not sufficiently establish a collaboration between the company and Wugen, with your disclosure making clear that the company has retained only manufacturing and supply rights, in addition to the economic terms of the out-license agreement. Therefore, these out-licensed products do not appear to be a part of the company's pipeline. In this regard, we note your disclosure on page 109 that "[a]ccording to the terms of the Wugen license, Wugen will fund all future clinical development and commercialization activities for any indications utilizing the licensed molecules for cell therapy as covered by the license. We have the opportunity to receive additional payments for development and commercialization milestones as well as single-digit royalties." We also note from disclosure in the MD&A section and the notes to your financial statements, particularly Notes 7 and 12, that the Wugen License is accounted for and characterized as a license, not a collaboration agreement.

**Response**: In light of the Staff's comment, the Company has changed references to "clinical stage" to "preclinical stage" on pages 1, 80, 100, F-7 and F-3 of the Amended Registration Statement and removed the Phase 2 clinical trials for HCW9201 from the Pipeline chart that appears on pages 3 and 108 of the Amended Registration Statement.

5. We note your response to our prior comment 7 and the related revisions on pages 2 and 104. However, it remains unclear from this disclosure whether you have an effective IND related to the pancreatic cancer trials discussed. We further note your statement on page 108 that you are planning to submit an IND in the second half of 2021 to initiate the Phase 1b/2 clinical trial of HCW9218 in patients with advanced and metastatic pancreatic cancer, clarifying that no effective IND exists. In light of this statement, please revise your disclosure in each place that you discuss

the Phase 1b/2 trials to make clear that you have not yet submitted and the FDA has not yet accepted an IND related to these trials, and the implications thereof. Your disclosure should be balanced in stating that the FDA may not accept the IND and the process to follow if such is the case.

Further, your disclosure throughout the prospectus that you "are preparing to initiate" clinical trials creates the impression that the company is further along in the development process than it is (i.e., that effective INDs are in place). Revise your disclosure in all places in which potential clinical trials are discussed to accurately characterize the process leading up to the commencement of human trials and the prerequisites thereto

**Response**: The Company acknowledges the Staff's comment and has revised the disclosure on pages 1, 81, 100, 109, and 111 of the Amended Registration Statement as requested.

In addition, the Company has expanded on language in the *Risk Factors to the Development and Clinical Testing of our Products* to further explain risks associated with FDA delaying approval of an IND or outright rejection of IND, failure to reach agreements with 7 NCI designated clinical sites we are negotiating with, delay or failure to reach an agreement with sponsor for basket trial to evaluate HCW9218 in solid tumors in the revised disclosures on pages 22-24 and 26 of the Amended Registration Statement.

Management's Discussion and Analysis of Financial Condition and Results of Operations Components of our Results of Operations—Revenues, page 83.

6. We note the following statement in the newly added disclosure on page 83: "As of March 31, 2021, Wugen ordered research and clinical grade materials, but they were not delivered." We also note that the company recognized deferred revenue in relation to this order. Please clarify why the company did not deliver the materials and the implications thereof (e.g., breach of contract, financial penalties, cancellation of order and return of payment).

**Response**: The Company acknowledges the Staff's comment and has revised the disclosure on page 84 of the Amended Registration Statement to clarify why the Company did not deliver the materials and the implications thereof. In addition, the Company supplementally advises the Staff that the orders placed during the three months ended March 31, 2021 were not delivered because the manufacturing process was not complete and delivery, and acceptance did not occur. The mutual arrangement between the Company and Wugen related to these materials (provided for under the terms of the Wugen license) allows for a delivery date subsequent to March 31, 2021. Accordingly, the Company believes there are no implications with respect to the ongoing satisfaction of its performance obligation at March 31, 2021.

## Principal Stockholders, page 159

7. We reissue comment 16 to the extent you have not identified the beneficial owners of the shares held by Pacific Treasure Global Limited or Axone Capital.

**Response**: The Company acknowledges the Staff's comment and has revised the disclosure on pages 161-162 of the Amended Registration Statement as requested.

June 15, 2021 Page Four

If you have any questions regarding this letter, please do not hesitate to contact me at (415) 773-5720 with any questions or further comments.

Sincerely,

/s/ William L. Hughes, Esq. William L. Hughes, Esq.

cc: Scott M. Iyama, Esq., Orrick, Herrington & Sutcliffe LLP Richard A. Friedman, Esq., Sheppard Mullin, LLP Stephen A. Cohen, Esq., Sheppard Mullin, LLP Hing C. Wong, HCW Biologics Inc. Rebecca Byam, HCW Biologics Inc.