



DIVISION OF
CORPORATION FINANCE

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

May 13, 2021

Hing C. Wong, Ph.D.
Chief Executive Officer
HCW Biologics Inc.
2929 N. Commerce Parkway
Miramar, FL 33025

Re: HCW Biologics Inc.
Draft Registration Statement on Form S-1
Submitted April 16, 2021
CIK No. 0001828673

Dear Dr. Wong:

We have reviewed your draft 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 providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. 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 the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

Prospectus Summary

Overview, page 1

1. We note your statement on pages 1, 78 and 95 that you will initiate your Phase 1b/2 trial "working with leading institutions affiliated with the National Cancer Institute." Please revise your disclosure in each section to provide more detail regarding these relationships, including the names of the parties and a discussion of any contractual agreements in place. In addition, please provide the same level of disclosure in relation to your statements that you have "extensive relationships at NCI-Designated Comprehensive Cancer Centers that have high-interest in participating in [y]our clinical trials."

2. Given your product candidates are at the preclinical stage of development, your belief that your approach has the potential to "fundamentally change" the treatment of age-related diseases and "to improve the efficacy and safety of chemotherapies for cancer" seems premature. Please either provide support for these statements or remove them from the prospectus.
3. We note your statement on page 1 regarding your "focus on developing first-in-class immunotherapies" and additional "first-in-class" references elsewhere in the prospectus. Use of this term suggests your product candidate will be effective and is likely to be approved by the FDA. Please delete these references throughout your registration statement.
4. In paragraph three, you disclose the investigator involved in the potential "investigator-sponsored investigational new drug ("IND") [sic] will be submitted to study HCW9218 as an adjunct to chemotherapy in patients with solid tumors (breast, ovarian, prostate, and colorectal cancers)." Identify any agreements with the investigator and clarify any access you have to the data generated during the trial or whether you have any control over the trial.
5. We note you describe yourself as a clinical-stage company, but in the second and third paragraphs you state that you are preparing your lead product candidate for clinical trials in the second half of 2021 and that both of your lead product candidates, HCW9218 and HCW9302, are preclinical. As the clinical-stage products to which you refer are those you have out-licensed to Wugen, HCCW9201 and HCW9206, revise to remove them from your pipeline table. We note that "Wugen will fund all future clinical development and commercialization activities for any indications utilizing the licensed molecules cell therapy as covered by the license," as disclosed on page 106. Please also revise your references to the company as a "clinical stage" company to more accurately characterize it as a "preclinical stage" company.
6. Please revise the pipeline table to remove the "lead op" column.
7. In the Summary, you disclose the potential timing of clinical trials without addressing whether you have submitted any INDs. Revise the summary to clarify when you plan to submit an IND for HCW9218 for pancreatic cancer. In this regard, we note the disclosure on page 100 that you plan to do so in the second quarter of 2021. To the extent this IND will only address pancreatic cancer, as disclosed on page 104, revise page 100 (which includes additional indications) to clarify. Please also clarify if you have submitted an IND for HCW9302, or if not, when you plan to do so.

Risk Factors

Risks Related to our Financial Position and Need for Additional Capital, page 10

8. On page 13 you disclose you "experienced delays in the development of HCW9218 as a result of the ongoing pandemic, including delays with certain third party vendors." Please revise to explain the nature of those delays and the degree to which they have

resolved. Also clarify in what way you “expect your clinical development program timelines may continue to be negatively affected by COVID-19” more specifically than the list of potential issues in the risk factor, given that you have experienced delays thus far and potentially continue to do so. Finally, as it has been over one year since the pandemic began, revise this risk factor to reflect current information. For example, uncertainty based on “the ultimate geographic spread of the disease” is outdated.

Risks Related to Our Dependence on Third Parties, page 42

9. Please disclose the third-party manufacturer you rely on to produce your drug product candidates, as discussed on page 45. Refer to Item 101(h)(4)(v) of Regulation S-K. As it appears you are substantially dependent on this supplier, file the agreement with this manufacturer as an exhibit pursuant to Item 601(b)(10)(ii)(B) of Regulation S-K or explain why such filing is not required.

Risks Related to Ownership of our Common Stock, page 59

10. Please revise this risk factor on page 66-67 to disclose that there is a risk that your exclusive forum provisions may result in increased costs for investors to bring a claim, and that the provisions may discourage claims or limit investors’ ability to bring a claim in a judicial forum that they find favorable.

Use of Proceeds, page 72

11. You disclose one amount of funds to “advance the development” of both your lead product candidates together, specifying some uses of those funds for HCW9218. Please revise your disclosure to quantify the amount of proceeds you expect to use to fund each of your product candidates and indicate how far it will allow you to proceed with the continued development of each of your product candidates. Please also disclose the sources of other funds needed to reach regulatory approval and commercialization for each product candidate. Refer to Instruction 3 to Item 504 of Regulation S-K.

Critical Accounting Policies, Significant Judgements and Estimates

Determination of Fair Value of Common Stock, page 92

12. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances. Please discuss with the staff how to submit your response.

Intellectual Property, page 107

13. Please revise your intellectual property disclosure to clearly describe on an individual or patent family basis the type of patent protection granted for each product, the expiration

year of each patent held, and the jurisdiction of each patent. Please clearly distinguish between owned patents and patents out-licensed to third parties. In this regard it may be useful to provide tabular disclosure.

License Agreements, page 109

14. We note the following statement on page 110: "We retained all other rights and use of the licensed molecules not granted under the Wugen License, including regulatory T cell-based cellular therapy, injectable rights, and manufacturing rights." Please revise this disclosure to clarify what aspect of the technology was out-licensed. In addition, we note the termination of the Wugen license agreement is tied to the last-to-expire valid patent claim. Please either disclose the out-licensed patent expiration here or in the Intellectual Property section immediately preceding the license discussion.

Executive Compensation

Employment, Severance, and Change of Control Agreements, page 135

15. We note your statement on page 135 that you have no offer letter or employment agreement with Dr. Hing Wong. However, the exhibit index lists exhibit 10.6 as an offer letter between Hing C. Wong and the registrant. Please reconcile.

Principal Stockholders, page 149

16. Please revise the footnotes to your table to identify the natural persons who are the beneficial owners of the shares held by the 5% or greater stockholders.

Exhibits

17. We note that you have agreed to issue warrants to Kingswood Capital Markets upon the closing of the offering. Please file the warrant agreement as an exhibit.

General

18. Please provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Hing C. Wong, Ph.D.
HCW Biologics Inc.
May 13, 2021
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You may contact Christine Torney at (202) 551-3652 or Brian Cascio at (202) 551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Abby Adams at (202) 551-6902 or Laura Crotty at (202) 551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: William L. Hughes, Esq.