

July 23, 2019

**VIA EDGAR AND COURIER**

Securities and Exchange Commission  
Division of Corporation Finance  
Office of Electronics and Machinery  
100 F. Street, N.E.  
Washington, D.C. 20549  
Attention: Tim Buchmiller  
Geoff Kruczek

**Re: Histogenics Corporation  
Registration Statement on Form S-4  
Filed June 14, 2019  
File No. 333-232147**

Dear Messrs. Buchmiller and Kruczek:

On behalf of Histogenics Corporation (the "Company"), we submit this letter in response to comments from the staff (the "Staff") of the Securities and Exchange Commission (the "Commission") received by letter dated July 8, 2019 relating to the Company's above-referenced Registration Statement on Form S-4 (the "Form S-4").

On behalf of the Company, we are also submitting via EDGAR a revised Form S-4 (the "Revised Form S-4"), and for the convenience of the Staff, we are providing to the Staff by courier copies of this letter and marked copies of the Revised Form S-4 against the Form S-4.

In this letter, we have recited the written comments from the Staff in italicized, bold type and have followed each comment with the Company's response.

[OCU300 for Patients with oGVHD, page 230](#)

1. ***Please revise the disclosure to include a brief explanation of the phrase "not powered for statistical significance" that is used under this heading, or "not sufficiently powered" in other locations such as on page 231, and describe the impact on the related results of Ocugen's studies. Also revise to ensure the significance of any disclosed p-values related to these studies in the context of the disclosure you provide in response to this comment.***

**RESPONSE TO COMMENT 1:**

In response to the Staff's comment, the requested additional disclosure has been added to page 232 of the Revised Form S-4. The Company has also clarified similar disclosures on pages 60 and 245 of the Revised Form S-4.

Registration Statement on Form S-4 filed June 14, 2019

OCU310 for Patients with DED, page 231

**2. We note the disclosure that "OCU310 is safe." Because approval by the FDA and other comparable regulatory agencies is dependent on their making a determination according to criteria specified in agency regulations that a product is both safe and effective, please clarify the basis for this statement.**

**RESPONSE TO COMMENT 2:**

In response to the Staff's comment, the Company has revised its disclosure throughout the Revised Form S-4 to remove all references that OCU310 is safe.

Prospective Phase 1/2 placebo-controlled study, page 247

**3. We note your disclosure in the first paragraph that this study was "not powered for statistical significance." Given that disclosure, please revise to explain how you derived the p-values indicated in the fourth paragraph of this section and the conclusion of a "statistically significant difference" in clause (1) of the fourth paragraph, or revise your disclosure as appropriate.**

**RESPONSE TO COMMENT 3:**

In response to the Staff's comment, the Company has revised the disclosure on page 249 of the Revised Form S-4.

**4. We note your assumption regarding independence between eyes within a subject. If this assumption factored into your disclosed conclusions for this study, please explain the basis for this assumption.**

**RESPONSE TO COMMENT 4:**

In response to the Staff's comment, the Company has added the requested additional disclosure on page 249 of the Revised Form S-4.

OCU310 Phase 2 Clinical Study, page 252

**5. We note your disclosure in the first paragraph that this study was "not powered for statistical significance." Given that disclosure, please revise to explain how you derived the p-values indicated in the first paragraph under "Symptom Assessment" on page 253, to disclose the basis for your statements regarding statistical significance in the second paragraph under that heading, and the conclusion of "no statistical difference" under "Conclusion" on page 254, or revise your disclosure as appropriate.**

**RESPONSE TO COMMENT 5:**

In response to the Staff's comment, the Company has revised the disclosure on pages 254, 255 and 256 of the Revised Form S-4.

6. *Please explain the factors used to generate the VAS Scores and what the score means.*

**RESPONSE TO COMMENT 6:**

In response to the Staff's comment, the Company has added the requested additional disclosure to page 254 of the Revised Form S-4.

License Agreements, page 263

7. *Please provide more specificity with regard to when each agreement may expire. For example, disclose the date that the last of the licensed patents will expire or how the relevant statutory or regulatory exclusivity period will be determined, as applicable.*

**RESPONSE TO COMMENT 7:**

In response to the Staff's comment, the Company has added the requested additional disclosure to pages 266 and 267 of the Revised Form S-4.

Intellectual Property, page 265

8. *Clarify which patents are owned and which are licensed and disclose the foreign jurisdictions where you have issued patents or pending patent applications.*

**RESPONSE TO COMMENT 8:**

In response to the Staff's comment, the Company has added the requested additional disclosure to page 267 of the Revised Form S-4.

Unaudited Pro Forma Condensed Combined Financial Information

Introduction, page PF-2

9. *We reference the disclosure that the acquisition of Histogenics is expected to be accounted for as an asset acquisition. Please explain to us how you considered the guidance in ASC 805-10-55 in determining that substantially all the fair value of the assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. As a related matter, tell us why you have multiple references to "business combination" throughout the pro forma financial information.*

**RESPONSE TO COMMENT 9:**

In response to the Staff's comment, the disclosure has been revised to remove the language related to the "initial screen test". After further consideration of the transactions to be consummated subject to and conditioned upon the merger, Ocugen's management has determined that it is not necessary to apply this initial screen test or assess the merger in accordance with ASC 805 in this circumstance. Instead, Ocugen's management has determined that the merger will be accounted for as an equity transaction as the substance of the transaction is an exchange of equity for the net monetary assets of Histogenics. Accordingly, Ocugen is not expected to receive material non-monetary assets as part of this transaction. Consequently, in response to the Staff's comment, all references to ASC 805, "business combination" and "asset acquisition" in the pro forma financial information have been removed.

10. *Please revise footnote (d) to clearly identify how all of the items disclosed result in the \$24.4 million adjustment to cash and cash equivalents. In addition, tell us why footnote (i) relating to the mark to market adjustment for the warrant liability resulted in an adjustment to cash and cash equivalents.*

**RESPONSE TO COMMENT 10:**

In response to the Staff's comment, the adjustment to cash and cash equivalents has been broken out into separate line items with corresponding footnotes. Additionally, footnote (i) relating to the mark-to-market adjustment was an incorrect reference to cash and cash equivalents and, therefore, has been deleted.

11. *Please revise footnote (f) to clarify how it relates to the \$3,003 adjustment to derivative liabilities.*

**RESPONSE TO COMMENT 11:**

In response to the Staff's comment, footnote (j) (previously footnote (f)) has been revised to include the following:

"Also, in accordance with ASC 815-15, *Embedded Derivatives*, there were embedded derivatives identified related to the convertible notes at inception. As a result of the conversion to equity, fair values of embedded derivatives totaling \$3.003 million were removed at the carrying value in connection with the extinguishment accounting."

12. *Please explain how footnote (g) referencing the increase in accrued expenses of \$0.6 million relates to the \$1.2 million adjustment to accrued expenses. In addition, tell us how the pro forma adjustments for accrued expenses foots across to \$13,697.*

**RESPONSE TO COMMENT 12:**

The accrued adjustment has been changed to \$1.6 million, with references to footnote (i) (previously footnote (g)) and footnote (g). Footnote (i) (previously footnote (g)) represents \$0.6 million of expected transaction expenses, as previously disclosed. Footnote (g) has been added to reflect \$1.0 million in cash of accrued expenses payable to Ocugen's financial advisor upon consummation of the merger (\$0.5 million each for the merger and the Pre-Merger Financing). This \$1.0 million amount is an increase of \$0.4 million from the \$0.6 million amount previously included in the accrued adjustment, which resulted from an updated transaction price analysis.

In response to the Staff's comment, the amount for pro forma combined accrued expense has been corrected to foot across.

13. *Please refer to footnotes (d), (f), (b) and (g). Revise to clarify how the amounts discussed in the footnotes agree with the adjustments to additional paid-in capital and accumulated deficit in the pro forma condensed combined balance sheet. Also, clarify in footnote (c) why the adjustment is different than the Histogenics additional paid-in capital.*

## RESPONSE TO COMMENT 13:

In response to the Staff's comment, the disclosures in footnotes (e), (f), (j), (i) and (h) (previously footnotes (c), (d), (f), (g) and (h), respectively) have been clarified and updated based on the updated transaction price analysis as described below. A reference to footnote (g) (previously part of footnote (d)) has also been added. The reference to footnote (b) in additional paid-in capital was an incorrect reference and has been deleted. Also, please refer to footnote (l) added to Note 3 of the pro formas for a reconciliation of the amounts to various footnotes.

Additional Paid-in Capital ("APIC") is impacted by the following transactions:

- 1) Merger and Pre-Merger Financing related fees payable to Ocugen's financial advisor:
  - a) In June 2019, 160,974 shares of Ocugen common stock were issued to Ocugen's financial advisor at \$5.95 per share for services provided related to the merger. This resulted in a minimal impact on equity.
  - b) Approximately \$1.0 million in cash is expected to be paid to Ocugen's financial advisor related to the merger and Pre-Merger Financing as described in footnote (g). The total fees of \$1.0 million have been split equally between the merger and the Pre-Merger Financing. While fees payable related to the merger are capitalized and shown as a reduction of APIC, fees related to the Pre-Merger Financing were also shown as a reduction of APIC in accordance with ASC 470-20-30-13, resulting in a total net decrease in APIC totaling \$1.0 million.
- 2) An increase in APIC totaling \$14.9 million due to the issuance of Ocugen shares in the Pre-Merger Financing to be exchanged in the merger for 131.6 million shares of Histogenics common stock, as described in footnote (f).
- 3) An increase in APIC totaling \$9.0 million as a result of the conversion of the convertible notes described in footnote (j).
- 4) An increase in APIC totaling \$1.9 million, due to the transactions listed in footnote (h).
- 5) A decrease of \$0.6 million in APIC as a result of expected transaction expenses described in footnote (i).

Accumulated Deficit is impacted by the following transaction:

An increase of \$2.97 million due to gain described in footnote (j), and a decrease of \$0.69 million due to original issuance discount related to the senior secured convertible notes issued in the bridge loan described in footnote (g).

In response to the Staff's comment, the wording in footnote (e) (previously footnote (c)) has also been revised to clarify why the aforementioned adjustment is different from Histogenics' paid-in capital.

**14. We reference the disclosure on page PF-8 that substantially all of the fair value of the asset acquisition is included in IPR&D. In this regard, we note that you did not provide an estimate of the fair value of the assets acquired and liabilities assumed, including IPR&D and the related allocation of the purchase price of Histogenics. While we note that Ocugen has not completed the detailed valuation work, please tell us why you have not provided your best estimate of the fair value of the assets and liabilities acquired. Also, tell us how you considered the guidance in ASC 805-50-30.**

## RESPONSE TO COMMENT 14:

### Estimate of fair value of assets and liabilities:

In response to the Staff's comment, the references to substantially all of the fair value of the assets being included in IPR&D have been updated and removed. These statements are incorrect as Ocugen did not acquire IPR&D assets. Histogenics has an agreement in place that calls for the sale of substantially all its assets to a third party subject to and conditioned upon the closing of the merger. Therefore, Ocugen is not expected to receive any material non-monetary assets or liabilities as a result of the merger.

The following explanation has been added in "Introduction" and "Note 2 – Basis of Presentation":

"The transaction between Ocugen and Histogenics represents an equity transaction rather than a business combination under Accounting Standards Codification 805, Business Combinations ("ASC 805"). Therefore, no goodwill or intangible assets will be recognized as a result of the transaction. The transaction is considered an equity transaction where in substance Ocugen is exchanging equity for the net monetary assets of Histogenics."

After further consideration of the transactions to be consummated subject to and conditioned upon the merger, the equity transaction is not accounted for under ASC 805. Therefore, the guidance in ASC 805-30-50 is not applicable based on Ocugen management's updated assessment.

*[Remainder of page intentionally left blank.]*

Please do not hesitate to contact Albert Vanderlaan at (617) 648-9298 or avanderlaan@gunder.com, if you have any questions or would like additional information regarding this matter.

Very truly yours,

GUNDERSON DETTMER STOUGH  
VILLENEUVE FRANKLIN & HACHIGIAN LLP

By: /s/ Albert Vanderlaan  
Albert Vanderlaan

cc: Adam Gridley  
Jonathan Lieber  
**Histogenics Corporation**

Marc Dupré  
Keith Scherer  
**Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP**

Shankar Musunuri, Ph.D., M.B.A.  
Kelly Beck  
**Ocugen, Inc.**

James W. McKenzie, Jr.  
Jacquelynn M. Hamilton  
**Morgan, Lewis & Bockius LLP**