



DIVISION OF
CORPORATION FINANCE

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

March 13, 2014

VIA E-mail

Kevin McArdle
Chief Financial Officer
Histogenics Corporation
830 Winter Street, 3rd Floor
Waltham, Massachusetts 02451

**Re: Histogenics Corporation
Confidential Draft Registration Statement on Form S-1
Submitted February 14, 2014
CIK No. 00001372299**

Dear Mr. McArdle:

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.

1. Please supplementally provide us with any written materials that you or anyone authorized to do so on your behalf provides in reliance on Section 5(d) of the Securities Act to potential investors that are qualified institutional buyers or institutional accredited investors. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

Overview, page 1

2. Your disclosure in the summary appears to rely excessively on jargon and may be difficult for an average investor to understand. Please revise your disclosure so that a non-medical field investor will be able to understand your product, business and market opportunity. For example, we note terms such as scaffolding, tissue engineering,

bioadhesives microfracture, and fibroblast growth factor variants, among others. Please revise your summary.

3. We note that you have provided in the summary a separate section on risks relating to your business. Rather than discussing the negative aspects in one area of your summary, your summary should provide a balanced, integrated discussion of the positive and negative aspects of your offering. For example, in your first paragraph, please clearly state that you are not yet approved to sell your product. In addition, please disclose that you have incurred net losses in each year since inception and quantify your net losses. Please revise your summary throughout.
4. Please expand your description of your first product candidate “NeoCart” so that investors can understand what the product is and how and why you believe it demonstrates “clinical superiority” over the current standard of care.
5. We note your statements regarding “statistically significant improvement in clinical efficacy based on pain and function measures as compared to microfracture” and “positive Phase 1 and Phase 2 clinical data.” Please expand your disclosure to describe the purpose and size of the Phase 1 and Phase 2 trials, respectively, and how the data supports your claim of significant improvement and positive data.
6. Please explain what it means when you state “NeoCart is currently enrolling a Phase 3 clinical trial in the United States under a Special Protocol Assessment with the U.S. Food and Drug Administration.” How is this different from other Phase 3 clinical trials and why are you pursuing this type of trial? Please also disclose the size of the trial and its anticipated schedule.

Impairment of Intangible Assets, page 60

7. We reference the discussion on page 60 that the suspension of the production and commercialization of BioCart was an indicator of potential impairment, and this resulted in \$1.8 million impairment charge to goodwill. Please explain to us how this suspension was considered in your assessment of the recoverability of the intangible assets related to the acquisition of ProChon.

Stock Based Compensation, pages 60-66

8. Please tell us the estimated initial public offering price. To the extent that there is a significant difference between the estimated grant-date fair value of your common stock during the past twelve months and the estimated IPO price, please discuss for us each significant factor contributing to the difference.

JOBS Act, page 68

9. Please clarify what you mean when you state that you “are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act.”

Business, page 76

10. Please provide copies of the reports, studies and industry data that you reference. Please clearly mark the relevant sections of these reports. For each report, please also tell us: how you confirmed that the data reflects the most recent available information; whether the data is publicly available; whether the data was prepared for use in the registration statement; whether the authors of the data consented to your use of it in the registration statement; and whether you paid for the compilation of the data. If you were affiliated with the preparation of the data in the studies, ensure that your disclosure clearly indicates the nature of all such affiliations.

Limitations of Current Alternatives for Treating Cartilage Damage, page 78

11. Please ensure that your disclosure presents a balanced view of the benefits and drawbacks of current alternatives. For example, it is unclear why you state that microfracture “in theory” forms joint cartilage. Is this in doubt? Please clarify and revise.

Our Regenerative Medicine Platform, page 79

12. Please revise the discussion of your technology so that investors who may not be familiar with medical technology will be able to understand how you develop your product. Among many examples, it is unclear what it means when you state your tissue engineering processors incubate your implants under conditions of cyclic hydrostatic pressure and low oxygen tension. Please revise throughout the prospectus.

Our Business Strategy, page 80

13. Please describe more fully the steps involved in implementing your business strategy. Explain the steps, size and time involved in completing your Phase 3 clinical trial. For example, what is involved in “transferring production of critical raw materials in-house?” What does means to “invest strategically in a U.S. commercial infrastructure” to support a successful launch and commercialization of NeoCart?

Our Phase 3 Product Candidate: NeoCart, page 81

14. Please expand your disclosure to explain the basis for your claim that your Phase 1 and Phase 2 trials “demonstrated very favorable safety and the potential for durable efficacy.” Please also explain what you mean when you state that your data has been “published in

well regarded peer-reviewed journals.” Also, explain the meaning of the phrase “acceptance as Level 1 evidence”.

15. Please expand your graphics to show the “NeoCart Manufacturing Process” in more detail so that investors can understand the steps involved.

Phase 3 Clinical Trial, page 82

16. Please revise your disclosure so that investors who are not in your industry can understand the steps involved in the Phase 3 trial. Why do you believe the BLA pathway is “rigorous” and how does it differ from other FDA approval processes? Why do you believe it is appropriate to use a one year endpoint, when you state that one of microfractures drawbacks is its limited efficacy after two years? What do you mean when you describe “control arm” and “treatment arm” and what is a “dual-threshold responder analysis.” Please also clarify your explanation of the schematic graphic you provide so it is clear.

Phase 2 Clinical Trial, page 83

17. Please disclose the size of the “treatment group” upon completion of the Phase 2 trial and describe how you determined the improvement was “statistically significant.” Also, please tell us why you believe investors will be able to interpret and understand the tables you provide on pages 84 and 85. It is unclear why the tables are necessary and what they add to the information you are trying to convey.

Phase I Clinical Trial, page 86

18. Please expand your disclosure regarding this trial to explain what it means when you refer to a “highly favorable safety profile.” Also, please discuss in greater detail the “[e]fficacy signals” that were noted.

NeoCart Manufacturing Process, page 87

19. We note your statement that your process is “organized with specific steps that [you] plan to control” through your supply chain strategy. Please explain the steps you intend to perform in-house and what steps require third party assistance.

Purpose Co., Ltd, page 89

20. Please expand your discussion of the shares to be issued upon completion of an initial public offering to explain which investors would be issuing the shares to Purpose. Also, please disclose the specific royalty percentages to be paid to Purpose. In this regard, it is unclear why you describe the royalty as a “low single digits of our net sales.”

Angiotech Pharmaceuticals..., page 90

21. Please disclose the specific royalty percentages to be paid to Angiotech. In this regard, it is unclear why you describe the royalty as a “low single digits of our net sales.”

Koken Co, Ltd, page 91

22. Please disclose the March 2013 fee paid to Koken and clarify whether there are other payment obligations.

Certain Relationships and Related Party Transactions, page 124

23. The relationships of the parties described in this section are unclear. Please identify the related parties and provide additional disclosure as required by Item 404 of Regulation S-K.

Financial Statements

Note 2. Restatement of Historical Financial Information, page F-11

24. We note that you identified certain material errors in the previously reported financial statements for the period from inception to December 31, 2009. Please explain to us in greater detail how you accounted for these errors and how the amounts in the table in Note 2 are reflected in your financial statements. Please also tell us where you have included the disclosures required by FASB ASC 250-10-50 related to these errors.

Note 3. Revenue Recognition, page F-19

25. Please revise to separately disclose product, license fee and government grant revenue in your financial statements. Please explain to us the nature of government grant funding and clarify the reference to this as a qualifying therapeutic discovery project tax credit program. Please also clarify where the related reimbursable expenses are recorded.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division’s October 11, 2012 announcement on the SEC website at <http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm>.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (<http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm>). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your

Kevin McArdle
Histogenics Corporation
March 13, 2014
Page 6

confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Andri Boerman at 202-551-3645 or Brian Cascio at 202-551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Jay Mumford at 202-551-3637 or Daniel Morris at 202-551-3314 with any other questions.

Sincerely,

/s/ Daniel Morris for

Amanda Ravitz
Assistant Director

cc: via E-mail Marc F. Dupré, Esq.
Richard C. Blake Esq.