



DIVISION OF
CORPORATION FINANCE

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

June 14, 2021

Jennifer Ernst
Chief Executive Officer
Tivic Health Systems, Inc.
750 Menlo Avenue, Suite 200
Menlo Park, CA 94025

Re: Tivic Health Systems, Inc.
Draft Registration Statement on Form S-1
Submitted May 14, 2021
CIK No. 0001787740

Dear Ms. Ernst:

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 submitted May 14, 2021

Prospectus Summary , page 2

1. We note your disclosure that ClearUP has received three regulatory clearances. Please revise to disclose that your product is a Class II medical device and specify the regulatory clearances that ClearUP has received.
2. Please revise your statements that you have shown that non-invasive bioelectronic treatments can safely and comfortably deliver therapeutic benefits, with favorable safety profiles, as determinations of safety and efficacy are solely within the authority of the FDA. In this regard we note that only your ClearUP product has received FDA clearance.

3. Please revise to provide the basis for your statement that your market research is "proprietary" and that the design of your product is your platform for "accelerated development" of additional product candidates.
4. We note your disclosure that studies demonstrated that ClearUP is highly effective at treating common symptoms with no substantive side effects. Please revise to specify the common symptoms referred to. In this regard, we note that you have received FDA clearance for the treatment of sinus pain from allergic rhinitis and moderate to severe congestion.

Market Opportunity and Regulatory Clearance, page 3

5. We note your disclosure that with the de novo clearance, the addressable estimated market for ClearUP expands to over 200 million U.S. adults. Please balance your disclosure with a discussion of the competition you face in this market, including your overall position in the market relative to your competitors.

Our Innovation, page 3

6. Please revise statements that your pilot study showed that your "approach is promising as an alternative to opioids for managing pain," to eliminate conclusions or predictions that your product candidates are effective as determinations of efficacy are solely within the authority of the FDA. You may provide a summary of the data that you used to draw these conclusions, and such discussion is more appropriate in the Business section where full and proper context can be provided.

Tivic Health Pipeline, page 3

7. Please identify the product candidates for the treatment of Post-Operative Pain Relief and Migraine, TMJ. Alternatively, please explain to us why such product candidates are sufficiently material to be included in your pipeline chart.
8. Please revise your pipeline chart to include separate columns for Phase 1, Phase 2 and Phase 3 clinical trials or tell us why it is appropriate to include "clinical proof of concept" and "pivotal" as stages for all products.
9. We note your disclosure that on page 4 that ClearUP Gen 2 version is in development. However, the status in your pipeline chart appears to indicate that it has received regulatory clearance. Please revise or explain.

Growth Strategy , page 4

10. We note your disclosure on pages 2 and 4 that your ClearUp Gen 2 is covered under the same regulatory clearances as ClearUP. However we note on page 16 you disclose that it is your belief that ClearUP Gen 2 devices will be covered by the same clearance as your existing ClearUP device. Please revise to clarify whether you have received regulatory clearance for your ClearUp Gen 2 device. To the extent you have not yet received clearance, please revise the summary to clarify that these statements are management's belief and revise to provide the basis for your belief that ClearUp Gen 2 will be covered by the same regulatory clearance for ClearUP.

Our business, financial condition, results of operations and growth may be impacted by the effects of the COVID-19 pandemic, page 17

11. We note your disclosure that although you have experienced growth in your sales volume during the COVID-19 pandemic, this and any other favorable impacts you have experienced in connection with the pandemic may subside, and the ultimate effect of COVID-19 on your sales volume and other results of operations could differ substantially from your expectations and your experience to date. Please revise to quantify the effect of the COVID-19 pandemic on your sales volume. Additionally, please specify the "other favorable impacts" you have experienced in connection with the pandemic as well as the "other results of operations" that have been impacted by the COVID-19 pandemic.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery, page 24

12. Please revise your risk factor to disclose that there is also a risk that your exclusive forum provision may result in increased costs for investors to bring a claim.

Use of Proceeds, page 28

13. We note your disclosure that you intend to use the net proceeds from the offering to support your organic growth, to expand your products in the bioelectronic markets, and for other general corporate purposes. Please revise to provide more meaningful and specific disclosure of the intended use of proceeds, as well as the approximate amounts intended to be used for each such purpose. Refer to Item 504 of Regulation S-K.

Market Opportunity , page 45

14. We note your disclosure that according to your research, among recurring sufferers, 90% are interested in treatments that reduce use of medications, 66% are concerned about the side effects of pharmaceutical choices, and over 40% are concerned about addiction. Please expand your disclosure to explain how you conducted your research, including the total number of recurring sufferers.

15. Please expand your disclosure to provide additional context regarding how the market and clinical research studies were conducted, including but not limited to, whether the studies were conducted by you or a third party and the number of subjects surveyed or observed.

Competitive Landscape, page 46

16. We note your disclosure regarding the types of pharmaceutical treatments that compete with ClearUp. Please expand your disclosure to identify your likely principal competitors and their products and/or product candidates that you believe may compete with your own products or product candidates.

Key Technical Features, page 47

17. We note your disclosure that studies showed an efficacy level for ClearUP comparable to that of intranasal glucocorticoids, without any significant side effects and that results observed in your pivotal study and open-label prospective trial were equivalent to efficacy seen in studies of fluticasone propionate after one-week of use. Please refrain from making such comparisons unless you have conducted head-to-head trials.

Research Initiatives: New Product Candidates, page 48

18. Please revise statements that data from your pilot study "has been promising for reduction of pain following functional endoscopic sinus surgeries ("FESS")," to eliminate conclusions or predictions that your product candidates are effective as determinations of efficacy are solely within the authority of the FDA. You may provide a summary of the data that you used to draw these conclusions.
19. Please revise to discuss the status of development of each of the research initiatives/new product candidates identified, including a discussion of your product candidates for post-operative pain relief and migraines.

Future Product Candidates/Pipeline, page 49

20. We note that the list of future product candidates include certain indications that appear to be repetitive of those associated with your ClearUP product as well as those listed in your current research initiatives. Please revise or advise.

Intellectual Property / Barriers to Entry, page 51

21. We note your chart of issued patents on page 51. Please revise your intellectual property disclosure to clearly identify each material patent or group of related patents, the type of patent protection granted for each technology, the product or product candidate(s) dependent on each patent, related expiration and jurisdiction, including any foreign jurisdiction, of each pending or issued patent.

Jennifer Ernst
Tivic Health Systems, Inc.
June 14, 2021
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General

22. 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.

You may contact Franklin Wyman at 202-551-3660 or Al Pavot at 202-551-3738 if you have questions regarding comments on the financial statements and related matters. Please contact Deanna Virginio at 202-551-4530 or Celeste Murphy at 202-551-3257 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Christopher L. Tinen, Esq.