United States securities and exchange commission logo

July 23, 2021

Reza Zadno, Ph.D.
Chief Executive Officer
PROCEPT BioRobotics Corporation
900 Island Drive
Redwood City, CA 94065

Re: PROCEPT BioRobotics Corporation
Draft Registration Statement on Form S-1
Submitted June 25, 2021
CIK No. 0001588978

Dear Dr. Zadno:

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 June 25, 2021

Market and Industry Data, page ii

1. We note your statement cautioning investors not to give undue reliance to estimates or market data included in the prospectus. Such statement may imply an inappropriate disclaimer of responsibility with respect to the third party information; therefore, please either remove the potential disclaiming language or clearly state in this section whether such information is reliable and that you are liable for such information.

Our Company, page 1

2. Please clarify the meaning of scientific or technical terms the first time they are used here and in the Business section or in close proximity thereto in order to ensure that lay readers will understand the disclosure. For example, please briefly explain what you mean by cystoscopic, endoscopic, CPU, resective surgery, hemostatis and peri-operative transfusion.

3. We note your disclosure on pages 38 and 125 that your currently

marketed AquaBeam
Robotic System is a Class II medical device, which was initially granted marketing
authorization pursuant to a de novo classification. Please revise to include disclosure of
the Class II classification in the Summary as well.
4. We note your disclosure on pages 1, 4 and throughout the Business section that your
Aquablation therapy delivers outcomes that are effective, safe and durable across all
prostate sizes and shapes. Please note that determinations of safety and efficacy are solely
within the authority of the FDA and comparable foreign regulators; therefore, please
revise the prospectus to remove all references and/or implications of safety and efficacy
for the use of your devices in treating indications for which you have not received an
approved PMA from the FDA.
5. Please revise to explain when you commenced work designing the AquaBeam Robotic
System, when you conducted the studies referenced in the prospectus and when your
product received 510(k) clearance. Please also include a detailed description of the patient
population for which your AquaBeam Robotic System for which you have received FDA
510(k) clearance.

Our Solution, page 3

6. Please balance your disclosure with equally prominent disclosure of the disadvantages of
your AquaBeam Robotic System, such as observed hemostatis, peri-operative transfusions
and any other adverse side effects observed in your clinical trials, as applicable.

Our Success Factors, page 4

7. We refer to your disclosure on page 4 and elsewhere in the prospectus to nine clinical
studies and over 100 peer-reviewed publications demonstrating the efficacy, safety and
durability of your Aquablation therapy. Please revise your disclosure in this section and
in greater detail elsewhere to disclose, if true, whether you funded or sponsored the
clinical studies and if your employees were involved in both the studies and publications.

Summary Risk Factors, page 6

8. Please disclose as a principal risk factor the risk of substantial dilution as discussed on
page 65. Also when discussing the risk of dilution in the risk factors section, please
discuss the affect that the redeemable convertible preferred stock may have upon
dilution.

We depend on third-party suppliers..., page 22

9. We note your risk factor disclosure on page 22 that for certain critical components and
raw materials for your products, you rely on single source suppliers and for which there
are relatively few alternative sources of supply. Please expand your disclosure in the
Business section to discuss your sources, the availability of raw materials and the names
of any principal suppliers. See Item 101(h)(4)(v) of Regulation S-K.

Delaware law and provisions in our amended and restated certificate of incorporation..., page 66

10. We note your disclosure that the forum selection provision in your amended certificate of incorporate may have the effect of discouraging lawsuits against you and your directors and officers. Please revise this risk factor and your disclosure in the Business section to disclose that there is also a risk that your forum selection provision may result in increased costs for investors to bring a claim.

Components of Our Results of Operations, page 83

11. We note your disclosure on page 83 that sales of your products outside the United States represented that approximately 66% and 47% of revenue for the years ended December 31, 2019 and 2020. You also disclose on page 102 that you are growing your existing presence in the large European markets, including Germany, France, Italy, Spain and the United Kingdom. Please expand your disclosure here to identify the key foreign markets that represented the sales of your products outside of the United States.

Critical Accounting Policies and Estimates
Common Stock Valuations, page 94

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 IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances, including stock compensation. Please discuss with the staff how to submit your response.

Business, page 97

13. We refer to your disclosure on page 98 under the first bullet point under the heading Significant and durable symptom relief and the surgical retreatment rates observed in your clinical studies. Please balance your disclosure to describe the surgical retreatment rates observed for patients who underwent TURP and other treatments, as applicable. We refer to your disclosure on page 116.

Market Overview, page 102

14. We note your disclosure on page 105 relating to dissatisfaction among patients with the effectiveness of their BPH medications. We also refer to your disclosure in the first bullet point on page 106 of your belief that the high rates of irreversible complications are largely due to use of heat-based technology to resect prostate tissue. Please revise to clarify the studies and the data that support your conclusions.

Our Clinical Results and Studies, page 111

15. Please revise to clarify whether each of your core clinical trials were powered for statistical significance and expand your discussion of the statistical significance and p-values with respect to improvements in IPSS and QoL scores, surgical retreatment rates and operative times, as applicable.

16. Please expand on the significance of peri-operative transfusion rates and hemostatis observed in your core clinical studies, including how the transfusion

rates and hemostatis
observed compare to TURP and other alternative surgical treatments.
17. We note your disclosure that you plan to follow patients in the WATER and WATER II
clinical studies for a total of five years, with three-year data already having been collected
and analyzed. Please clarify your follow-up plans for patients in your OPEN WATER
clinical study beyond the 12-month follow-up.
Intellectual Property, page 123

18. We note your disclosure on page 123 relating to your patent portfolio in the U.S. and in
foreign jurisdictions. Please expand your disclosure to identify for each material patent
and patent application, as applicable, the scope and technology of each such patent or
patent application, the type of patent protection and expiration dates. Consider adding
tabular disclosure in addition to the narrative for ease of use.

19. You disclose on page 62 that you are dependent on intellectual property licensed from
third parties, including AquaBeam LLC. To the extent material, please expand your
disclosure in this section to disclose any additional third parties from whom you license
intellectual property, the scope of and technology related to such patent rights and the
material terms of such license agreements. Please also revise your disclosure here and in
the risk factor disclosure section to identify AquaBeam LLC as an entity affiliated with
your company.
License Agreement with AquaBeam, page 124

20. Please revise to disclose when the last-to-expire licensed patent and PROCEPT Patent is
set to expire under the AquaBeam license agreement. Please also disclose the upfront fee
and the aggregate amount of milestone payments to be paid or received, if any, as well as
the aggregate amounts paid or received under the license agreement.
Principal Stockholders, page 152

21. In your revised prospectus, please include in the footnotes to your table to identify the
natural persons who are the beneficial owners of the shares held by Viking Global
Opportunities Illiquid Investments Sub-Master LP and for the Entitles Associated with
Fidelity, as well as the address of each such natural person, as applicable.
Note 2. Summary of Significant Accounting Policies
Revenue Recognition, page F-12

22. We note that you record revenue for both the sale and rental of equipment and that on
page F-18 you have $1.2 million of capitalized rental equipment. Please revise the filing
to clearly describe the accounting treatment for your rental revenue, including general or
material terms of the lease agreements including any minimum purchase commitments.
Tell us how your accounting treatment complies with ASC 842. Tell us and disclose, if
material, the amount of rental revenue that is outside the scope of ASC 606. Refer to ASC
606-10-50-4(a).
General

23. Please provide us with supplemental 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,
have presented or expect to present to potential investors in reliance
on Section 5(d) of the
Securities Act, whether or not you retained, or intend to retain,
copies of those
communications.
Reza Zadno, Ph.D.
FirstName
PROCEPT LastNameReza Zadno, Ph.D.
BioRobotics Corporation
Comapany
July NamePROCEPT BioRobotics Corporation
23, 2021
July 23,
Page 6 2021 Page 6
FirstName LastName
You may contact Christine Torney at 202-551-3652 or Kevin Kuhar at
202-551-3662 if
you have questions regarding comments on the financial statements and related
matters. Please
contact Jane Park at 202-551-7439 or Thomas Kluck at 202-551-3233 with any
other questions.

Sincerely,

Division of
Corporation Finance

Office of Life
Sciences

cc: Drew Capurro, Esq.