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

DIVISION OF
CORPORATION FINANCE

June 21, 2021

Eyal Shamir
Chief Executive Officer
IceCure Medical Ltd.
7 Ha'Eshel St., PO Box 3163
Caesarea, 3079504 Israel

Re: IceCure Medical Ltd.
Amendment No. 1 to
Draft Registration Statement on Form F-1
Submitted May 24, 2021
CIK 0001584371

Dear Mr. Shamir:

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.

Amendment No.1 to Draft Registration Statement submitted May 24, 2021

Cover page

1. We note your disclosure that you have applied to list your ordinary shares on the Nasdaq Capital Market and that no assurance can be given that your application will be approved. Please clarify whether the offering is contingent upon receiving Nasdaq listing approval and if it is not, please revise your disclosure to clarify this fact. If applicable, please disclose whether you plan to rely on any exemptions from corporate governance listing requirements as a "controlled company."

2. Please tell us which Nasdaq listing standard you are relying on in connection with your application to list your ordinary shares.

Our Company, page 2

3. We note your disclosure on page 64 that your lead indication is breast tumors and on page 24 that you expect to commence the process of requesting approval under Section 510(k) for the use of your ProSense system for the treatment of breast cancer. We also note your disclosure on page 76 relating to the FDA's classification of medical devices into one of three classes (Class I, Class II and Class III) depending on their level of risk. Please expand your disclosure in the Summary to briefly discuss the FDA's regulation of medical devices and the implications if you do not receive approval under the Section 510(k) regulatory pathway.

   Please also revise to briefly explain whether there are any differences in your cryoablation systems for the treatment of malignant as compared to non-malignant tumors. Additionally, please revise to substantiate your disclosure that cryoablation produces less pain than thermoablation.

4. We note your disclosure that you expect your next generation systems to be more efficient and user friendly. Your Summary should present a balanced discussion of your business. Please revise to provide a discussion of the challenges you face in gaining market acceptance of your products and growing your market share against competitors, as referenced on pages 12 and 13. Please also place your disclosure in appropriate context with reference to your limited sales to date, history of losses and accumulated deficit of approximately $48.5 million.

5. We note your disclosure indicating that following preliminary results of your ICE3 trial, the American Society of Breast Surgeons (ASBrS) updated its guidelines on performing cryoablation procedures on breast malignant tumors in their early stages. Please revise to clarify whether the ASBrS guidelines reference the results of your study.

Risks Related to Our Business and Industry
We are dependent upon third-party manufacturers and suppliers..., page 17

6. You disclose on page 18 that you rely on certain single-source suppliers, as well as a limited number of third parties who manufacture and assemble certain components. Please expand your disclosure under an appropriate heading in the Business section to identify the suppliers and manufacturers on which you rely and the material terms of your agreements with such parties. Refer to Item 101(h)(4)(v) of Regulation S-K.

We may not receive, or may be delayed in receiving, the necessary clearances or approvals..., page 24

7. Please expand your disclosure to discuss the risk that the FDA may request clinical data in addition that provided from clinical sites located outside of the United States.

Business

Clinical Trial in Fibroadenoma (Benign) Breast Tumors, page 64

8. We note your disclosure on page 64 that a publication concluded that a cryoablation treatment using a LN2 system "proved efficacious and safe…" We also refer to your disclosure on page 74 that you believe that your products and services can deliver "safe and effective treatments" in-office or ambulatory hospital settings. 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 FDA approval, including those cited above.

9. Please clarify whether you sponsored the clinical trial in benign breast tumors in Czech Republic, Germany and Israel between 2009 and 2012, and whether any clinical sites were based in Israel. Please also disclose which cryoablation device was used in the trial, the primary endpoint, the criteria used for the enrollment of participants, the p-value, serious adverse events and the number of patients who experienced them.

Clinical Trials in Cancerous (Malignant) Breast Tumors, page 65

10. We note your disclosure of the multi-site clinical trial of the cryoablation system ICE3 in the United States. Please revise your disclosure to include the criteria used for the enrollment of participants.

11. We refer to your disclosure on page 66 of the independent clinical trials of the cryoablation systems in Japan, Hong Kong and China. Please revise your disclosure to specify which of your cryoablation devices were used in the trials, the primary endpoints and the criteria used for the enrollment of participants.

Lung Cancer Clinical Trial, page 66

12. Please expand your disclosure to specify the cryoablation devices used in the lung cancer clinical trial and disclose serious adverse events and the number of patients who experienced them. Please also provide disclosure of serious adverse events observed in the kidney tumors trial ongoing in Israel.

Regulatory Approvals, page 69

13. We refer to your disclosure on page 69 of the FDA 510(k) approval you received for IceSense3, ProSense and MultiSense for the treatment of breast fibroadenomas, prostate and kidney tissue, among other indications. Please revise to explain when you commenced work designing these products and when the various products received 510(k) clearance.

Research and Development, page 69

14. You disclose on page 69 that you expect to complete development of your third generation single probe system by the second quarter of 2022. Please expand your disclosure to discuss the differences between your first, second and third generation single probe systems.

Commercialization, page 70

15. We refer to your disclosure on page 70 of your exclusive distribution agreements with Terumo Corporation in Japan and Thailand. Please disclose the term of each agreement, the termination provisions and the amounts of any up-front payments you have received to date, as applicable.

Intellectual Property, page 72

16. Please revise your disclosure to describe the type of patent protection for each of the issued patents and the patent application. With respect to your U.S. patent application, please also disclose the expected expiration date.

17. We refer to Patent no. 8083733 listed on page 73 relating to cryosurgical instrument with enhanced heat exchange, which expired in 2019 and numerous other patents scheduled to expire in 2023. Please discuss the impact on your business of such expiry and pending expiry.

Competition, page 74

18. We note your disclosure on page 75 of the benefits of LN2 technology over argon-based technology. You also reference on page 75 certain direct competitors for cryoablation treatments. Please disclose whether any of the direct competitors referenced also utilize LN2 technology for their cryoablation treatments.

Management

Employment Agreements with Executive Officers, page 90

19. Please revise to disclose the material terms of your employment agreements with each of your executive officers and file such agreements as exhibits to your registration statement. Refer to Item 601(b)(10) of Regulation S-K.

Principal Shareholders, page 108

20. Please revise the footnotes to list the address of each natural person who is a beneficial owner of the shares held by Epoch Partner Investments Limited, Clover Wolf Capital Limited Partnership, Clover Alpha L.P. and Alpha Capital Anstalt. Please also indicate the amount known to be shares with respect to which such listed beneficial owner has the right to acquire beneficial ownership. Refer to Item 403 of Regulation S-K.

Consolidated Financial Statements
Notes to the Consolidated Financial Statements
Note 10 - Revenues , page F-23

21. We note your agreement with Terumo Corporation includes exclusive distribution rights. Please tell us the basis of your consideration that such exclusive rights is not a performance obligation.

22. Please describe how you allocate the transaction price to the identified performance obligations pursuant to ASC 606-10-32-31 through 32-33 and how you measure progress toward the completion of obtaining the regulatory approval over time. Refer to ASC 606-10-25-33.

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.

You may contact Christie Wong at 202-551-3684 or Terence O'Brien at 202-551-3355 if you have questions regarding comments on the financial statements and related matters. Please contact Jane Park at 202-551-7439 or Christine Westbrook at 202-551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: David Huberman, Esq.