IceCure Medical Ltd.
7 Ha'Eshel St., PO Box 3163
Caesarea, 3079504 Israel

July 6, 2021

Via EDGAR
Jane Park
Christine Westbrook
Securities and Exchange Commission
Division of Corporation Finance
Office of Energy & Transportation
100 F Street, NE
Washington, DC 20549

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

Dear Madames:

The purpose of this letter is to respond to your letter of June 21, 2021, regarding the above-mentioned registration statement. For your convenience, your original comments appear in bold text, followed by our response. On July 6, 2021, we confidentially submitted an amended draft registration statement on Form F-1 (the "**Registration Statement**"). Page references in our responses are to the Registration Statement.

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."**

   Response: We have revised the disclosure throughout the Registration Statement to clarify that the offering is contingent upon receiving Nasdaq listing approval. We do not intend to take advantage of any of the exemptions from Nasdaq's corporate governance listing requirements available to 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.**

   Response: We respectfully advise the Staff that we comply with the financial and liquidity requirements of the Nasdaq Capital Markets under the Equity Standard of Nasdaq Listing Rule 5550(b)(1), and maintain Stockholders' equity of more than $5 million, market value of unrestricted publicly held shares of more than $15 million, and have 15 years of operating history.

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.

   Response: We have expanded our disclosure in the Summary to briefly discuss the FDA's regulation of medical devices and the implications if we do not receive approval under Section 510(k). We have also revised our disclosure in the Summary to clarify that while the same system configuration can be used and was designed to treat both malignant and non-malignant tumors, there is usually a different configuration for the probe handle between the systems used to treat breast tumors (with a primarily straight handle) and used to treat other indications (with a 90-degrees handle). Additionally, we revised our discussion in the Summary to substantiate our disclosure that cryoablation produces less pain than heat ablation.

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.**

   Response: We have revised the Summary to provide a discussion of the challenges we face in gaining market acceptance of our products and our market share against competitors and to include a discussion on our limited sales to date, history of losses and accumulated deficit.

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.**

   Response: We have revised our disclosure in the Summary to clarify that while the ASBrS guidelines do not reference the results of the ICE3 study, we believe that the results of our study were a factor in the ASBrS decision to update its guidelines.

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.**

Response: We have revised our disclosure on page 18 to remove reference to sole or single source suppliers. In addition, we have revised our disclosure on page 74 under the new heading "Production and Manufacturing," to identify the primary suppliers for our systems and to note that our agreements with suppliers are based on industry-standard terms.

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.**

Response: We have expanded our disclosure on page 24 to note 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.**

Response: We have revised the prospectus to remove all references and/or implications of safety and efficacy for the use of our systems in treating indications for which we have not received FDA approval.

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.**

Response: We have revised our disclosure on page 64 to clarify that we have sponsored the clinical trial in benign breast tumors in Czech Republic, Germany and Israel, that one clinical site was based in Israel, and to disclose which cryoablation device was used in the trial, the primary endpoint, the criteria used for the enrollment of participants, the expected probability of success, and to disclose if any serious adverse events occurred. We respectfully advise the Staff that no p-value was extracted from the findings of the clinical trial.

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.**

Response: We have revised our disclosure on page 65 to include the criteria used for the enrollment of participants in the multi-site clinical trial of the cryoablation system ICE3 in the United States.

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.**

Response: We have revised our disclosure on page 66 to specify which cryoablation devices were used, the primary endpoints and the criteria used for the enrollment of participants in each of the independent clinical trials in Japan, Hong Kong and China.

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.**

Response: We have expanded our disclosure on page 66 to specify the cryoablation devices used in our lung cancer clinical trial, to clarify that no serious adverse events reported. In addition, we have revised our disclosure on page 66 to disclose that one serious adverse event was reported in our 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.

Response: We have expanded our disclosure on page 69 to explain when we designed our systems and when we received 510(k) for each of our IceSense3, ProSense and MultiSense systems.

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.

Response: We have expanded our disclosure on page 69 to discuss the differences between our 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.

Response: We have expanded our disclosures on pages 70 and 71 of our exclusive distribution agreements with Terumo Corporation in Japan and Thailand, to discuss the term of each agreement, the termination provisions and the amounts of payments we have received to date.

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.

Response: We have revised our disclosure on pages 72 and 73 to describe the type of patent protection for each of our issued patents and our patent application, and to disclose the expected expiration date with respect to our U.S. patent application.

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.

Response: We have revised our disclosure on page 73 to discuss the impact of the expiry and pending expiry of certain patents on our business.

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.

Response: We have revised our disclosure on page 75 to disclose which of our direct competitors utilize LN2 technology for 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.

Response: We have expanded our disclosure on pages 90 and 91 to disclose the material terms of our employment agreements with each of our executive officers. We respectfully advise the Staff that, pursuant to Item 601(b)(10)(iii)(C)(5) of Regulation S-K, as a foreign private issuer that has furnished the compensatory information under Item 402(a)(1) and for which the public filing of the employment agreements is not required in our home country and not otherwise publicly disclosed by us, we are not required to file such employment agreements as exhibits to our registration statement.

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.

Response: We have revised the footnotes on page 108 to list the mailing 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. and to indicate the amount known to be shares with respect to which such listed beneficial owner has the right to acquire beneficial ownership.

Consolidated Financial Statements
Notes to 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.

Response: We respectfully advise the Staff that we have reached a conclusion that the exclusive rights in the agreement with Terumo Corporation are not identified as a separate performance obligation because exclusivity does not affect the nature of our performance to provide the underlying goods or services. We have based our consideration on an analogy from the guidance under the Basis of Conclusion of ASU 2014-09.

In paragraph BC412(b) of ASU 2014-09, the FASB and IASB discussed the effect of exclusivity clauses in the context of licenses of IP. They acknowledged that many respondents to the boards' 2010 exposure draft on revenue "explained that a distinction based on exclusivity was inconsistent with the control principle because exclusivity does not affect the determination of the entity's performance." In addition, the boards noted that "exclusivity is another restriction that represents an attribute . . . rather than the nature of the underlying intellectual property or the entity's promise in granting a license." As a result, exclusivity is not accounted for separately in a license arrangement.

Although the discussion above was in the context of licenses of IP, we believe that the comments made are equally valid in the context of other goods and services. Accordingly, exclusivity would generally be seen as an attribute of the goods or services supplied, as opposed to a separate promise in itself, because exclusivity does not affect the nature of the entity's performance to provide the underlying goods or services.

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.

Response: We respectfully advise the Staff that a total amount of $4,250 was allocated to the identified performance obligations in the contract with Terumo Corporation as follows:

- submission of an application for regulatory approval (the "submission fee");
- sale of consoles and disposables; and
- assistance in obtaining the regulatory approval (the "assistance services").

In accordance with the FASB's Accounting Standard Codification 606 Revenue from contracts with customers ("ASC 606"), an entity must allocate the transaction price identified in the contract to the identified performance obligation based on their relative standalone selling price. ASC 606-10-32-32 explains that: "The standalone selling price is the price at which an entity would sell a promised good or service separately to a customer. **The best evidence of a standalone selling price is the observable price of a good or service when the entity sells that good or service separately in similar circumstances and to similar customers**. A contractually stated price or a list price for a good or service may be (but shall not be presumed to be) the standalone selling price of that good or service." (emphasis added) An allocation of the transaction price based on relative standalone selling prices can be achieved if an entity is able to determine the standalone selling price of each identified performance obligation in the contract.

We have historically engaged with customers solely in selling consoles and disposables and is therefore able to determine their standalone selling price. However, we have not historically engaged with customers to provide services such as guidance and support in the process of obtaining the necessary regulatory approvals for the purpose of selling the Company's products in the relevant jurisdiction. As such, we have yet to establish a price for this service and this service has never been sold by the Company on a standalone basis (or at all). It should further be noted that each jurisdiction is subject to different rules, regulations and bureaucracy and it would therefore be difficult to determine the overall needed resources and invested time to obtain such approvals.

Thus, since we can determine the standalone selling price only of the consoles and disposables and the submission fee, the transaction price allocated to the assistance services is based on the residual approach under the provisions of ASC 606-10-32-34c that states the following: "Residual approach—An entity may estimate the standalone selling price by reference to the total transaction price less the sum of the observable standalone selling prices of other goods or services promised in the contract. However, an entity may use a residual approach to estimate, in accordance with paragraph 606-10-32-33, the standalone selling price of a good or service only if one of the following criteria is met:

1. The entity sells the same good or service to different customers (at or near the same time) for a broad range of amounts (that is, the selling price is highly variable because a representative standalone selling price is not discernible from past transactions or other observable evidence).

2. **The entity has not yet established a price for that good or service, and the good or service has not previously been sold on a standalone basis (that is, the selling price is uncertain)**." (emphasis added)

Based on all of the above:

1. We have allocated a total amount of $250 thousand attributed to the submission of an application for regulatory approval for the products in Japan. This price is identified and accounted for as a variable consideration since it will only be received if (and when) the application will be submitted. The remaining transaction price (i.e. $4 million) will be received regardless of the submission (by selling the consoles and disposables and providing the assistance services), and thus this price ($250 thousands) represents a standalone selling price of the submission fee.

2. We have allocated an amount of $866 thousand out of the overall transaction price to the sale of Consoles and disposables based on sale prices of these products to similar customers in similar contracts over the last four years, prior to the agreement (some of which are in Japan). This price also aligns with the stated price in the agreement for subsequent orders (following the initial order) which does not form part of the total consideration as defined above. Accordingly, we have recognized revenue relating to the consoles and disposables in an amount of $866 thousand when the control over these products was transferred to Terumo corporation.

3. In accordance with the above analysis and description of facts and circumstances a total amount of $3,134 thousand was allocated to the assistance services for the information, documents and support provided to Terumo corporation following signing of the agreement until obtaining the regulatory approval. This allocation is based on the residual approach as described and determined above since we have not yet established a price for this service and has not sold it on a standalone basis.

Due to the fact that our co-operation with Terumo corporation is provided continuously, the recognition of revenue from the assistance services will be recognized on a straight-line basis over the estimated period of obtaining the regulatory approval. The payments to be received (and have been received) from Terumo are not based on achieving certain milestones but merely for providing the availability of the Company to provide assistance, guidance and materials to Terumo based on requests made by Terumo along the process.

We hold bi-weekly meetings (calls/videoconference) with Terumo corporation which usually includes the following participants: our CEO (oversees the project from the Company's side), VP Clinical, Regulatory & QA, Clinical Director, Regulatory Director, QA Director . The meetings are held for the purpose of allowing Terumo to raise regulatory issues that arise during the process and for allowing the Company to share with Terumo's staff its experience in submitting for cryoablation regulatory approvals in other territories. We also regularly update Terumo's staff regarding clinical evidence that is being collected in different territories and from different trials, for example the interim Ice3 trial results from May 2021.

Since regulatory data is being created and updated by us on an ongoing basis and clinical data is being produced by medical professionals who use our products on an ongoing basis, the data is shared regularly, and will continue to be shared until the request for regulatory approval in Japan is submitted.

These services align with the description under ASC 606-10-25-18e which describes a stand ready obligation as an example of a promised service: "…Providing a service of standing ready to provide goods or services (for example, unspecified updates to software that are provided on a when-and-if-available basis) or of making goods or services available for a customer to use as and when the customer decides…" Further, ASC 606-10-55-184 through to ASC 606-10-55-186 provide an example of a stand ready obligation and explains that: "… the entity concludes that the best measure of progress toward complete satisfaction of the performance obligation over time is a time-based measure, and it recognizes revenue on a straight-line basis…"

The assistance services are structured in such a way that Terumo corporation pays for the availability of the Company to provide guidance and other forms of assistance on an as-needed basis and Terumo corporation benefits from the Company's service of making the assistance services available evenly throughout the process of obtaining the relevant regulatory approval. Thus, we recognize the revenue allocated to the assistance services on a straight-line basis, as this recognition method best measures the progress towards complete satisfaction of our performance obligation.

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.

Response: The Company respectfully advises the Staff that the Company has not undertaken any written communications, as defined in Rule 405 under the Securities Act, to potential investors in reliance on Section 5(d) of the Securities Act. Should the Company undertake any such written communication following the submission of this letter, the Company will supplementally provide the Staff with a copy of any such written communications made to potential investors in reliance on Section 5(d) of the Securities Act. We respectfully request that the Staff destroy such materials, if any, upon completion of its review

If you have any questions or require additional information, please call our attorney Oded Har-Even at (212) 660 5002, of Sullivan & Worcester LLP.

Sincerely,

IceCure Medical Ltd.

By: /s/ Ronen Tsimerman
Chief Financial Officer

cc: Christie Wong
Terence O'Brien