

DIVISION OF CORPORATION FINANCE

June 4, 2021

Sharon Levkoviz Chief Financial Officer IR-Med, Inc. Z.H.R. Industrial Zone Rosh Pina, Israel

> Re: IR-Med, Inc. Registration Statement on Form S-1 Filed May 7, 2021 File No. 333-255894

Dear Mr. Levkoviz:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

### Registration Statement on Form S-1 filed May 7, 2021

# About This Prpspectus, page 3

1. You state on page 3, "This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents." Investors are entitled to rely on your disclosure. Revise the document to disclose the material terms of these documents and eliminate this inappropriate disclaimer, and similar disclaimers throughout your document, including that on page 7.

# Prospectus, page 4

2. On page 4 you state that of the 37,973,724 shares being offered by the selling security holders, 28,645,395 are currently issued and outstanding. You note on page 13 that you

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issued warrants exercisable for 9,328,329 shares in your 2020 private placement. You list 9,484,569 shares underlying options in the selling stockholders table, which, by our calculation, totals more than the number of shares being registered. Please clarify.

## Prospectus Summary, page 5

- 3. As your medical devices must receive FDA clearance before you are able to commercialize them, and your products are not yet marketable, revise to clarify references to your product candidates as "compelling solutions to currently unmet medical needs." Further clarify the niche nature of your product candidates in light of your disclosure on pages 60-61 that you expect each of your product candidates, if successfully developed, to have direct competition.
- 4. At the bottom of page 5, you briefly reference the "appropriate approvals" needed before you will be able to market your product candidates. Revise to briefly explain those approvals and cross-reference a more detailed explanation in the prospectus.
- 5. Revise the summary to disclose at what stage you are in the development of each of your potential products. For example, on page 55, you state that you are "currently in advanced prototype phase of development" for your PressureSafe device. As you began testing your device in 2018, clarify what you mean by "advanced prototype phase" and explain what further development you plan to undertake prior to conducting additional clinical trials. Briefly explain this information in the summary with additional detail in the business section.

# **Risk Factors**

We depend on licenses from third parties for certain technologies that we integrate into our planned products, page 25

6. Please provide a summary of the material terms of your license agreements in the Business section and file the agreements as exhibits or tell us why you do not believe it is required.

# Risks Related to the Ownership of Our Common Stock, page 32

- 7. Revise the risk factor on page 35 regarding undiscovered liabilities to further clarify how this problem arises from the acquisition transaction.
- 8. We note that your forum selection provision in Article XI of the amended charter identifies the Eighth Judicial District Court of Clark County, Nevada as the sole and exclusive forum for certain litigation, including any "derivative action." Revise to clearly and prominently describe the provision in an appropriate section of the prospectus, and also revise this section to address the associated risks. Please disclose whether this provision applies to actions arising under the Securities Act or Exchange Act. In that regard, we note that Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the

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rules and regulations thereunder, and Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. If the provision applies to Securities Act claims, please also revise your prospectus to state that there is uncertainty as to whether a court would enforce such provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. If this provision does not apply to actions arising under the Securities Act or Exchange Act, please also ensure that the exclusive forum provision in the governing documents states this clearly, or tell us how you will inform investors in future filings that the provision does not apply to any actions arising under the Securities Act or Exchange Act. Finally, please be certain your risk factor disclosure includes the risks that your exclusive forum provision may result in increased costs for investors to bring a claim and that the provision can discourage claims or limit investors' ability to bring a claim in a judicial forum that they find favorable.

## **Business**

## Overview, page 50

- 9. You cite to reports for statistical information regarding your industry. Please note that when an issuer includes an active hyperlink or an inactive URL for a website that could be converted into an active hyperlink within a document required to be filed or delivered under the federal securities laws, the issuer assumes responsibility for the information that is accessible through the hyperlinked website as if it were part of the filing. Refer to Release No. 34-42728 for further guidance regarding the use of hyperlinks in your document.
- 10. Revise this section to provide further information describing your devices under development. For example, clarify what type of disposables they require to function. We note disposables addressed in the discussion of revenue generation on page 61.

### Intellectual Property, page 60

11. Please revise your intellectual property disclosure to clearly describe on an individual or patent family basis the type of patent protection for each product candidate, the expiration year of each patent held, and the jurisdiction of each patent or application. Please clearly distinguish between owned patents and patents licensed from third parties. We note the risk factor on page 25 regarding your reliance on licensed technology.

### Facilities, page 62

12. We note your lease more than doubled, retroactive to January 2021. File the lease agreement as an exhibit pursuant to Item 601(b)(10)(ii)(D) of Regulation S-K.

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#### Employees & Consultants, page 67

13. Revise to quantify your full-time and part-time employees. Clarify whether the individuals disclosed here include the five consultants disclosed on page 60. Refer to Item 101(h)(4)(xii) of Regulation S-K.

Security Ownership of Certain Beneficial Owners and Management, page 86

14. We note that Mr. Bashan is the controlling shareholder of Med2BWell, Ltd, which beneficially owns 13.33% of the company's shares, yet the table does not list him as a director individually or reflect any shares beneficially owned by him. Similarly, we note that Mr. Levy is a director and also a selling shareholder, yet he is only listed in the footnote as a control person related to the holdings of Liat Electronics Ltd., and his beneficial ownership as a director is not reported. Revise this table to disclose the beneficial ownership of each officer and director, as required by Item 403(b) of Regulation S-K, following Instruction 2 to Item 403 in determining beneficial ownership.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Kristin Lochhead at (202) 551-3664 or Mary Mast at (202) 551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Abby Adams at (202) 551-6902 or Jeffrey Gabor at (202) 551-2544 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: David Aboudi, Esq.