



DIVISION OF
CORPORATION FINANCE

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

March 5, 2024

Eliyahu Haddad
Chief Executive Officer
Dror Ortho-Design, Inc.
Shatner Street 3
Jerusalem , Israel

Re: Dror Ortho-Design, Inc.
Registration Statement on Form S-1
Filed February 9, 2024
File No. 333-276981

Dear Eliyahu Haddad:

We have conducted a limited review of your registration statement and have the following comments.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe a comment applies 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 this letter, we may have additional comments.

Registration Statement on Form S-1

Cover Page

1. We note your common stock is currently quoted on the OTC Pink marketplace. You also disclose that the selling shareholders may sell through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. To sell shares at market prices, we require an existing trading market for those shares, and we do not consider the OTC Pink marketplace to be such a market for the purposes of satisfying Item 501(b)(3) of Regulation S-K. Accordingly, please revise to clarify that the selling stockholders will sell at a fixed price until your shares are listed or quoted on an existing public trading market, such as the OTCQB, OTCQX or OTCBB, and thereafter at prevailing market prices or privately negotiated prices. Please also disclose the fixed price.
2. Please revise your cover page to disclose the differences between your common stock and preferred stock, including any disparate voting and dividend rights.

Summary of the Prospectus, page 8

3. Please significantly revise your summary section to describe your current business operations and products. In your revised disclosure, provide balanced disclosure to highlight the stage of your development, recent net losses, lack of revenues and any additional funding needs to develop your business. Also revise the Summary and Risk Factors sections to disclose that your auditor has issued an opinion noting that the accompanying financial statements have been prepared assuming that the Company will continue as a going concern.
4. Please revise to highlight in your Summary section that your products are subject to regulatory approval which you have not obtained yet.
5. You state that a customer "can get a perfect smile discreetly and hassle-free even while they sleep with our FDA-cleared proprietary solution." Revise or provide a basis for this statement for your products.

Business, page 70

6. You state that "Based on our internal quality assurance and FDA guidance, the Company believes that the second generation Aerodentis Platform will be found to be substantially equivalent to the first generation Aerodentis System and ultimately cleared by FDA for marketing; however, we cannot make any assurances to that effect, nor can we predict the extent to which FDA will require additional information, testing, changes, or other acts prior to engaging in the substantive review that precedes a clearance determination." Stating, implying or predicting that your medical device will be "substantially equivalent" is not appropriate. Only the FDA or equivalent foreign government entity has the authority to determine that a product candidate is "substantially equivalent". Please revise or remove your statements that Aerodentis System and Aerodentis Platform, in your belief, are "substantially equivalent." Please make conforming changes throughout the registration statement.
7. Please provide cites for any articles or studies cited throughout the prospectus. For example, we note your disclosure that "[a]ccording to a 2022 study conducted by Precedent Research, the global clear aligners market size was estimated at \$6.29 billion in 2022..."
8. Please revise to provide a status update on your 510(k) application and clarify whether your new product, the "Platform," will be submitted as a Class II medical device.

The Platform, page 72

9. Please revise to explain how the prototype of the Platform incorporated recent developments in "artificial intelligence, secure wireless and Internet communications with IoT devices." Also revise to define IoT devices.

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Network of Dental Professionals, page 77

10. Here and throughout the prospectus, you refer to a "network" of dental professionals and providers. Please revise to describe your dental network and clarify whether you have written agreements with such dental professionals.

Competition, page 79

11. Please revise to identify any existing competitors in the clear aligner market that use a similar technique and/or have obtained intellectual property rights relating to or similar to those used for your product.

General

12. We note your disclosures throughout the registration statement that substantially all of your operations are conducted in Israel. Please revise to disclose whether your executive officers and directors reside outside of the United States. Please also add disclosures regarding service of process and enforcement of civil liabilities against the company given its significant foreign operations and disclose, to the extent applicable, difficulties in enforcement against any directors residing outside of the United States.

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.

Please contact Jeanne Bennett at 202-551-3606 or Terence O'Brien at 202-551-3355 if you have questions regarding comments on the financial statements and related matters. Please contact Robert Augustin at 202-551-8483 or Lauren Nguyen at 202-551-3642 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Industrial Applications and
Services