



DIVISION OF  
CORPORATION FINANCE

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

December 11, 2024

William Conkling  
Chief Executive Officer  
Rafael Holdings, Inc.  
520 Broad Street  
Newark, New Jersey 07102

**Re: Rafael Holdings, Inc.**  
**Amendment No. 1 to Registration Statement on Form S-4**  
**Filed November 22, 2024**  
**File No. 333-282558**

Dear William Conkling:

We have reviewed your amended 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. Unless we note otherwise, any references to prior comments are to comments in our November 5, 2024, letter.

Amendment No. 1 to Form S-4 filed November 22, 2024

Questions and Answers About the Transactions and the Special Meetings, page ii

1. We note your response to prior comment 3 and re-issue the comment in part. Please expand your newly created Q&A "*How will the companies operate post-merger*" on page vii to include disclosure, as mentioned elsewhere, that Rafael intends to focus its efforts on Trappsol Cyclo as its lead clinical program. Please also briefly explain the extent to which Rafael will continue to operate or invest in the Pharmaceutical Companies and their described operations, discussing the potential impact of Rafael's planned shift in focus to Trappsol Cyclo post-merger on these operations.

Risk Factors

We are dependent on certain third-party suppliers, page 26

2. We note your response to prior comment 12. Please explain your assertion that Rafael and Cyclo are not "involved in the targeted industry" that is the subject of the BIOSECURE Act. In addition, your response states that you do not sell to any of the biotechnology companies of concern; however, you have not indicated whether either company purchases from any of the biotechnology companies of concern. Please clarify.

Information About the Companies

Rafael Holdings, Inc., page 29

3. We note your disclosure both here and in the Rafael Form 10-K for the fiscal year ended July 31, 2024, incorporated by reference, that Cornerstone received negative results from its Avenger 500 Phase 3 study for Devimistat in pancreatic cancer as well as a recommendation to stop its ARMADA 2000 Phase 3 study due to a determination that the trial would unlikely achieve its primary endpoint. Please revise your disclosure to clarify where the Phase 3 study and trial were being conducted, and which regulatory authority oversaw such determinations.
4. We note your disclosure that LipoMedix has completed various clinical stages of Prometil including a Phase 1A and 1B trial. Please revise your disclosure to state where these trials were held. In addition, please provide data from the completed trials where discussed, including information regarding endpoints and SAEs, to the extent applicable.

Incorporation of Certain Information by Reference, page 138

5. We note your response to prior comment 7. Please further revise your disclosure regarding Cyclo's business, incorporated by reference from Cyclo's Form 10-K for the fiscal year ended December 31, 2023, to remove or revise the below statements implying safety or efficacy, as the company's product candidates have not yet received regulatory approval:
  - The statement on page 4 of Cyclo's Form 10-K/A filed November 26, 2024 that "...to date, [Cyclo's] clinical studies have preliminarily demonstrated that Trappsol Cyclo is safe and efficacious in the treatment of NPC over a range of dose groups."
  - The statements that Trappsol Cyclo demonstrated a "favorable safety profile" on pages 5 and 34 of Cyclo's Form 10-K/A filed November 26, 2024.You may present objective data from your trials but should not draw conclusions regarding safety and efficacy, as such determinations are within the sole purview of the FDA and equivalent foreign regulators.
6. Please revise your disclosure regarding Rafael's Pharmaceutical Companies, both here and in the Rafael Form 10-K for the fiscal year ended July 31, 2024, to remove or revise all statements implying safety and/or efficacy, as the company's product candidates have not yet received regulatory approval. Examples of such statements

include, but are not limited to, the following:

- "... Promi-Fol holds the potential to be a safe and effective therapeutic alternative to widely used instillation of mitomycin-c for local treatment of the growing elderly patient population with superficial bladder cancer".
- "Preclinical studies have shown that MMC was effective in killing of BRCA2 mutant tumors. Clinical efficacy of MMC has also been reported in heavily pretreated ovarian cancer patients with BRCA1 mutations."
- LipoMedix's product candidate holds the potential to be "an innovative, safe, and effective cancer therapy".
- "In these studies, Promitil was found to be more efficacious and less toxic than MMC by a 3-fold factor."
- Your references to the "improved safety profile of Promitil in humans".
- Your statements that "CPI-613...holds the potential to be minimally toxic to healthy cells (i.e., safe and well-tolerated)", "exhibited anti-cancer activities" and that "prolonged survival was observed".

Safety and efficacy conclusions are within the sole authority of the FDA or equivalent foreign regulators. You may present the objective data observed in your clinical trials but should not draw safety and efficacy conclusions based on such results.

7. In the Rafael Form 10-K for the fiscal year ended July 31, 2024, we note your listing of some of the observed data from the U.S. Phase I Clinical Study of Trappsol Cylco. Please clarify the material significance of the data point "[a]ll eligible patients requested continuation of Trappsol<sup>®</sup> Cyclo<sup>™</sup> administration in the extension protocol via home infusion."
8. Please amend your disclosure in the Rafael Form 10-K for the fiscal year ended July 31, 2024, to clarify where in the clinical development process Promi-Fol and Promi-Dox currently are.
9. We note your statements, both in this filing and in Rafael's Form 10-K for the fiscal year ended July 31, 2024, that Day Three "empowers third-party manufacturers to reimagine their existing cannabis offerings enabling them to bring to market better, cleaner, more precise and predictable versions by utilizing Day Three's pharmaceutical-grade technology and innovation like Unlokt". Please amend your filing to expand your disclosure regarding this technology, providing details regarding its application, functionality and use, and provide support for this statement and your references to such technology as "pharmaceutical-grade". To the extent the company has received any form of approval or certification of the technology as a basis for these claims, please describe where appropriate.
10. Please revise your disclosure both here and in the Rafael Form 10-K for the fiscal year ended July 31, 2024, to provide more detail regarding the operations and product candidates of Rafael Medical Devices, where appropriate. Your disclosure should include information regarding the "surgical and procedural devices" the company is currently developing. To the extent the company has not yet developed any devices and has no devices in its product portfolio, please revise your disclosure to make clear that the claims associated with Rafael Medical Devices are aspirational in nature and are not references to current operations.

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11. Please revise the risk factor contained in Rafael's Form 10-K for the fiscal year ended July 31, 2024, relating to Israel's war with Hamas to clarify whether the company has experienced material disruptions to date based on the war and conflicts discussed, either as a result of employees being called for service or otherwise.
12. Please revise your disclosure in the risk factor entitled "*The relationship between Howard S. Jonas and IDT Corporation, and Genie Energy could conflict with our stockholders' interests*" in Rafael's Form 10-K for the fiscal year ended July 31, 2024, to provide more detail regarding the conflict of interest with stockholders briefly noted in this risk factor.

Please contact Tracie Mariner at 202-551-3744 or Daniel Gordon at 202-551-3486 if you have questions regarding comments on the financial statements and related matters. Please contact Tamika Sheppard at 202-551-8346 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Dov Schwell