



DIVISION OF
CORPORATION FINANCE

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

December 11, 2024

David Polinsky
Chief Financial Officer
Rafael Holdings, Inc.
520 Broad Street
Newark, New Jersey 07102

Re: Rafael Holdings, Inc.
Form 10-K for Fiscal Year Ended July 31, 2024
File No. 001-38411

Dear David Polinsky:

We have reviewed your filing and have the following comments.

Please respond to this letter within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe a comment applies to your facts and circumstances, please tell us why in your response.

After reviewing your response to this letter, we may have additional comments.

Form 10-K for Fiscal Year Ended July 31, 2024

Item 1. Business

Overview, page 1

1. Please revise your disclosure regarding Rafael's Pharmaceutical Companies 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.

2. 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[®] Cyclo[™] administration in the extension protocol via home infusion."
3. Please amend your disclosure to clarify where in the clinical development process Promi-Fol and Promi-Dox are currently.
4. We note your statements, both here and elsewhere, 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.
5. Please amend your filing to provide more detail regarding the operations and product candidates of Rafael Medical Devices, both in the Overview and on page 8 where discussed. 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.
6. We note your disclosure 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 amend your disclosure to clarify where the Phase 3 study and trial were being conducted, and which regulatory authority oversaw such determinations.
7. We note your disclosure that LipoMedix has completed various clinical stages of Promitil including a Phase 1A and 1B trial. Please amend your disclosure to state where these trials were held. In addition, please provide data from the completed trials on page 6 where discussed, including information regarding endpoints and SAEs, to the extent applicable.

Item 1A. Risk Factors

Risks Related to Employee Matters, Managing Our Growth, and Other Risks Related to Our Business

Conditions in Israel, including the ongoing war between Israel and Hamas..., page 86

8. We note your disclosure stating that certain of your employees and consultants in Israel, in addition to employees of your service providers located in Israel, have been called for service in the current war with Hamas, and such persons may be absent for an extended period of time. As a result, operations of LipoMedix and Day Three may be disrupted by such absences, which may materially and adversely affect their business and results of operations. Please expand the disclosure in your MD&A to quantify and discuss any material impact that the war between Israel and Hamas has had on your financial condition and result of operations in the periods presented. If there has been no material impact, then so state.
9. Please amend this risk factor 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.

The relationship between Howard. S. Jonas and IDT Corporation..., page 87

10. Please amend your disclosure to provide more detail regarding the conflict of interest with stockholders briefly noted in this risk factor.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Liquidity and Capital Resources

Capital Resources, page 106

11. Given your historical net losses and negative cash flows from operations, please expand your disclosure of capital resources to provide the information required by Item 303(b)(1) of Regulation S-K, as applicable to you.

Financial Statements

Note 1- Description of Business, page F-8

12. We note your disclosure, on page F-10, stating that you have an effective 45% interest in CS Pharma Holdings, LLC. Please expand your disclosure, where appropriate, to discuss your accounting methodology for your interest in this entity.

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.

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.

December 11, 2024

Page 4

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Dov Schwell