Kairos Pharma, Ltd.
2355 Westwood Blvd. #139
Los Angeles CA 90064

June 27, 2023

Division of Corporation Finance
Office of Life Sciences
U.S. Securities and Exchange Commission
Washington, D.C. 20549

Attn: Ms. Christine Torney
Mr. Daniel Gordon

Re: Kairos Pharma, Ltd.
Draft Registration Statement on Form S-1
Submitted March 29, 2023
CIK No. 0001962011

Ladies and Gentlemen:

We are hereby transmitting the response of Kairos Pharma, Ltd., a Delaware corporation (the "*Company*," "*we*," or "*our*"), to the comment letter we received from the staff (the "*Staff*") of the U.S. Securities and Exchange Commission (the "*Commission*") on April 25, 2023, regarding the Draft Registration Statement on Form S-1 (the "*Draft Registration Statement*"), as submitted confidentially to the Commission on March 29, 2023 (the "*March 29, 2023 Filing*"). An Amendment to the Draft Registration Statement (the "*Amended Draft Registration Statement*") is being submitted to the Commission concurrently with this letter.

For your convenience, we have repeated below the comments of the Staff in bold and have followed the Staff's comments with the Company's response.

Draft Registration Statement on Form S-1

Cover Page

1. We note your disclosure on page 4 that "[w]hile we have applied to have our common stock approved for listing on The Nasdaq Global Market, we may not successfully achieve listing of our common stock on that or any other exchange..." Disclose whether your offering is contingent upon final approval of your NASDAQ listing on your cover page and revise your disclosure on page 4 as appropriate. Please ensure your revised disclosure is consistent with your underwriting agreement.

Response: On the cover page we added the disclosure that our offering is contingent upon our receipt of final approval of our Nasdaq listing application, and have also updated the disclosure at page 5. In addition, we have updated the disclosure in the Amended Draft Registration Statement to reflect that the Company has applied to be listed on the Nasdaq Capital Market instead of the Nasdaq Global Market.

Our Science, page 1

2. As your product candidates have not been approved by the FDA or any other comparable foreign regulator as safe and effective, please revise the statement here and on page 82 that ENV-105 has "demonstrated safety measures" to remove safety implications. Relatedly, please revise the following statements here and on pages 75 and 82 to remove efficacy implications:

- **"We are developing small molecules that target these central checkpoints to induce the immune system into attacking cancer cells";**
- **"[W]e are developing an activated T cell therapy that transforms a patient's T cells into killer activated T cells against cancerous stem cells";**

- **"The mechanism of action for ENV105 outsmarts a difficult-to-target resistance mechanism of tumor dormancy";**
- **"ENV105 can extend and even restore sensitivity to standard-of-care chemotherapy, radiation therapy, androgen targeted therapy, EGFR inhibitors, or checkpoint inhibition when given in combination"; and**
- **"[T]he co-administration of ENV105 serves in asynthetic lethal mechanism of tumor selective tumor killing...."**

Response: We have revised our disclosure at pages 1, 3, 75 and 82 of the Amended Draft Registration Statement to remove efficacy implications. We deleted the sentence indicating that ENV105 "demonstrated safety measures." In addition, we also removed the above-mentioned efficacy implications globally throughout the Amended Draft Registration Statement.

Prospectus Summary
Overview, page 1

3. Please balance your disclosure that your proprietary technologies are licensed "in part from Cedars-Sinai Medical Center" with disclosure, if true, that all of your patent rights are in-licensed from third parties under license agreements that require you to meet certain milestones for continuation of those agreements. We note disclosure to this effect on pages 89 and 90. Please also balance your disclosure that you "have leveraged molecular insights to develop a new class of novel drugs that reverse drug resistance and checkpoints of immune suppression" with disclosure that your product candidates have not been approved as safe or effective by the FDA or any other comparable foreign regulator.

Response: We have revised our disclosure to add that all of our patent rights are in-licensed from third parties under license agreements that require us to meet certain milestones for continuation of those agreements. In addition, we revised our disclosure regarding the new class of novel drugs and further revised our disclosure to add that our product candidates have not been approved as safe or effective by the FDA or any other comparable foreign regulator. We discuss that we will be obligated to make certain milestone payments at various places in the registration statement, but specifically detail those payment obligations at pages 89 and 92.

Our In-Development Products and Pipeline, page 2

4. Please revise the statement that "[i]n the earlier Phase 2 trial involving a heavily pretreated population, the 43% progression free survival rate was extraordinary" to include a broader discussion of the primary endpoint(s) and result(s) of that trial, including the type of pre-treatment and why you believe the 43% rate was extraordinary.

Response: We have revised the disclosure to include additional background as follows: Enzalutamide (Xtandi®, Pfizer) and abiraterone (ZYTIGA®, Jassen) are two forms of hormone therapy that blocks the androgen receptor and its target ligand, testosterone, respectively. These two agents are considered standard of care for nearly all recurrent prostate cancer patients. The primary endpoint of the trial was radiographic progression. While some patients showed PSA (prostate specific antigen) response, this is not considered a reliable marker for late-stage prostate cancer subjects due to the development of therapy-induced neuroendocrine differentiation that does not express PSA.

The trial accrued patients that were resistant to the very androgen targeted therapy (enzalutamide or abiraterone) that was given in the trial in addition to ENV105. Importantly, ENV105 administration alone has no clinical benefit, based on pre-clinical (performed by us) and previous clinical findings (performed by the National Cancer Institute). Thus, the basis for considering the finding "extraordinary" was that two agents that apparently have no clinical effect, when combined result in halting tumor progression. However, the finding is well justified by numerous publications (and unpublished work) demonstrating hormone therapy resistance develops through the induction of CD105, the target of ENV105.

Further support for the use of the word "extraordinary" was that all the patients in the trial were not only resistant to the two hormone therapy agents, but at least one other intervention. For some they had failed to respond to five other drugs. Their tumors were refractive to different forms of hormone therapy and chemotherapy following recurrence from surgical or radiation intervention – meaning the patients had exceedingly few other options for survival. Of note, one patient was responsive to the combination therapy of ENV105 and enzalutamide for over one year.

We have also revised our disclosure regarding the 43% rate on pages 2 and 83 of the Amended Draft Registration Statement.

5. Please balance your disclosure here and on page 83 that you "believe ENV 205 to be a first-of-its-kind biologic that restores sensitivity of prostate cancers that have become otherwise resistant to chemotherapy" with disclosure that ENV 205 has not been approved by the FDA or any other comparable foreign regulator. Similarly, revise the statement here and on page 83 that your companion biomarkers are "paving the way to lower the bar to Phase 3 success" to remove safety and efficacy implications.

Response: We have revised our disclosure to indicate that ENV 205 has not been approved by the FDA or any other comparable foreign regulator. In addition, we also removed safety and efficacy implications at page 2 and page 83 of the Amended Draft Registration Statement.

6. We note your disclosure that Enviro Therapeutics will strive to co-develop companion biomarkers with all drugs in its portfolio. Please clarify whether there are currently any approved companion diagnostic tests available to be used in connection with your product candidates and, if there are not, please revise to clarify that separate approval would be required, or advise. Please also include appropriate risk factor disclosure regarding development and approval of companion diagnostic tests.

Response: We revised our disclosure to clarify that there are no currently approved companion biomarkers for the Enviro Therapeutics assets and separate approval would be required for companion biomarkers. This disclosure is set forth on page 2, 83 and 86. We also added the following risk factor "*If we are unable to successfully develop any required companion diagnostic tests for our product candidates, experience significant delays in doing so, or rely on third parties in the development of such companion diagnostic tests, we may not realize the full commercial potential of our product candidates*" on page 27 of the Amended Draft Registration Statement.

Pipeline Table, page 3

7. There are six separate columns in the pipeline table related to pre-clinical development. Please combine them into one or two columns. Additionally, revise the pipeline table to:

- **add a column showing the indication for each drug candidate;**
- **add separate columns for each clinical trial stage;**
- **more clearly depict the current pre-clinical or clinical stage for each product candidate; and**
- **update your "next milestone" column to remove previously completed tasks.**

Response: Each of the above recommendations have been implemented in the new Pipeline Table, page 4.

8. Your pipeline table states Janssen and AstraZeneca are "clinical trial partner[s]." Please disclose the nature of your partnership with these two companies in the prospectus summary and in the business section.

Response: There are no formal agreements with the pharmaceutical companies that provide the standard of care interventions for apalutamide (Janssen) and osimertinib (AstraZenica) for their respective diseases. However, they are supportive of the current trials that are being conducted with their drugs. As there is no financial support or guarantees for licensing, we have taken out "clinical partner" on page 2 of the Amended Draft Registration Statement.

Corporate Information, page 4

9. We note your disclosure that your "corporate address" is in Los Angeles, CA. Please revise to clarify whether you conduct corporate operations at this address or whether this is the address of your registered agent. If you are unable to use this location to conduct operations, please revise your disclosures on pages 3, 83, and 107 concerning "working virtually, when possible" and "partially operating virtually" to clarify, if true, that your operations are all conducted virtually or clarify where your operations are conducted. In this regard, we note your disclosure on page 107 that you do not currently lease any properties.

Response: We have revised our disclosure on page 5, 83 and 112 to clarify that our "corporate address" in Los Angeles, CA is the address of our registered agent and as of the date of this prospectus all of our operations are conducted virtually.

The Offering, page 6

10. When you provide the "[other]" disclosure in the second bullet on this page, please ensure that it includes all sources of potential dilution to investors such as those indicated in the bullet points at the bottom of page 72.

Response: We removed the reference to "[other]" and will further update the disclosure in the registration statement in the event additional disclosure is required related to potential dilution.

Risk Factors

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company. . ., page 61

11. Your statement that you are incorporated in Delaware conflicts with disclosure on the cover page and page 4 that you are incorporated in California. In this regard, we note other references to Delaware incorporation and/or Delaware law throughout the filing. Please revise or advise.

Response: We converted our Company from a California corporation to a Delaware corporation in advance of filing this amendment to the draft registration statement. On May 10, 2023, we filed a certificate of conversion with the Secretary of State of the State of California, and on the same date, we also filed a certificate of conversion from a non-Delaware corporation to a Delaware corporation pursuant to Section 265 of the Delaware General Corporation Law, which was filed with the Secretary of State of the State of Delaware. In addition, on May 10, 2023, we also filed a certificate of incorporation with the Secretary of State of the State of Delaware. Accordingly, on May 10, 2023, we completed our conversion from a California corporation into a Delaware corporation. We have included the California and Delaware certificates of conversion and related Delaware certificate of incorporation as exhibits to this Amended Draft Registration Statement.

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware. . ., page 61

12. Please revise this risk factor to disclose that there is also a risk that your exclusive forum provision may result in increased costs for investors to bring a claim.

Response: We revised this risk factor and disclosed that our exclusive forum provision may result in increased costs for investors to bring a claim against us.

Use of Proceeds, page 70

13. Please update the first bullet in this section, when possible, to state how far in the development process you estimate the proceeds from this offering will enable you to reach for each of your candidates.

Response: As we have not yet determined the total amount of the offering, we are not yet able to fully update the use or proceeds section. We anticipate we will be able to complete this section at the time we publicly file this registration statement.

Business, page 82

14. We note the following statements on page 86:

- **"ENV 105 is an antibody therapeutic with demonstrated efficacy in prostate cancer patients resistant to androgen-targeted therapy"; and**
- **"ENV205, an antibody fragment targeting mitochondrial DNA with demonstrated efficacy for chemotherapy resistant prostate cancer, is in the preclinical stage of development."**

Please revise these statements to remove the implication of efficacy as such statements are too early given the status of the regulatory approval for these candidates.

Response: We have adjusted the disclosure to remove the implication of efficacy.

Enviro and Enviro-Licensed or -Acquired Products, page 86

15. Please revise the statement that ENV 105's IND has been "cleared by the FDA" to remove any implication that the FDA has approved ENV 105. We note your disclosure on page 95 that, barring safety concerns, an IND automatically becomes effective 30 days after receipt by the FDA.

Response: We have adjusted the language so that it removes any implication that the FDA has approved ENV 105.

16. Your statement that ENV 105 was "reasonably well-tolerated" implies that there were prior preclinical and/or clinical trials of ENV 105. If true, please present data from these trials and their results that would be material to investors, including, but not limited to, primary endpoints, who conducted the trials and when, the regulatory jurisdictions of the trials and why they were not continued. If you are referring to the Phase 2 trial mentioned on pages 2 and 83, please also make that clear. Moreover, please explain what it means that "no grade 3-4 toxicities were observed." If you are referring to serious adverse events, please so specify and ensure that all material adverse events observed in prior clinical trials of ENV 105 are disclosed.

Response: The statements related to ENV 105 being "reasonably well-tolerated" were in reference to the completed Phase 2 (NCT03418324) trial referenced on pages 2 and 85. The reference to "no grade 3-4 toxicities were observed" relates to the lack of serious adverse events as defined by the FDA. We have added clarification to the aforementioned language in the Amended Draft Registration Statement.

17. Please revise the following statements on pages 86 and 87 to remove the implication that your product candidates will ultimately be approved or become first-in-class:

- **"We believe ENV 205 is a first in class drug targeting endoglin"; and**
- **"ENV 205 is a first-in-class molecule found to limit the process of muscle wasting...."**

Response: We have revised the disclosure to remove the implication that our product candidates would ultimately be approved or become first-in-class on pages 86 and 87 of the Amended Draft Registration Statement.

Enviro Intellectual Property Agreements with Cedars-Sinai Medical Center, page 89

18. Please revise your disclosure about the terms of Enviro's agreements with Cedars-Sinai Medical Center in the following ways:

- **disclose the milestones that must be met and when;**
- **quantify the aggregate potential fees that Enviro may have to pay in exchange for the licenses;**
- **revise your description of the "non-royalty sublicense revenue" to clarify a range that is within ten percentage points (e.g., a double-digit percentage in the teens);**
- **specifically quantify the maximum aggregate milestone payments; and**
- **disclose when the last-to-expire licensed patents are scheduled to expire**

Response: We have revised the disclosure and added the above requested disclosure on page 89 of the Amended Draft Registration Statement.

Intellectual Property, page 89

19. Please revise your intellectual property disclosure to disclose for each material patent and patent application the specific products or technologies to which such patents or patent applications relate. Also clearly describe on an individual basis the type of patent protection granted for each product or technology (composition of matter, use, or process), the expected expiration of each patent, and the jurisdiction, including any foreign jurisdiction, of each pending or issued patent. In this regard, it may be useful to provide this disclosure in tabular form to support the narrative already included.

Response: We revised our intellectual property disclosure to better disclose which technologies and products apply to which patents and have put such disclosure in tabular form beginning at page 90 of the Amended Draft Registration Statement.

Kairos Intellectual Property Agreements with Cedars-Sinai Medical Center, page 89

20. Please revise your disclosure about the terms of your agreements with Cedars-Sinai Medical Center in the following ways:

- **For agreement 1: revise your description of the "non-royalty sublicense fees" to clarify a range that is within ten percentage points (e.g., a double-digit percentage in the teens) and specifically quantify the maximum aggregate milestone payments;**
- **For agreements 2, 3, and 4: specifically quantify the "initial license fee[;]" and**
- **For all agreements: disclose patent expiration dates, royalty and non-royalty payment expiration dates, and the specific jurisdictions of foreign patents, and specifically quantify the maximum aggregate milestone payments.**

Response: We have revised our disclosure and added the above requested disclosure at page 89 of the Amended Draft Registration Statement.

Enviro License and Supply Agreement with Tracon Pharmaceuticals, Inc., page 90

21. Please revise your disclosure in this section as follows:

- **Disclose when the royalty and non-royalty payments would terminate;**
- **Clarify the percentage of ownership that the Tracon-Enviro Equity represents; and**
- **As it concerns the patents underlying your agreement with Tracon Pharmaceuticals, please disclose the type of patent protection (such as composition of matter, use, or process), when the patents are scheduled to expire, and the specific jurisdictions of the foreign patents.**

Response: We revised our disclosure and added the above requested disclosure at page 90-91 of the Amended Draft Registration Statement.

Management, page 108

22. We note your disclosure that Drs. Mazanet and Keyoung will become members of your board of directors upon the consummation of your offering. Please file the consents of these director nominees to be named in your registration statement as exhibits. Refer to Securities Act Rule 438.

Response: We have included the consents of Drs. Mazanet and Keyoung as Exhibits 99.1 and 99.2 to the Amended Draft Registration Statement.

23. We note your disclosure on page 120 that you will have a classified board. Please identify which class each director will belong to and when each class's term will expire.

Response: After further discussion, we determined not to maintain a classified board of directors and such provision was not included in our recently adopted Delaware Certificate of Incorporation and Bylaws. We have updated the disclosure on page 114 and throughout the Amended Draft Registration Statement.

Executive Compensation

Equity Benefit Plans, page 114

24. Please file the 2022 Equity Incentive Plan and the 2022 Employee Stock Purchase Plan as exhibits pursuant to Regulation S-K, Item 601(b)(10)(iii).

Response: The Company intends to adopt its 2023 Equity Incentive Plan before our registration statement is declared effective by the SEC. Accordingly, we have updated our disclosure regarding the 2023 Equity Incentive Plan throughout the Amended Draft Registration Statement. In addition, we do not intend to adopt an employee stock purchase plan at this stage and have deleted all references regarding the Employee Stock Purchase Plan throughout the Amended Draft Registration Statement.

Principal Stockholders, page 119

25. Please identify in a footnote to the table all natural persons who have voting and/or investment power over the shares held by Technomedics Management and Systems.

Response: We have updated the disclosure to disclose that Manfred Mosk exercises voting control over and is the 100% owner of Technomedics Management and Systems, Inc. on page 122 of the Amended Draft Registration Statement.

Certain Material U.S. Federal Income Tax Consequences to Non-U.S. Holders, page 126

26. Please remove the disclaimer indicating that the discussion of material tax considerations is provided for informational purposes only.

Response: We have removed the above referenced disclaimer language from the "Certain Material U.S. Federal Income Tax Consequences to Non-U.S. Holders" section of the Amended Draft Registration Statement.

Signatures, page II-5

27. Please indicate by parenthetical disclosure who is signing the registration statement in their capacity as your principal executive officer, principal financial officer, and principal accounting officer or controller. Refer to Instruction 1 to Signatures on Form S-1.

Response: We have updated the disclosure accordingly in the Amended Draft Registration Statement.

General

28. Please furnish the information required by Item 505 of Regulation S-K in your prospectus. See Item 5 of Form S-1.

Response: We have included a new sub-section entitled "Determination of Offering Price" in the "Underwriting" section to include the disclosure required by Item 505 of Regulation S-K regarding the market price of our shares of common stock in light of the absence of an established trading market.

29. Please provide us with 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, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Response: At this time, the Company has not presented any written communications to investors, as defined in Rule 405 under the Securities Act. In the event the company does present such information to investors, we will supply such document to the SEC.

We thank the Staff in advance for its review of the foregoing in relation to the Company's filing of its Registration Statement. We respectfully request that you provide us with any additional comments on or before July 11, 2023. Should you have any questions or concerns, please kindly contact our counsel, Megan J. Penick, Esq. or Stephen Weiss, Esq. of Michelman & Robinson, LLP, by telephone at (646) 320-4104 or (917) 797-0015, respectively.

Sincerely,

/s/ John S. Yu

John S. Yu
Chief Executive Officer
Kairos Pharma, Ltd.