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

DIVISION OF
CORPORATION FINANCE

April 25, 2023

John Yu, M.D.
Chief Executive Officer
Kairos Pharma, Ltd.
2355 Westwood Blvd. #139
Los Angeles CA 90064

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

Dear John Yu:

We have reviewed your draft 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 providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. 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 the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

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.

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...."

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.

Our In-Development Products and Pipeline, page 2

4. Please revise the statement that "[i]n the earlier Phase 2 trial involving a heavily pre-treated 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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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...."

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.

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.

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.

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.

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.

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.

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).

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.

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.

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.

General

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

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.

You may contact Christine Torney at 202-551-3652 or Daniel Gordon at 202-551-3486 if you have questions regarding comments on the financial statements and related matters. Please contact Dillon Hagius at 202-551-7967 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Megan Penick, Esq.