United States securities and exchange commission logo

August 27, 2020

Norbert Bischofberger, Ph.D.
President and Chief Executive Officer
Kronos Bio, Inc.
1300 So. El Camino Real, Suite 300
San Mateo, CA 94402

Re: Kronos Bio, Inc.
Draft Registration Statement on Form S-1
Submitted July 31, 2020
CIK No. 0001741830

Dear Dr. Bischofberger:

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 submitted July 31, 2020

Prospectus Summary
Overview, page 1

1. We note several discovery programs included in your pipeline table. Given the early-stage development of these programs, please provide us with your analysis as to why you believe each of these programs is sufficiently material to your business to warrant inclusion in your pipeline table.

2. Please revise your Pipeline table to present Phase 1 and Phase 2 trials in separate columns or provide us with your analysis as to why you believe the current presentation is appropriate. Please revise the heading in the sixth column to read "Phase 3 Trial" instead of "Registrational Trial."

3. We note your disclosure on page 3 that you are currently in the process of completing IND-enabling studies with respect to KB-0742. However, your pipeline table suggests that you have already completed the IND-enabling studies. Please shorten the arrow for KB-0742 as appropriate to illustrate how far along you are in the

IND-enabling studies.

4. Please revise to limit the discussion of clinical trial results in your prospectus summary to the endpoints of the trial and whether they were met. For example, we note you characterize your Phase 1b/2 clinical trial results as revealing "encouraging complete response (CR) rates and overall survival."

5. We note that, following feedback from regulatory agencies, you plan to directly proceed to a registrational Phase 2/3 clinical trial of ENTO in combination with IC. Please expand your disclosure to state that you have not yet discussed with the FDA the potential of your Phase 2/3 clinical trial to serve as a registrational trial, as you state on page 20.

Risks Associated with our Business, page 5

6. Please revise your bullet point regarding companion diagnostics to explain that they will need to be approved by the FDA as medical devices, as you explain on page 24.

Implications of Being an Emerging Growth Company, page 7

7. 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.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Critical Accounting Policies and Use of Estimates

Determination of Fair Value of Common Stock, page 100

8. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features.

Prior Development of ENTO, page 114

9. We note your reference on page 115 to adverse events Grade 3 or greater. Please revise to disclose the definition of an adverse event Grade 3 or greater. To the extent a serious adverse event has occurred, please clearly disclose the event and the number of affected patients.

10. Please remove your statement that the "safety results were considered acceptable" as safety is a determinations that is solely within the authority of the FDA or similar foreign regulators. You may state that your product candidate is well tolerated, if true.

Therapeutic Rationale and Clinical Data in HOX/MEIS-High AML, page 115

11. Please expand your disclosure to provide a brief narrative discussion of the data presented in the graphs at the top of page 116.

12. We note your disclosure that "sensitivity to ENTO correlated, with

high statistical
significance, with the presence of NPM1 mutations alone or in
combination with FLT3 or
DNMT3A mutations." Please disclose the p-value used to measure
statistical significance.
Please also label the horizontal axis with the appropriate unit of
measure in the graphic at
the top of page 117.
13. We note your disclosure of CR rates for patients enrolled in Arm A.
Please clarify
whether CR was measured in MLL-r subjects and NPM1 mutation subjects
in Arm B. If
so, please revise to include a discussion of such results. Please
clarify whether the data
observed in Arm B and C of the Phase 1b/2 clinical trial was
considered statistically
significant.
14. Please disclose the basis for your statement that "the high HOX/MEIS
patients also
experienced superior overall survival."
CDK9 Inhibitor Product Candidate: KB-0742, page 119

15. We note your disclosure that you believe KB-0742 may possess
"best-in-class"
selectivity for CDK9. This term suggests that the product candidate is
effective and likely
to be approved. Please delete these references throughout your
registration statement. If
your use of this term was intended to convey your belief that the
product is based on a
novel technology or approach and/or is further along in the
development process, you may
discuss how your technology differs from technology used by
competitors and, if
applicable, that you are not aware of competing products that are
further along in the
development process. Statements such as these should be accompanied by
cautionary
language that the statements are not intended to give any indication
that the product
candidate has been proven effective or that it will receive regulatory
approval.

Intellectual Property, page 128

16. We note your disclosure that your ENTO and LARNA patent portfolio
includes additional
foreign patents and patent applications. Please disclose the foreign
countries in which you
have foreign patents, the type of patents and the term.
Family Relationships and Other Arrangements, page 147

17. We note that two directors have the same surname. If applicable, state
the nature of any
family relationship between any director, executive officer, or person
nominated or chosen
to become a director or executive officer. See Item 401(d) of
Regulation S-K.
You may contact Sasha Parikh at 202-551-3627 or Julie Sherman at
202-551-3640 if you
have questions regarding comments on the financial statements and related
matters. Please
contact Deanna Virginio at 202-551-4530 or Tim Buchmiller at 202-551-3635 with
any other
questions.

Sincerely,

Division of
Corporation Finance

Office of Life Sciences

cc: Charles J. Bair, Esq.