

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

December 7, 2020

Steven D. Harr, M.D.
President and Chief Executive Officer
Sana Biotechnology, Inc.
188 East Blaine Street, Suite 400
Seattle, Washington 98102

Re: Sana Biotechnology, Inc.
Draft Registration Statement on Form S-1
Submitted November 10, 2020
CIK No. 0001770121

Dear Dr. Harr:

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

Prospectus Summary

Overview, page 1

- 1. Please tell us the basis for your belief stated in the first paragraph that engineered cells will have a therapeutic potential that will be "at least as disruptive" as biologics. Please also tell us why you believe it is appropriate to cite the amount of global revenues for all branded biologic drugs when you do not have any product candidates in development beyond the preclinical stage and which address only certain indications.
- 2. We note your disclosure on page 1 that you "expect to file multiple INDs per year." Given the unpredictability of drug development, please remove this statement and a similar

statement in the Business section as such statements are speculative.

- 3. We note your disclosure on page 1 and in the Business section that you have shown that you can specifically target numerous cell surface receptors that, when combined with delivery vehicles to form fusosomes, allow cell-specific delivery across multiple different cell types. Please revise the second paragraph of the Summary and the statements in the Business section to clarify that you have not conducted clinical development efforts to date.
- 4. Please revise your pipeline table on page 2 to include a separate column for preclinical, Phase 1, Phase 2 and Phase 3 and to provide the indications that you are actually pursuing as opposed to the "potential" indications. It appears that you have included every in-house program in your pipeline table. Please explain to us why each program is sufficiently material to your business to warrant inclusion in your pipeline table or revise your table as appropriate.

Our in vivo Cell Engineering Platform and Programs, page 4

- 5. We note your disclosure here and in the Business section that your fusogen technology should allow you to rapidly create multiple therapies targeting a variety of diseases with each successful fusogen and accelerate development of subsequent therapies targeting that same cell type. Please revise these statements and any similar statements to remove any implication that you will be able to accelerate the development of your product candidates. Please also revise the statements here and in the Business section that success with any initial therapy targeting a given cell type meaningfully "de-risks" development of subsequent therapies targeting that same cell type and any similar statements that imply that you will be successful in mitigating the risk associated with drug development.
- 6. We note your disclosure that your preclinical data demonstrate that you can make an "effective" CAR T cell *in vivo* with a single intravenous injection. Efficacy is a determination that is solely within the authority of the FDA or similar foreign regulators. You may present clinical trial end points and objective data resulting from trials without concluding efficacy. Please revise this statement accordingly.

Risks Associated with Our Business, page 11

7. Please expand the second to last bullet point in this section or add another bullet point to address the risks associated with the licensed technology and the related agreements you have with Harvard, UCSF, Washington University, Cobalt, Oscine and Cytocardia as discussed in the risk factor on page 61.

Implications of Being an Emerging Growth Company, page 12

8. Please supplementally 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.

Risk Factors, page 18

9. Given the length of your risk factor section, please revise to comply with Regulation S-K Item 105 by relocating risks that could generically apply to any registrant or offering to the end of the section under the caption "General Risk Factors."

Risks Related to Intellectual Property and Information Technology

We may be dependent on intellectual property licensed or sublicensed to us from..., page 66

10. We note your disclosure that government agencies have provided assistance in connection with the development of certain intellectual property rights owned by or licensed to you, and these government agencies may have retained rights in the intellectual property. Please revise this risk factor to identify the intellectual property or technologies and what rights in the intellectual property the government agencies have retained.

Use of Proceeds, page 91

11. Please revise to identify the specific product candidates for which you intend to use the proceeds of this offering and how far in their development you intend to get using the proceeds of this offering.

<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> Stock Based Compensation, page 118

- 12. 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. Please discuss with the staff how to submit your response.
- 13. You state on page 120 that you used the backsolve method for inferring the equity value implied by a recent financing transaction. Tell us why you believe that the contemporaneous financing transactions were arms' length transactions.

Business, page 121

14. Please revise the statements in this section that you are uniquely positioned to develop transformative engineered cells as medicines and that you can increase your likelihood of success. These statements are not appropriate given the number of companies currently developing product candidates and the number of product candidates that never receive FDA approval.

Our T Cell Fusosome Approach, page 138

15. Please remove the reference to potential "first-in-class" product candidates as this statement implies an expectation of regulatory approval and is inappropriate given the length of time and uncertainty with respect to securing marketing approval.

Intellectual Property, page 184

16. Please revise to disclose the type of patent protection you have (composition of matter, use or process) and the material foreign jurisdictions where you have patents or pending patent applications.

Key Intellectual Property Agreements, page 187

17. Please provide the current expiration date for the last-to-expire licensed patent right under each of the agreements in this section if the royalty term for such agreement is determined using such information.

Principal Stockholders, page 235

18. Please revise your disclosure to identify the natural person or persons who have voting and investment control of the shares held by F-Prime Fund VI.

2. Summary of significant accounting policies

Acquisitions, page F-8

19. Please clarify that in an asset acquisition, amounts allocated to IPR&D are recorded in research and development expense if they do not have an alternative future use. Refer to ASC 730-10-25-2c.

3. Acquisitions, page F-16

- 20. Please clarify, in Management's Discussion and Analysis and elsewhere in the filing as appropriate, the amount of any payment expected to be paid upon the IPO or within 12 months after the IPO. In this respect we note the following:
 - You state on page F-17 that the valuation measurement dates for the Cobalt Success payment are triggered by an IPO at a time when at least one company program using technology acquired from Cobalt is currently in a clinical trial, has been submitted to the FDA for approval, or has been approved by the FDA. You also state that the valuation measurement dates are triggered upon a change of control when at least one of your programs based on fusogen technology is subject of an active research program.
 - For the Harvard College agreement you state on page F-20 that the milestone payments of up to \$76 million would double upon a change of control. In addition, we note that the success payment measurement dates are triggered by an equity financing of more than \$25.0 million as well as the one year anniversary of an IPO.

21. For the Cobalt Success payments, clarify the triggering points in which Success payments will be made. For example, clarify if an ongoing clinical trial would trigger a payment or if the ongoing clinical trial has to also be submitted to the FDA for approval to trigger a payment. In addition, clarify if you currently are undergoing a program based on the fusogen technology which is the subject of an active research program, which would trigger a Success payment and how much. Finally, please clarify for both the Harvard and Cobalt agreements that a change of control includes an IPO, if such is the case, that could result in Success payments.

Financial Statements for the Years Ended December 31, 2019

Notes to Consolidated Financial Statements

11. Convertible preferred stock

Rights issued with Series A-1 and Series A-2 convertible preferred stock

Conversion, page F-26

22. You state on page 111 that all outstanding shares of convertible preferred stock will convert into shares of your common stock. On page F-53 you state that the Series A-1, Series A-2, and Series B convertible preferred stock will automatically convert into shares of the Company's common stock upon closing of the sale of shares of common stock to the public in an underwritten public offering at a price that generates at least \$75.0 million in gross proceeds pursuant to an effective registration statement in which the shares will be listed on a national securities exchange. You also state on page F-53 that the convertible preferred stock will automatically convert into shares of common stock upon the vote or written consent of the holders of at least 61% of the outstanding convertible preferred stock, voting together as a single class, which must include a majority of the Series B preferred stock held by the investors that purchased at least \$29 million in the Series B financing. Please clarify in the filing why you believe all convertible preferred stock will convert into common stock upon the IPO, given the above conditions to conversion.

You may contact Tracie Mariner at 202-551-3744 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Ada D. Sarmento at 202-551-3798 or Mary Beth Breslin at 202-551-3625 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Brian J. Cuneo, Esq.