

Divakar Gupta + 1 212 479 6474 dgupta@cooley.com

March 2, 2021

U.S. Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, D.C. 20549

Attn: Ms. Christie Wong Mr. Al Pavot Mr. Chris Edwards Mr. Tim Buchmiller

Re: LAVA Therapeutics B.V.

Draft Registration Statement on Form F-1 Submitted on January 25, 2021

CIK No. 0001840748

### Ladies and Gentlemen:

On behalf of our client, LAVA Therapeutics B.V. (the "Company"), we are responding to the comments of the staff (the "Staff") of the Securities and Exchange Commission (the "Commission") contained in its letter dated February 21, 2021 (the "Comment Letter"), relating to the above referenced Confidential Draft Registration Statement on Form F-1 (the "DRS"). In response to the comments set forth in the Comment Letter (the "Comments"), the Company is concurrently publicly filing its Registration Statement on Form F-1 (the "Registration Statement"), which reflects changes made in response to certain of the Comments.

VIA EDGAR

Set forth below are the Company's responses to the Comments. The numbering of the paragraphs below corresponds to the numbering of the Comments in the Comment Letter, which for your convenience we have incorporated into this response letter. Page references in the text of this response letter correspond to the page numbers of the Registration Statement.

# <u>Draft Registration Statement on Form F-1 submitted January 25, 2021</u>

# Cautionary Statement Regarding Forward-looking Statements, page ii

 Please revise the last sentence of this section to indicate that you will update or revise forward-looking statements to the extent required by applicable law.

# Response to Comment 1:

In response to the Staff's comment, the Company has revised its disclosure on page iv of the Registration Statement.



# Overview, page 1

2. Please remove any references to the company being a clinical-stage biotechnology company until you initiate a Phase 1 clinical trial.

### **Response to Comment 2:**

In response to the Staff's comment, the Company has revised its disclosure throughout the Registration Statement, including on pages iii, 1, 14, 29, 92, 104, and F-7.

3. We note your statement here that data collected in preclinical trials demonstrate your gamma-delta bsTCEs kills patient-derived tumor cells with "high potency and selectivity." We also note the disclosure that LAVA-051 is designed to be an "effective" anti-tumor agent against CD1d-expressing tumor cells. As your product candidate has not received FDA approval, it is premature to suggest or imply that it is effective. Please revise your disclosure here and any similar statements throughout the prospectus accordingly.

#### **Response to Comment 3:**

In response to the Staff's comment, the Company has revised the disclosure on pages 1, 3, 4, 92, 104, 105, 106, 120, 130, 131, 143, and F-7 of the Registration Statement.

4. We note your disclosure here and elsewhere in your prospectus that gamma-delta bsTCE could materially improve clinical responses while maintaining a "favorable safety profile." Since this disclosure may imply that your product candidate is safe, and safety determinations are solely within the authority of the FDA and comparable regulatory bodies, please revise your disclosure to remove this implication. We also note the disclosure that you demonstrated that the CD1d-binding moiety of the bsTCE led to effective iNKT cell activation and anti-tumor activity. Please provide the basis for this statement. Please revise throughout including where you indicate your gamma-delta bsTCE platform has the potential to generate potent and safe therapeutics.

### **Response to Comment 4:**

In response to the Staff's comment, the Company has revised its disclosure on pages 1 and 104 of the Registration Statement.

### Our Pipeline, page 3

- 5. Please revise your product pipeline table as follows:
  - For purposes of consistency with the discussion of the regulatory drug approval process, replace the term "Pivotal" with Phase 3. If "Pivotal" is intended to mean something other than Phase 3, please provide further explanation.
  - We note you have created a distinction between "preclinical" and "IND-enabling." As "IND-enabling" studies are preclinical, please revise your table to show all your product candidates in the preclinical phase.



- Your table indicates that the Phase 1/2a clinical trial for LAVA-051 has begun but elsewhere you state that LAVA-051 has not yet
  entered the clinic. Please revise the arrows in the pipeline table to accurately reflect where each product candidate is in
  development.
- Include separate columns for Phase 1 and Phase 2 trials or tell us the basis for your belief that you will be able to conduct Phase 1/2 trials for all your product candidates. In this regard, we note your disclosure page 104 that patients from the U.S. would be included in the Phase 1 part of your clinical trial for LAVA-051, if approved.
- We note the last two rows in your pipeline table with unnamed product candidates and "undisclosed targets" that are not discussed elsewhere in the prospectus. To the extent these are material programs, disclose the targets and provide descriptions of these programs. If you have not yet identified product candidates or target indications, please remove them from the table or explain the basis for your belief that they are material and should be included in your pipeline table.

Please also state whether larger Phase 2b clinical trials will be required prior to commencing Phase 3 clinical trials and if so, please revise your table to clarify that there will be multiple Phase 2 trials.

### **Response to Comment 5**:

In response to the Staff's comment, the Company has revised its product pipeline table on pages 3, 105 and 130 of the Registration Statement. In response to the Staff's comment regarding whether there will be multiple Phase 2 trials, the Company respectfully notes that it cannot predict whether additional or larger Phase 2b clinical trials will be required prior to commencing Phase 3 clinical trials as the clinical development plan will depend on the results of earlier clinical trials and discussions with the U.S. Food and Drug Administration. As a result, the Company believes that disclosure to the effect that there will be multiple Phase 2 trials would be misleading.

### Use of Proceeds, page 83

6. Please revise your disclosure in this section to specify which candidates will be advanced with the proceeds of the offering and which clinical trials will be funded. Please indicate how far you expect the proceeds from the offering will allow you to proceed in the clinical development of your product candidates. If the anticipated proceeds from your offering will not be sufficient to complete those trials, please disclose the amount and sources of other funds needed.

### **Response to Comment 6:**

In response to the Staff's comment, the Company has revised its disclosure on pages 9 and 83 of the Registration Statement and respectfully notes to the Staff that it intends to further revise its disclosure under "Use of Proceeds" in a future amendment to the Registration Statement once it has determined the size of the offering.



### Series C Preferred Financing, page 92

7. Please revise to disclose the milestones that would have to be satisfied in order to close the remaining two tranches of your Series C preferred financing. Please also clarify if those tranches could be closed after your public offering and if preferred stock would be issued please include risk factor disclosure if appropriate.

## **Response to Comment 7**:

The Company acknowledges the Staff's comment and respectfully advises the Staff that the Board of Directors of the Company and the Company's investors have approved the acceleration of the remaining two tranches of the Series C preferred financing in March 2021, and therefore disclosure of the milestones related to the Series C preferred financing would no longer be meaningful to investors. In addition, the Company has revised its disclosure throughout the Registration Statement to reflect that the remaining tranches of the Series C preferred financing are being accelerated prior to the offering.

## VUmc Agreement, page 140

8. We note you are obligated to pay VUmc a tiered percentage of your value upon the listing of majority of your shares on a stock exchange. Please clarify if the current offering will trigger this payment obligation and quantify the amount that would be due.

### **Response to Comment 8:**

In response to the Staff's comment, the Company has revised its disclosure on pages 145 and F-30 of the Registration Statement.

## Janssen Collaboration and License Agreement, page 141

9. Please specify the research stages that must be completed before milestone payments become payable pursuant to the agreement and disclose the aggregate amount of those payments. Please also quantify the royalties payable under the agreement upon commercialization and the fixed period for which royalties are payable.

### **Response to Comment 9:**

In response to the Staff's comment, the Company has revised the disclosure on pages 93 and 145 of the Registration Statement. The Company has also filed the Janssen Collaboration and License Agreement as Exhibit 10.2 to the Registration Statement.

### Government Regulation, page 146

10. Please include a description of the material foreign regulations that apply to the development of your product candidates or include disclosure, if true, indicating the process is substantially similar to the process in the United States.



## **Response to Comment 10:**

In response to the Staff's comment, the Company has revised its disclosure on pages 155 through 159 of the Registration Statement.

### Principal Shareholders, page 168

11. Please include footnotes to your table that disclose the natural persons who have beneficial ownership of the shares held by each of the entities listed in your table.

### **Response to Comment 11:**

In response to the Staff's comment, the Company has revised its disclosure on pages 176 and 177 of the Registration Statement.

### **Exhibits**

12. Please revise to mark exhibits 10.1 and 10.2 to indicate, if true, that certain portions of these exhibits have been redacted because they are both not material and would likely cause competitive harm if publicly disclosed.

### **Response to Comment 12:**

In response to the Staff's comment, the Company has revised the exhibit index of the Registration Statement.

#### General

13. Please provide us with supplemental 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, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications. Please contact the staff member associated with the review of this filing to discuss how to submit the materials, if any, to us for our review.

### **Response to Comment 13**:

The Company respectfully acknowledges the Staff's comment and will supplementally provide to the Staff, under separate cover, a copy of all written communications, as defined in Rule 405 under the Securities Act of 1933, as amended (the "Securities Act"), that the Company, or anyone the Company authorized to on its behalf, presented to potential investors in reliance of Section 5(d) of the Securities Act.

\* \* \* \*



Please direct any questions or comments concerning the Registration Statement or this response letter to either the undersigned at +1 212 479 6474, Joshua Kaufman at +1 212 479 6495 or Christian Plaza at +1 703 456 8006.

Very truly yours,

/s/ Divakar Gupta

Divakar Gupta

CC: Steve Hurly, LAVA Therapeutics B.V.
Joshua Kaufman, Cooley LLP
Christian Plaza, Cooley LLP
Erika Kaneko, Cooley LLP
Deanna Kirkpatrick, Davis Polk & Wardwell LLP
Yasin Keshvargar, Davis Polk & Wardwell LLP