

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

May 28, 2020

Ingmar Hoerr
Chief Executive Officer
CureVac B.V.
Friedrich-Miescher-Strasse 15
72076
Tubingen
Germany

Re: CureVac B.V.

Draft Registration Statement on Form F-1
Submitted April 29, 2020
CIK No. 0001809122

Dear Dr. Hoerr:

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 F-1 submitted April 29, 2020

Our Company, page 1

1. The prospectus summary should include a balanced presentation of your business, including your competitive position in the industry. In the presentation of your business, you state that you are "a leading global clinical-stage biopharmaceutical company" and that you have a "differentiated technology platform." Please tell us the basis for these claims. We note that your most advanced is currently in a Phase 1 clincal trial and that no mRNA products have been approved by any regulatory agency and that you have not yet obtained regulatory approval for any product. Please balance your summary presentation

as well as presentations of your business elsewhere in the document by providing equally prominent disclosure about the competitive and regulatory challenges you face.

- 2. We note your disclosure that your lead clinical programs have "generated promising early efficacy and safety results" or "shown potential" in clinical trials. Safety and efficacy are determinations that are 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 and you may state that your product candidates have been well tolerated, if accurate. Please revise these statements here and throughout the document.
- 3. We note your disclosure that mRNA-based medicines "represent a foundational class of medicine" and that they have "inherent advantages." Please provide the source for this statement and clarify your disclosure to explain why mRNA-based medicines are foundational and potentially provide an advantage compared to other treatments.
- 4. Recent news coverage indicates that you are focused on developing a vaccine for SARS-CoV-2. A news release posted on your website on March 15, 2020 stated that "internal efforts are focused on the development of a coronavirus vaccine" and an interview with one of your executives stated that "[your] key focus is [your] SARS-CoV-2 vaccine." An additional article summarizing an interview with Dr. Hoerr stated that Dr. Hoerr acknowledged that your search for a vaccine has "all but consumed" your company. Please revise the summary section and other relevant portions throughout the document to disclose the impact that your focus on a potential SARS-CoV-2 vaccine has had, and will continue to have, on the rest of your business, including preclinical and clinical development of your other product candidates.
- 5. We note you count your in house manufacturing infrastructure as a strength yet on page 17, you state that you rely on CMOs to manufacture and supply your product candidates. Please clarify the disclosure throughout the document to explain the the apparent discrepancy.
- 6. Please revise the description of your programs to eliminate the reliance on overly technical language so investors can understand the nature of your product candidates. For example, please explain the significance of "activation of the toll like receptors 7, or TLR7, TLR8, and retonic acid-inducible Gene-I, or RIG-I pathways."
- 7. We note that you intend to initiate the first Phase 1/2a clincical trial for COVID-19 in _____. Please clarify whether you have submitted an NDA or when you expect to submit an NDA.

Our Product Portfolio, page 3

8. Please revise your pipeline table to include a column for Phase 3, include all indications that the identified product candidates/programs are designed to treat and remove programs that are not material to your operations. To the extent that you have licensed a

> program/product candidate to another party, please clarify your continued involvement in the program and why it is appropriate to consider it as part of your product development pipeline. Your response should address your indications that collaborative partners exercise full control over development and commercialization.

> We note your inclusion of references to collaborators such as Yale, Harvard Medical School and SERI without describing your collaborative agreements. To the extent the collaborations are material, please disclose the material terms of these agreement. If they are not material, remove the collaborative partner and the program from your pipeline table.

Additionally, we note your statement that you are advancing multiple undisclosed programs in preclinical studies across liver and rare diseases, eye disorders, lung disease and delivering theraputic antibodies and you have included them in your pipeline table. It is not appropriate to highlight programs that are not material. Similarly, it is not appropriate to omit disclosures relating to material programs.

Implications of Being an Emerging Growth Company, page 6

9. 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.

We depend on strategic partnerships..., page 15

10. We note that in certain cases your collaborative partners exercise full control over further development and potential commercialization and that collaborators can independently develop product that compete with the collaborative product candidate. Additionally, we note that you are subject to diligence requirements. Please clarify whether your collaborative partners are also subject to diligence requirements and whether you have contractual rights to information about clinical trial developments and results.

We may face business disruption and related risks..., page 21

11. We note your disclosure about potential disruptions due to the COVID-19 pandemic. To the extent you have experienced delays in clinical trials, difficulties enrolling new participants, participants terminating their participation, or any other disruptions, please revise the discussion to describe the events and their potential impact.

If we are unable to obtain, maintain and enforce intellectual property protection for our products..., page 37

12. Please identify all your product candidates that are subject to march in rights.

Use of Proceeds, page 78

13. We note your disclosure that you intend to use the proceeds of this offering to advance your preclinical and clinical programs, invest in your mRNA technology platform and fund expansion of your manufacturing capabilities. Please also what amounts will be allocated to each of your programs and specify how far in the development of each of your pipeline projects you expect to reach with the proceeds of the offering. If any material amounts of other funds are necessary to accomplish the specified purposes, state the amounts and sources of other funds needed for each specified purpose and the sources. Refer to Item 3.C.1 of Form 20-F.

Our Collaborations and License Agreements, page 86

- 14. Please revise the descriptions of each of your agreements to disclose:
 - each parties' rights and obligations under the agreement;
 - quantify all payment made to date;
 - disclose separately the aggregate amount of all potential development, regulatory and commercial milestone payments;
 - disclose the amount of option fees for additional targets;
 - quantify the royalty rate, or a range no greater than 10 percentage points per tier;
 - disclose when royalty provisions expire, if the expiration is based on a number of years following commercialization, disclose the number of years;
 - disclose the expiration date; and
 - describe any termination provisions.

Please note disclosures such as "mid-nine figure amount" and "low seven figure amount" are not sufficent.

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

<u>Year Ended December 31, 2018 Compared to Year Ended December 31, 2019</u> <u>Research and development expenses, page 90</u>

15. You have two clinical stage programs and a COVID-19 program which you identify as key programs. We acknowledge your breakout of research and development costs by type of expenditure. To the extent known, please further disaggregate your costs by each key program. Costs related to insignificant product candidates may be aggregated into one line item with any unallocated costs on a separate line item to reconcile the total costs to the total on the Statement of Operations.

Contractual Obligations, page 93

16. Please provide narrative disclosure quantifying the total aggregate amount of potential future milestone payments under your collaboration and licensing agreements.

Business, page 99

17. We note that your disclosures throughout this section reference to "progressive disease," "stable disease," "complete response," and "partial response." Please revise your document to define these terms and disclose how responses were measured. Please also revise your document to provide definitions for Grade 1, Grade 2 and Grade 3 or higher adverse events.

Overview, page 100

18. We note your disclosure on page 100 that you have "made rapid advances in de-risking [your] RNAoptimizer platform through rational disease selection." Please clarify to explain how your disease selection process has de-risked your RNAoptimizer platform and to explain the significance of de-risking your platform.

Overview, page 101

19. We note your disclosure on page 100 that your "protein therapy platform has the potential to be used as a treatment against infectious diseases and toxins and to be applied in many disease indications including cancer, cardiovascular diseases, and autoimmune diseases." Please clarify whether your protein therapy platform is separate from the RNAoptimizer platform.

Our Strengths, page 103

- 20. Please explain the basis for your beliefs that mRNA-based medicines have advantages over existing treatment modalities and mRNA vaccines offer advantages over existing vaccine technologies.
- 21. Please balance your claim that you have a broad portfolio of mRNA-based medicines by clarifying that you are still developing your product candidates and that to date you have only conducted preclinical studies and initiated Phase 1 trials of those product candidates.

Management, page 188

22. Please file the consulting agreement with Dr. Winterhalter as an exhibit to your registration statement.

Management

Equity Incentive Plans, page 198

23. 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.

Description of Share Capital and Articles of Association, page 206

24. On page F-29 of the document, you state that your Series B and Series C shares include preference rights in the case of a defined exit event. Please update this section to discuss any outstanding shares of preferred stock or whether the preferred stock will convert to common stock in the reorganization. See Item 10.A of Form 20-F.

3.1 Revenue from contract with customers, page F-22

- 25. Please include disclosure of your collaboration agreement with Eli Lilly and Company, or identify which of your disclosed agreements generated the revenues attributed to Eli Lilly and Company in the tables on page F-22.
- 26. You recorded EUR 17,416,000 of revenue in 2019 of which EUR 8,617,000 was from product sales and EUR 5,777,000 was from revenue recognized from upfront payments. Please clarify the nature of the remaining revenue recognized and the accounting policy. Clarify in Management's Discussion and Analysis the reason for the increase in the revenue from the prior year.
- 27. You state on page F-8 that you generally concluded that you act as a principal in sales transactions as you customarily have control over the goods or services before transferring control to the customer. Please clarify the following:
 - the circumstances in which you would or would not act as a principal in sales transactions,
 - what you mean by "customarily has control over the goods or services before transferring control to the customer",
 - how your accounting policy for recording product sales as a principal or agent is consistent with B34-B38 of IFRS 15, and
 - if the product sales relate to sales to the collaborative partner and if so, where the performance obligations relating to those sales are disclosed for each significant agreement

3.2 Cost of Sales, page F-23

28. You disclose that your revenues have been recognized pursuant to license and collaboration agreements. Please explain to us what differentiates expenses recorded as cost of sales from those recorded as research and development expenses. In addition, please clarify in Management's Discussion and Analysis the reasons why each component of cost of sales increased, why quantitatively the cost of sales increased more than the increase in revenue, and why the percentage increase in cost of sales was higher than the percentage increase in revenue.

Notes to the Consolidated Financial Statements

12. Convertible loans, page F-35

29. Please disclose the conversion rate of the convertible loans.

You may contact Rolf Sundwall at 202-551-3105 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Alan Cambell at 202-551-4224 or Suzanne Hayes at 202-551-3675 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences