United States securities and exchange commission logo

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
Year Ended December 31, 2018 Compared to Year Ended December 31, 2019
Research and development expenses, page 90

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