United States securities and exchange commission logo

December 9, 2020

Berndt Modig
Chief Executive Officer
Pharvaris, B.V.
J.H. Oortweg 21
2333 CH Leiden, The Netherlands

Re: Pharvaris, B.V.
Draft Registration Statement on Form F-1
Submitted November 12, 2020
CIK No. 0001830487

Dear Mr. Modig:

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 November 12, 2020

Market and Industry Data, page ii

1. Your statement that you have not independently verified third-party market and industry information may imply an inappropriate disclaimer of responsibility with respect to the third party information. Please either delete the statement or specifically state that you are liable for such information.

Prospectus Summary
Overview, page 1

2. Here and elsewhere throughout your prospectus you refer to your product candidate, PHA121, as being "highly potent," "a potent antagonist" and a "potent and selective treatment for acute HAE." Given the stage of your product development, it appears premature to describe your product candidates as potent, which implies they are effective.

Similarly, we note your reference to your product candidates' "anticipated therapeutic profile." Please revise your disclosure to remove such statements throughout your

prospectus.

3. We refer to the comparisons here and elsewhere in your prospectus where you state that: "PHA121 was shown to be consistently 25-fold more potent than icatibant on a molar basis," "more potent than icatibant," "observed greater potency for PHA121 compared to icatibant," and "observed that PHA121 was more potent in blocking the effects of BK in humans than icatibant, when comparing the PHA121 results of the trial to published data on icatibant." Please remove these comparisons as they do not appear to be based on a head-to-head studies or tell us why you believe such comparisons are appropriate.

4. We note your disclosure in this section and in the Business section that you plan to initiate a "pivotal" trial in the on-demand setting following your planned RAPIDe-1 trial. Please revise the disclosure in these sections to make it clear that even if you receive positive data from RAPIDe-1 trial, the U.S. Food and Drug Administration (FDA) or other regulators may require you to conduct additional trials.

5. Please place your discussion of the bradykinin challenge in appropriate context with reference to your limited trial data to date and indicate that you have not yet conducted a Phase 2 study. Additionally, we note your disclosure on page 3 that you expect your planned trials of PHVS416 and PHVS719 will support a regulatory application for PHVS719 in prophylaxis for HAE. Please remove this disclosure as it is premature and speculative given the current stage of development.

Differentiation of PHA121, page 3

6. We note your statements here and throughout your document that your product candidates are designed or have the potential to be "best-in-class." 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.

Our Pipeline, page 4

7. Please revise the pipeline table on page 4, which also appears on page 91, so that it reflects the current status of your product candidates. For example, we note your disclosure on page 97 that you still have ongoing and planned Phase 1 studies for your

product candidate, such that it does not appear that you have completed your Phase 1 studies. In addition, we note your disclosure on page 103 that you plan to conduct a Phase 1 bridging study in 2021 for PHVS719 and that you only have a "prototype formulation

for extended release." Accordingly, please remove the dashed box from your pipeline
chart for PHVS719.

Recent Developments
COVID-19, page 6

8. We note your disclosure that the COVID-19 pandemic caused you to experience a delay
in enrollment in your Phase 1 study of PHA121. Please revise to discuss in greater detail
the extent of the delay and also disclose if any of your other clinical trials have been
affected. Please also revise any associated risk factors to specifically discuss the impact
COVID-19 has actually had on your clinical trials to date given the amount of time that
has passed since the initial outbreak.

Implications of Being an Emerging Growth Company and a Foreign Private Issuer, page 9

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.

Risk Factors, page 14

10. Please update your risk factor disclosure by relocating risks that could apply generally to
any company or offering of securities to the end of the risk factor section under the
caption General Risk Factors. Refer to Item 105 of Regulation S-K and
SEC Release Nos. 33-10825; 34-89670.

Use of Proceeds, page 67

11. We note your disclosure that you intend to use a portion of the net proceeds to fund the
clinical development of PHVS416 and PHVS719. Please revise to specify how far in the
clinical development of the associated product candidates you expect to reach with the net
proceeds. In this regard, we note that you have a number of clinical trials planned for the
associated product candidates. Also, to the extent material amounts of other funds are
necessary to accomplish your specified purposes, state the amounts of such other funds
and the sources thereof.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Estimates and Judgments
Share-Based Payments, page 85

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.

Business
Current Treatments and Their Limitations, page 94

13. We note your disclosure that "four other angioedema-specific oral medications for acute,

as well as prophylactic, use are in clinical development." Please provide additional
disclosure about these potential competitors, including the stage of development.

PHA121
Overview, page 95

14. We note your statement here that "PHA121 showed efficacy and clear dose-dependent
activity." You also state on page 97 that, "PHA121 was safe and well tolerated when
administered orally up to single doses of 22 mg." Please revise these and all similar
statements throughout your prospectus that state or imply that your product candidates are
safe or effective as these determinations are solely within the authority of the FDA and
comparable regulatory bodies.

15. We note your disclosure that "PHA121 demonstrated longer duration and faster onset of
activity than injected icatibant in the same study." Please expand your disclosure to
describe the icatibant study, including who completed the study, how the 0.6 mg/kg dose
of icatibant compares to the doses depicted in PHA121, and discuss the vehicle in the
icatibant study. To the extent the icatibant study is not a head-to-head study please remove
this disclosure or tell us why you believe your comparison is appropriate.

16. The graphic provided on the bottom of page 95 contains text that is illegible. Please revise
this figure accordingly. In addition, the graphic contains abbreviations such as "HMWK"
that are not defined. Please define abbreviations in all graphics here and
elsewhere. Additionally, all graphics throughout the prospectus should be accompanied
by narrative disclosure that clearly explains the context for the graphic.

Bradykinin Challenge Study, page 98

17. We note your comparison of the results of PHA121 observed in your Bradykinin
Challenge Study to published reports of clinical trial data for icatibant as well as your
related predictions on page 2. As these comparisons are not based on head-to-head studies,
please tell us why you believe it is appropriate to include them. Address in your response
whether you expect to be able to rely on such comparisons to support an application for
marketing approval.

PHA121-C002 (SAD extension), page 100

18. We note your disclosure regarding the occurrence of treatment-related adverse events
related to PHA121. Please expand your disclosure to provide the number of patients who
experienced each such treatment-related adverse event.

Intellectual Property, page 104

19. Please expand your disclosure to clarify the patent term for your sole granted U.S. patent
for PHA121. In addition, please identify the material jurisdictions that are included in
your "27 pending non-U.S. applications."

Corporate Structure, page 127

20. In order to provide appropriate context for your disclosure, please revise to include an
organizational chart that identifies the significant subsidiaries of

the Company. Refer
to Item 4(a) of Form F-1 and Item 4.C of Form 20-F.
Employees, page 127

21. Please provide a breakdown of each main category of activity and geographic location for
each of your employees. Refer to Item 4(a) of Form F-1 and Item 6.D of Form 20-F.
Related Party Transactions, page 140

22. We note your disclosure that you issued shares of Series C preferred stock in November
2020. Please identify the related parties and describe the related party interest.
Financial Statements
Note 21. Events After the Reporting Period, page F-26

23. We see from your disclosure herein that you granted 600,000 share options on January 1,
2020. Please reconcile this disclosure with that on page II-2 that indicates that 600,000
share options were granted on December 13, 2019.
General

24. At first use, please define abbreviations. For example only, we note that "DDI," "SAD"
and "GLP" on page 97 and "DBP" on page 99 are not defined at first use.

You may contact Julie Sherman at 202-551-3640 or Kate Tillan at 202-551-3604 if you
have questions regarding comments on the financial statements and related matters. Please
contact Jason L. Drory at 202-551-8342 or Christine Westbrook at 202-551-5019 with any other
questions.

Sincerely,

Division of
Corporation Finance
Office of Life
Sciences

cc: Sophia Hudson, Esq.