

Alvotech Lux Holdings S.A.S.
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Grand Duchy of Luxembourg

April 4, 2022

Via EDGAR

Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, N.E.
Washington, D.C. 20549-3628

Attention: Franklin Wyman
Vanessa Robertson
Jessica Ansart
Jeffrey Gabor

Re: **Alvotech Lux Holdings S.A.S.**
Amendment No. 2 to Registration Statement on Form F-4
Filed on March 14, 2022
File No. 333-261773

Ladies and Gentlemen:

On behalf of Alvotech Lux Holdings S.A.S. (the “**Company**”), we are providing this letter in response to the comments provided by the staff (the “**Staff**”) of the Securities and Exchange Commission (the “**Commission**”) in its comment letter dated March 30, 2022 (the “**Comment Letter**”) with respect to the Company’s Amendment No. 2 to Registration Statement on Form F-4 (“**Amendment No. 2**”) filed on March 14, 2022.

Concurrently with the submission of this response letter, the Company is filing, through EDGAR, Amendment No. 3 to the Registration Statement (“**Amendment No. 3**”).

The numbering of the paragraphs below corresponds to the numbering of the comments contained in the Comment Letter, which, for your convenience, we have incorporated into this response letter in bold and italics. Page references in the text of this response letter correspond to the page numbers of Amendment No. 3. Capitalized terms used but not otherwise defined in this letter shall have the meanings set forth in Amendment No. 3.

Amendment No. 2 to Registration Statement on Form F-4

Risk Factors

Clinical drug development involves a lengthy and expensive process and Alvotech may encounter substantial delays in its clinical studies, page 60

1. ***We note your revised disclosure here relating to the Russian invasion of Ukraine, your ongoing clinical trial for AVT04 and the collection of safety data from trial participants in Ukraine and your plans to conduct additional trials in Ukraine in 2022. Please disclose whether and how AVT04 is currently materially impacted, including, but not limited to:***

- *whether you are able to communicate with those patients you are still in the process of collecting safety data from;*
- *the percentage of your enrollment that may be impacted (out of 581 patients);*
- *whether you still expect to report topline results in the second half of 2022;*
- *potential impacts on the AVT04 trial;*
- *where you plan to initiate the “other clinical trials” that were previously planned for Ukraine; and*
- *clarification as to your planned development timeline for AVT04.*

Please also revise your Business section accordingly and explain whether and how you have undertaken efforts to mitigate the impact and where possible quantify the impact to your business, if material.

Response: The Company acknowledges the Staff’s comment and has revised its disclosure on pages 60 and 233 to provide more detail around the impact of the Russian invasion in Ukraine on Alvotech’s ongoing AVT04 clinical trial and its planned trials.

Due to an increase in patient enrollment by approximately 10%, the original sample size of patients is larger than originally planned. The 188 patients in Ukraine make up approximately 32% of the total patient population of 581. The Company does not consider its AVT04 trial to be materially impacted and still expects to report topline results in the second half of 2022, principally because:

- all patients, including those located in Ukraine, have completed the study primary endpoint assessment (at week 12);
- approximately 70% of the patients worldwide (408/581) and 69% of the patients in Ukraine (130/188) have reached the end of stage-1 (at week 28); and
- in a worst-case scenario where patients in Ukraine are not able to continue beyond stage-1, there is a sufficiently large patient population to ensure an acceptable and robust safety assessment by the end of the study (at week 52).

With respect to the other planned trials, the Company respectfully informs the Staff that it had originally planned clinical trial sites for its AVT03 and AVT06 studies in Ukraine and Russia. Due to the conflict, the Company is now considering alternative trial sites, including in South Africa and Poland. The Company does not expect these relocations to impact the timelines of the programs.

Comparable Public Companies, page 166

2. ***We acknowledge the additional information provided in response to prior comment 3, which addresses the “TAM-Current Pipeline” for Alvotech of \$82.2 billion and the corresponding discussion of the \$85 billion originator market on page 233. However, the market opportunities for your current product candidates as of March 2022 on page 233 aggregate to only \$56.3 billion. Please explain the \$28.7 billion difference between these amounts and revise your presentations accordingly. Also, provide an appropriate linkage between the amounts for Alvotech’s “TAM-Current Pipeline” on page 166 and the potential originator market on page 233.***

Response: The Company acknowledges the Staff’s comment and has revised its disclosure on page 230 to clarify that the difference between the \$56.3 billion aggregate market opportunity of its current product candidates and the over \$85 billion of its aggregate market opportunity is due to two undisclosed product candidates whose aggregate market opportunity is approximately \$30 billion. In addition, the Company has clarified its disclosures with respect to “TAM—Current Pipeline” to indicate that the figure with respect to Alvotech does not take into account AVT23, a product candidate that was not under development when its projections were initially made to the OACB Board and management, but that now is part of its current pipeline. Finally, the Company has further enhanced its disclosures to make clear that originator market opportunities do not account for price erosion.

Business of Alvotech

Commercial Partnerships, page 255

3. ***We note that you have revised your disclosure on pages 225-232 and 284-287 in response to our prior comment 8 to reflect additional detail concerning each of your commercial partnerships and we reissue the comment in part. For each of your partnership agreements, please expand your disclosure to ensure that you are disclosing all material terms, including the quantification of any royalty rate, or a range no greater than 10 percentage points per tier. For example, with respect to multiple agreements, you currently state that the partner “will exclusively buy the relevant biosimilar candidate from [you] at a royalty or the applicable floor price, whichever is higher, for the duration of the agreement.”***

Response: The Company acknowledges the Staff’s comment and has revised its disclosure on page 222 to further clarify that, unless otherwise indicated, each commercial partnership described pays a royalty of approximately 40% (within the 10 percentage point range of 35% to 45%) or the applicable floor price, whichever price is higher. The Company further explained that a floor price is a minimum price per unit specific to each presentation to be paid by the commercial partner for the product, and is determined per each presentation and product taking into consideration Cost of Goods of manufacturing, supply and commercial market environment.

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Please direct any questions or comments regarding the foregoing or with respect to Amendment No. 3 to the undersigned at (212) 479-6446, Michal Berkner of Cooley LLP at +44 (0) 20 7556 4321 or Divakar Gupta of Cooley LLP at (212) 479-6474.

Very truly yours,

/s/ Nicolas H.R. Dumont

Nicolas H.R. Dumont

cc: Robert Wessman, Alvotech Lux Holdings S.A.S.
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