

March 14, 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. 1 to Registration Statement on Form F-4
Filed on February 4, 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 February 25, 2022 (the “***Comment Letter***”) with respect to the Company’s Amendment No. 1 to Registration Statement on Form F-4 (“***Amendment No. 1***”) filed on February 4, 2022.

Concurrently with the submission of this response letter, the Company is filing, through EDGAR, Amendment No. 2 to the Registration Statement (“***Amendment No. 2***”).

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. 2. Capitalized terms used but not otherwise defined in this letter shall have the meanings set forth in Amendment No. 2.

Amendment No. 1 to Registration Statement on Form F-4

The Business Combination

The Background of the Business Combination, page 151

1. ***We note your response to our prior comment 16 and reissue the comment in part. We note that you have substantially revised this section to include further detail on the negotiations, including reference to certain proposals and responses concerning material terms of the transaction. For example, on page 153 you state that “OACB returned comments to the Term Sheet to Alvotech, including with respect to certain binding provisions, the amount of contemplated PIPE financing, exclusivity terms, the Sponsor earn-out terms, transaction***

approvals and registration rights,” however, you do not describe the proposals concerning these terms. Please revise your disclosure throughout this section to describe each proposal (preliminary or otherwise) and counterproposal concerning a material transaction term and to identify the party putting it forward. In this regard, we continue to note that the Background section as written discusses in general terms the topical areas discussed by the parties during the eight month negotiations and some of the final terms they mutually agreed upon but does so with little indication of how those terms evolved during the course of the discussions/negotiations.

Response: The Company acknowledges the Staff’s comment and has revised the disclosures on pages 153 through 159 in response thereto.

2. *We note your revised disclosure on page 158 where you discuss the subsequent PIPE financing arrangement and related subscription agreements that you entered into on January 18, 2022. Please expand your discussion in the background section to provide detail on the negotiation and marketing processes for this subsequent PIPE transaction.*

Response: The Company acknowledges the Staff’s comment and has revised the disclosures on page 159 in response thereto.

Comparable Public Companies, page 164

3. *We acknowledge the additional information provided in your response to prior comment 24 but continue to have difficulty in understanding the relevance of the “TAM—Current Pipeline” (market opportunity) for Alvotech. Please quantify the estimate of peak WW sales from 2021-2026 for each of your biosimilar products, as assumed in your forecast on page 168, and the estimate of peak WW sales from 2021-2026 for each of the corresponding reference products. Also, on page 169 you state that global markets for biologic and biosimilar medicines are forecasted to grow to approximately \$555 billion and \$80 billion by 2026, respectively. It is not clear how the combined estimated peak global sales of the product candidates in your pipeline could be \$85.5 billion when the global market for biosimilar medicines is forecasted to reach \$80 billion by 2026. Explain the relationship between these amounts. Revise your presentation accordingly.*

Response: The Company acknowledges the Staff’s comment about the relevance of the “TAM – Current Pipeline” figures on page 166 and has revised its disclosure to explain how and why target markets for products in the biosimilar industry are described in relation to estimated peak sales of corresponding originator products.

The Company further notes the Staff’s request to quantify peak worldwide sales from 2021-2026 for each of its biosimilar products, and the estimate of peak worldwide sales from 2021-2026 for each corresponding reference originator product. In response thereto, the Company has revised the disclosure on pages 170 through 171 to include tabular disclosure of peak actual and estimated revenues for the originator medicines addressed by the Company’s development pipeline in each year from 2021-2026, as provided by Evaluate Pharma.

Nevertheless, the Company respectfully advises the Staff that it is unable for competitive reasons to disclose estimated peak worldwide sales of each of its biosimilar products from 2021-2026.

As described elsewhere in Amendment No. 2, much like generic drugs, biosimilars offer a lower cost alternative to their name-brand reference products. Unlike developers of originator products that quite often are creating their own market with no existing competition, the Company is not developing a new innovative product. Instead, biosimilars enter into direct competition with what is typically a large-scale incumbent producer. This results in the biosimilar market being characterized by fundamentally different development, regulatory, legal and commercial attributes as compared to originator businesses where a brand new, intellectual property protected, pharmaceutical product is being developed.

Estimates of peak sales of the Company's biosimilar medicines, as with all biosimilars, depend on several factors, including (1) peak sales of the relevant originator medicine, as adjusted for the proposed discounted price of the biosimilar medicine; (2) the market share ultimately achieved by the biosimilar medicine; (3) Alvotech's share of in-market sales from its commercial partners; (4) estimated launch date; and (5) the product's probability of success ("POS"). As discussed in turn below (with the exception of POS, which is discussed in the Company's response to Comment 6), each of these elements are highly confidential elements of the Company's commercial strategy that the Company believes would be harmful to its business interests and therefore also harmful to its future public company investors if disclosed publicly.

Within the biosimilars industry, pricing is a key element of commercial strategy and assumptions around pricing are therefore confidential and highly sensitive information until a biosimilar medicine has launched and a price for the medicine has been publicly announced. As a result, we believe that such pricing information should not be disclosed as competitors could use that information to undercut the Company's products on the basis of price. Nevertheless, in response to the Staff's comment, the Company has disclosed expected originator market size by year as measured by peak sales of those products, with a sensitivity analysis using different pricing erosion assumptions. In addition, the Company has provided historical pricing data for biosimilar launches to contextualize this presentation and indicated that the biosimilar price discounts assumed in the Company's forecasts are greater than the average historical market examples provided. The Company believes that investors can assess expected pricing and resulting biosimilar market size based on these disclosures.

The pricing of a biosimilar medicine is also a major determinant of the market share that the biosimilar medicine achieves, which also renders assumptions regarding market share highly confidential and competitively sensitive. While the Company believes it would be harmful to the Company and its investors and is therefore not in a position to provide precise assumptions for competitive reasons, the Company has disclosed in response to the Staff's comment that its projections assume market share ranging from high-single digits to 20% in certain cases. With respect to its share of revenue, the Company has also disclosed that it receives on average 40% of in-market sales from its commercial partners.

The other significant factor in determining peak sales of biosimilar medicines is the date of commercial launch of the biosimilar product. The date of estimated launch of a biosimilar product is also competitively sensitive that the Company must protect. Because biosimilars enter into direct competition with what is typically a large-scale incumbent producer, that is, the originator product company, a sensitive legal pathway must typically be successfully traversed in order to launch a biosimilar, much like in the generic space. Alvotech may need to, from time to time, engage in patent litigation (e.g. under the Biologics Price Competition and Innovation Act in the United States) with the originator before launching a biosimilar. Other IP litigation is also

possible, including those adverse to non-originator third-party competitors that may hold patents allegedly infringed by Alvotech. These legal considerations are typically less relevant in the originator market, but are characteristic of the biosimilar industry where originators routinely seek to prevent more cost-effective biosimilar products from coming to market through such patent claims. The timing of any particular biosimilar launch depends largely on the Company's ability to navigate the patent landscape, which may be achieved by litigation, settlement, or expiration of the patent exclusivity of the reference products, among other methods. The Company's recent litigation with AbbVie is a direct example of the dynamics articulated in this paragraph. As a result, the Company devotes significant resources to understanding when and under what circumstances a given biologic patent expires, and then the Company must establish a development, regulatory, and legal strategy contingent on that analysis. Such legal considerations are discussed elsewhere in Amendment No. 2.

In response to the Staff's comment and to assist investors in assessing the reasonableness of the projections provided to the OACB board of directors and management, the Company has revised its disclosure to provide launch date ranges between 12 and 24 months between anticipated timing between regulatory filing and product launch for each product. As disclosed elsewhere in the registration statement, the Company has a relatively short timeframe for its expected launches as it has disclosed that it plans to launch its first five product candidates by 2025. Further, the Company is committed to informing investors promptly when launch dates become certain as regulatory and legal pathways are clarified. The recent settlement agreement with AbbVie is again a compelling example, where the Company announced that it planned to enter the US market on July 1, 2023 following announcement of the settlement agreement.

In contrast to the biosimilars market, developers of originator products can publish estimates of the market size for each of the products they are developing and expected revenues based on announced estimated launch dates, but those estimates rarely make a difference to competitors as the originator is often times creating its own new market. However, in contrast and much like the generics market, each one of Alvotech's products is designed to take market share away from a product, the originator of which will be determined to maintain their market share. If the Company were to announce when it planned on launching a product, what it expected revenues to be in future years for those products and its contemplated pricing, market incumbents would triangulate their own competitive strategy against the Company on the basis of price or other factors. Further, developers and manufacturers of corresponding originator products would, in substance, be granted a roadmap as to when and how to enjoin future development of the Company's products, perhaps even years in advance. Such litigation or legal action could imperil the development of the Company's biosimilar products and would result in a material competitive disadvantage to the Company. As a result, the Company believes that the specific disclosure the Company is being asked to provide, would, if provided, undermine the information itself and invalidate the Company's assumptions and therefore not be in the best interests of the Company or its investors.

Due to these competitive concerns, the Company believes it would be detrimental to the interests of the Company and its investors to publicly quantify peak sales for each of its anticipated biosimilar product to the extent requested by the Staff as these disclosures could provide insight to competitors around highly sensitive elements of the Company's commercial strategy, including anticipated pricing and launch timing. Further, the Company believes that these unique legal and commercial dynamics of the biosimilar industry are very well understood by investors in the generics and biosimilars space, and thus this information would be beneficial mostly to the Company's competitors and not to its public investors.

The Company further acknowledges the Staff's comment regarding the estimated total biosimilars market size of approximately \$80 billion in 2026 relative to the total peak originator sales of \$85.5 billion that is addressed by the Company's current development pipeline. The Company respectfully advises the Staff that it believes that these figures are not directly comparable. Firstly, and most significantly, the \$80 billion of biosimilar market sales in 2026 represents the expected sales of biosimilar medicines in that year rather than peak originator sales for all biosimilars that are commercially available in 2026, which is expected to be significantly higher. Secondly, the peak originator sales figure is based on the pricing of the branded originator medicines, whereas the 2026 biosimilars market revenues reflects the pricing of the biosimilars that are commercially available at that point, which are typically priced at a discount to originator medicine prices. Where applicable, the Company has clarified that the \$85 billion figure relates to originator sales.

4. ***Please explain and quantify the expected impact of price erosion on "originator" branded biologic products as biosimilar products are introduced in these markets in each year over the next 3 years and your consideration of these market dynamics in determining "our product candidates' market opportunity" as you quantified on page 223. Also, describe and quantify the "historical market examples for biosimilars" that you reference on page 169. Revise your presentation accordingly.***

Response: The Company acknowledges the Staff's comment and, as described further in its response to Comment 3, has revised the disclosures on pages 171 through 173 to provide a price erosion sensitivity analysis by reference to corresponding originator product and to describe in general terms anticipated timing between regulatory filing and product launch. The Company has included a sensitivity analysis illustrating the potential impact on total biosimilar revenues for each of its pipeline candidates with respect to a range of potential price discount levels relative to the originator price based on peak sales between 2021 and 2026. In addition, the Company has also included quantitative and qualitative details of the "historical market examples for biosimilars".

Certain Unaudited Alvotech Prospective Financial Information, page 166

5. ***We acknowledge the additional information provided in your response to prior comment 25 but continue to believe that your presentation does not provide investors with sufficient information to evaluate the reasonableness of your financial projections. Please provide additional discussion that facilitates an understanding of the risk that estimates underlying your forecasted market share, revenue and adjusted EBITDA are sensitive to changes in underlying assumptions and quantify the impact on your forecast, resulting from likely variability in these assumptions. Also, provide additional discussion that facilitates an understanding of the progression in each year over the period 2022 through 2025 of growth in market share, revenue and adjusted EBITDA, including underlying changes in percentages for cost of goods sold and operating costs. In addition, provide us the following information and revise your presentation accordingly.***
- ***Identify the principal target markets and quantify estimated revenues for each market by 2025.***
 - ***Describe the expected timing for regulatory approval of your seven pipeline products and subsequent commercialization activities in each of the principal target markets.***
 - ***Provide a breakdown of forecasted 2025 revenues by product for each market.***

- ***Discuss the key market dynamics underlying price erosion affecting reference products associated with your biosimilar products during the period 2022 through 2025 and quantify the degree of price erosion by product and principal market that is expected by 2025.***
- ***Provide a breakdown of future milestone payments aggregating \$916 million by type and year.***
- ***Explain whether alternate financial projections were prepared, acknowledging your statement that “no alternative financial projections were considered by OACB’s Board.”***

Response: The Company acknowledges the Staff’s comment and has revised the disclosures on pages 171 through 173 to include additional discussion of certain requested elements of our financial projections.

The Company acknowledges the Staff’s comments regarding the progression in market share, revenue and adjusted EBITDA, including target market revenues, regulatory approval and product revenues, pricing erosion and expected pricing erosion during the period 2022 through 2025. As discussed in the Company’s response to Comment 3, the Company is unable to provide such information without causing competitive harm to its business and future prospects because any one of these elements would reveal anticipated product launch timing and pricing information.

In response to the Staff’s comment, however, the Company has provided disclosure with respect to milestone payments, including dollar amounts to be collected by year and by type of milestone. In addition, the Company has revised its disclosure on page 175 to clarify that it estimates the Cost of Goods sold to be approximately 15% of total revenue by 2025 and that, ahead of launches, the Company expects to build up inventory to mitigate potential supply delays which, in the event the launches are delayed, may result in an unfavorable, or higher, Costs of Goods Sold as a percentage of revenues than currently estimated. The Company respectfully submits that it believes that providing more precise figures would disclose highly confidential information that informs margin and pricing information, which would be detrimental to the Company and its investors.

On the basis of these disclosures, the Company respectfully submits that it has provided all material information underlying the assumptions of its forecasts to the extent such information does not cause competitive harm. Where possible, the Company has provided additional disclosures and to aid investors in assessing the biosimilar industry and the Company.

6. ***We acknowledge the additional information provided in your response to prior comment 28 but continue to have difficulty in understanding how you determined probability of technical success (“POS”). Please describe and quantify the methods and key assumptions underlying your POS estimates for each development phase. In addition, expand your presentation as follows:***

- *Identify the “over a dozen biosimilars” developed by your management team in the past, describe the development time frame for each biosimilar product and quantify associated revenues generated upon its commercialization.*
- *Describe your experience with development of biosimilar products from each of your “host cell lines (CHO and SP2/0) and processes (Fed batch and perfusion),” identifying those products that did or did not achieve regulatory approval and commercialization.*
- *Describe the expected timing for pre-clinical, clinical and submission phase development, as well as regulatory approval and commercialization for each of your five pipeline products to be launched in more than 50 markets by 2025.*
- *Describe the significant risks associated with your planned development and regulatory approval processes, described on pages 215- 216, and provide data supporting your assertion that these processes for biosimilar products are “less uncertain relative to originator biologics.”*
- *Describe the significant risks governing successful future commercialization for your five biosimilar products, given the level of apparent competition described on pages 229-230, and explain how these risks were considered in determining your forecasts of Alvotech Revenue and Adjusted EBITDA on page 168.*

Response: The Company acknowledges the Staff’s comment and has expanded its disclosure on pages 173 to 175. The Company also respectfully advises the Staff that the probability of success (POS) assumptions applied by the Company are based on its management’s extensive experience and judgment acquired at other companies as applied to the Company’s development approach for biosimilars, and on the less uncertain development and regulatory pathway to commercialization inherent in biosimilars. Unlike innovative pharmaceutical companies, the goal of a biosimilar development program is to demonstrate biosimilarity between the proposed biosimilar product and the originator product, not to independently establish the safety and effectiveness of the proposed product.

As previously described in the Company’s response to prior comment 28, the Company follows a rigorous, stage-gate process designed to grant the organization confidence in a stage of product development before advancing to its next succeeding stage. The Company has expanded its disclosure on page 174 to 176 to describe in more detail this stage-gate process, by which management assigns an individual stage probability of success (each, a “Stage POS”). This risk adjustment factor is based on management experience and judgment with respect to development and regulatory risk. The Company is unaware of any market standard or norm for these figures, but Amendment No. 2 reflects management’s view on these risks on a product-by-product basis with a range from 75% to 100%.

In response to the Staff’s request to discuss “*the development time frame for each biosimilar product and quantify associated revenues generated upon its commercialization*” for the products that were developed and commercialized by Alvotech’s management team, the Company has clarified in Amendment No. 2 that these were in connection with their service in senior roles at former employers, Pfizer and Novartis/Sandoz, respectively, and not during their tenure at the Company. The Company therefore included revenue and sales information for Pfizer and Novartis/Sandoz for the years 2020 and 2021, as reported on their most recent annual reports filed with the SEC. The Company submits that it is not privy to more detailed information regarding the development time frames or revenues of its managers’ former employers and, even where such information is published, the Company is not in a position to ascertain its veracity. Moreover, the Company respectfully advises the Staff that it believes that this information is not material to

investors, as the Company's products will not necessarily follow the same or similar development and manufacturing processes, regulatory pathways, commercialization and distribution model and/or aim to establish the same originator products, which establishes addressable market.

In response to the Staff's comment regarding the experience with development of biosimilar products from each of your "host cell lines (CHO and SP2/0) and processes (Fed batch and perfusion)", the Company has clarified its experience with these cell lines in light of its status as a new company in the market.

In response to the Staff's request to discuss the "significant risks governing successful future commercialization for your five biosimilar products, given the level of apparent competition," the Company has added disclosure on page 175 to explain how, while competition was not considered to determine the POS of a product candidate, the Company's assumptions on market share incorporate our assessment of competition risk, as further described in the Company's response to Comment 3.

Business of Alvotech

Third Party Suppliers and Manufacturers, page 217

7. ***We note your revised disclosure in response to our prior comment 31. You state that "[t]he availability of master cell banks is critical to [y]our ability to manufacture products for the commercial market" and that "[s]hould [y]our cell banks (despite any redundancies) be compromised, [you] would be unable to produce usable products for patients in any market." Please expand your disclosure to explain what "master cell banks" are and to describe why they are critical to your operations. Please also revise your risk factor disclosure to cover the particular risk posed to your business by your dependence on master cell banks.***

Response: The Company acknowledges the Staff's comment and has expanded the disclosure on pages 58 and 223 regarding master cell banks.

Commercial partnerships, page 219

8. ***We note your response to our prior comment 32 and reissue the comment in part. For each of your partnership agreements as described on pages 219-222 and 274-275, please expand your disclosure to ensure that you are disclosing all material terms, including the following:***
- *the nature and scope of any intellectual property transferred;*
 - *each parties' rights and obligations;*
 - *quantification of all up-front or execution payments received or paid to date;*
 - *aggregate amounts paid or received to date under the agreement;*
 - *aggregate amounts of all potential development, regulatory and commercial milestone payments;*
 - *quantification of the royalty rate, or a range no greater than 10 percentage points per tier;*
 - *disclosure of the duration of the agreement and when royalty provisions expire; and*
 - *disclosure of termination provisions.*

For example, we note your description of your agreement with Fuji Pharma where you state that "Fuji Pharma agreed to make certain payments to Alvotech upon the achievement of certain milestones [...]," and your description of your partnership with Biosana where you state that "[you] have agreed to make certain tiered royalty payments to Biosana," however, you do not quantify the aggregate amount of these potential milestone payments or royalty rates.

Response: The Company acknowledges the Staff's comment and, in response thereto, has expanded the disclosure on pages 225 through 232 and 284 through 287 to clarify that no intellectual property rights are transferred under the partnership agreements unless noted otherwise, and to describe the nature and scope of transferred intellectual property, each party's material rights and obligations, payments received upon execution of the agreements aggregated per partnership, royalty rates, the duration of each agreement and when royalty provisions expire, and termination provisions. In addition, the Company has revised its disclosure to quantify amounts of upfront and milestone payments received or paid as of December 31, 2021 (which equals to total amounts paid or received to date under the partnership agreements) on an aggregate basis per partnership. However, the Company respectfully advises the Staff that it has not quantified future milestone amounts for certain partnerships that it deems to be individually not material to the Company's historical performance or prospects. While the Company has indicated amounts received upon execution of the agreements with such other partners, future milestone payments for such other partnerships combined amount to \$90.1 million, or only approximately 11% of the \$915 million the Company expects to receive as future milestone payments under all its partnerships combined. No partnership for which such information on the individual level was omitted represents more than 3.7% of the amount of future milestones for all partnerships combined.

The Company also respectfully advises the Staff that it has not provided these amounts per partnership with respect to all potential development, regulatory and commercial milestone payments because the Company believes that presenting such figures, even on an aggregated basis per partnership, would place the Company at a competitive disadvantage with respect to any future partners with whom it may negotiate such fees. In addition, the Company respectfully submits that it does not believe disclosure of such figures is material to investors, nor were such figures disclosed to the OACB board of directors in connection with their approval of the business combination.

Our Pipeline, page 222

9. ***We note your response to our prior comment 34 and reissue the comment in part. To the extent that all 8 of your product candidates are material, please revise your pipeline table to identify all 8 candidates. Alternatively, revise your summary to indicate you have 6 material product candidates in development and remove these two undisclosed programs from your pipeline table.***

Response: The Company acknowledges the Staff's comment and has revised its disclosure in part to remove the pipeline table.

The Company further respectfully advises the Staff that, in order to accurately inform investors about its pipeline, it continues to make reference to AVT16 and AVT33 and the general market opportunities that these product candidates potentially represent, because the Company has entered and expects to enter into future commercial partnerships with respect to these two programs and the Company expects such partnerships will generate milestone payments. While the Company has not included any estimated future revenues for these products in its financial projections, it has included the significant expected R&D expenses for these products in its financial projections, and has incurred and expects to incur significant R&D expenses with respect to these potential product candidates. Thus, the Company believes it is appropriate to include general references to these products when discussing its pipeline.

10. ***We note your response to our prior comment 35. For each serious treatment-emergent adverse event, clearly describe the event including whether it was assessed as drug-related.***

Response: The Company acknowledges the Staff's comment and has revised its disclosure on page 234 to include descriptions of the disclosed serious treatment-emergent adverse events and whether they were assessed as drug related.

11. ***We note your response to our prior comment 36 and reissue the comment. In particular, please revise the text of the legend contained in the bottom left of the graphic as it does not currently appear to be legible.***

Response: The Company acknowledges the Staff's comment and has revised the graphic and legend on page 234.

12. ***We note your response to our prior comment 37 and reissue the comment in part. We also note your disclosure with respect to your agreements with STADA and Teva where you state that you have received \$32.8 million and \$75 million, respectively, in upfront and milestone payments combined. Please revise your disclosure to distinguish between aggregate amounts received to date for upfront payments and for milestone payments, providing separate amounts for each.***

Response: The Company acknowledges the Staff's comment and has expanded the disclosure on pages 237 through 239 regarding its partners.

13. ***We note your response to our prior comment 39 and reissue the comment in part. With respect to the two categories of patent applications that you have pending related to you AVT02 product, please also disclose the type of patent protection for which you are applying such as composition of matter, use or process.***

Response: The Company acknowledges the Staff's comment and revised the disclosures on page 241 to clarify that the pending patent applications are for composition of matter (formulations).

* * * *

Please direct any questions or comments regarding the foregoing or with respect to Amendment No. 2 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.
Tanya Zharov, Alvotech Lux Holdings S.A.S.
Michal Berkner, Cooley LLP
Divakar Gupta, Cooley LLP
Christian O. Nagler, Kirkland & Ellis LLP
Peter Seligson, Kirkland & Ellis LLP
Allison Gallagher, Kirkland & Ellis LLP