



DIVISION OF
CORPORATION FINANCE

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

February 25, 2022

Robert Wessman
Executive Chairman
Alvotech Lux Holdings S.A.S.
9, Rue de Bitbourg
L-1273 Luxembourg
Grand Duchy of Luxembourg

**Re: Alvotech Lux Holdings S.A.S.
Amendment No. 1 to Registration Statement on Form F-4
Filed February 4, 2022
File No. 333-261773**

Dear Mr. Wessman:

We have reviewed your amended 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments. Unless we note otherwise, our references to prior comments are to comments in our January 18, 2022 letter.

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.

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.

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.
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.

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.”
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.

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.

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.

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.

Robert Wessman
Alvotech Lux Holdings S.A.S.
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Our Programs, page 223

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.

AVT02, our high-concentration biosimilar to Humira, page 224

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.

Material Agreements, Partnerships and Suppliers, page 227

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.

Intellectual Property , page 230

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.

You may contact Franklin Wyman at (202) 551-3660 or Vanessa Robertson at (202) 551-3649 if you have questions regarding comments on the financial statements and related matters. Please contact Jessica Ansart at (202) 551-4511 or Jeffrey Gabor at (202) 551-2544 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Nicolas Dumont