
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the Month of September 2023

Commission File Number: 001-41421

Alvotech

(Translation of registrant's name into English)

**9, Rue de Bitbourg,
L-1273 Luxembourg,
Grand Duchy of Luxembourg
(Address of principal executive office)**

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F Form 40-F

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

Incorporation by Reference

This Report on Form 6-K (this “Report”) of Alvotech (the “Company”), excluding Exhibit 99.1 attached hereto, shall be deemed to be incorporated by reference into the Company’s registration statements on Forms F-3 (File Nos. 333-266136 and 333-273262) and the Company’s registration statement on Form S-8 (File No. 333-266881) and to be a part thereof from the date on which this Report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit 99.1 to this Report is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

Press Release

On September 20, 2023, Alvotech issued a press release (“Press Release”) announcing that the U.S. Food and Drug Administration (“FDA”) has accepted Alvotech’s resubmitted Biologics License Application (BLA) for AVT02, Alvotech’s high-concentration, interchangeable biosimilar candidate to Humira® (adalimumab). The FDA also announced that February 24, 2024 would be the Biosimilar User Fee Act (BsUFA) goal date for approval of the resubmitted AVT02 BLA. The FDA indicated that Alvotech’s resubmission is considered to be a complete response to the agency’s June 28, 2023, action letter, given the additional Chemistry, Manufacturing and Controls information submitted by Alvotech with the BLA to address manufacturing facility deficiencies identified earlier by the FDA. A copy of the Press Release is furnished herewith as exhibit 99.1.

Cautionary note on forward-looking statements

This Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “may,” “will,” “expect,” “plan,” “anticipate,” “estimate,” “intend” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on the Company’s expectations and assumptions as of the date of this Report. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from those expressed or implied by these forward-looking statements. For a discussion of risk factors that may cause the Company’s actual results to differ from those expressed or implied in the forward-looking statements in this Report, you should refer to the Company’s filings with the U.S. Securities and Exchange Commission, including the “Risk Factors” sections contained therein. Except as required by law, the Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing the Company’s views as of any date subsequent to the date of this Report.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated September 20, 2023.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALVOTECH

Date: September 21, 2023

By: /s/ Tanya Zharov

Name: Tanya Zharov

Title: General Counsel



Alvotech Provides U.S. Regulatory Update on AVT02, a High-Concentration Interchangeable Biosimilar Candidate to Humira® (adalimumab)

REYKJAVIK, Iceland, September 20, 2023 - Alvotech (NASDAQ: ALVO, or the "Company"), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, announced today that the U.S. Food and Drug Administration (FDA) has accepted Alvotech's resubmitted Biologics License Application (BLA) for AVT02, a high-concentration, interchangeable biosimilar candidate to Humira® (adalimumab). The FDA has also announced a Biosimilar User Fee Act (BsUFA) goal date for approval of the resubmitted AVT02 BLA.

The BsUFA goal date provided by the FDA is February 24, 2024. The FDA indicated that Alvotech's resubmission is considered to be a complete response to the agency's June 28, 2023, action letter, given the additional Chemistry, Manufacturing and Controls information submitted by Alvotech with the BLA to address manufacturing facility deficiencies identified earlier by the FDA.

"We remain committed to bringing AVT02 to patients in the U.S., where the need for a high-concentration, interchangeable biosimilar to Humira remains significant and unmet," said Robert Wessman, Chairman and CEO of Alvotech. "No deficiencies in our BLA have been noted by the FDA other than those associated with our facility. We now await further guidance from the FDA on timing of a reinspection, which we expect to occur in advance of the BsUFA date."

An interchangeable biosimilar may be substituted at the pharmacy without the intervention of the healthcare professional who prescribed the originator biologic, subject to variations in state pharmacy laws and practices. No interchangeable high-concentration adalimumab biosimilar is currently available to U.S. patients.

About AVT02 (adalimumab)

AVT02 is a monoclonal antibody and that has been approved as a biosimilar to Humira® (adalimumab) in several countries globally, including the 27 member states of the European Union, Norway, Lichtenstein, Iceland, the UK, Switzerland, Canada, Australia, Egypt and Saudi Arabia. It is currently marketed in multiple European countries and in Canada. Dossiers are also under review in multiple countries globally.

About Alvotech

Alvotech is a biotech company, founded by Robert Wessman, focused solely on the development and manufacture of biosimilar medicines for patients worldwide. Alvotech seeks to be a global leader in the biosimilar space by delivering high quality, cost-effective products, and services, enabled by a fully integrated approach and broad in-house capabilities. Alvotech's current pipeline contains eight biosimilar candidates aimed at treating autoimmune disorders, eye disorders, osteoporosis, respiratory disease, and cancer. Alvotech has formed a network of strategic commercial partnerships to provide global reach and leverage local expertise in markets that include the United States, Europe, Japan, China, and other Asian

countries and large parts of South America, Africa and the Middle East. Alvotech's commercial partners include Teva Pharmaceuticals, a US affiliate of Teva Pharmaceutical Industries Ltd. (US), STADA Arzneimittel AG (EU), Fuji Pharma Co., Ltd (Japan), Advanz Pharma (EEA, UK, Switzerland, Canada, Australia and New Zealand), Cipla/Cipla Gulf/Cipla Med Pro (Australia, New Zealand, South Africa/Africa), JAMP Pharma Corporation (Canada), Yangtze River Pharmaceutical (Group) Co., Ltd. (China), DKSH (Taiwan, Hong Kong, Cambodia, Malaysia, Singapore, Indonesia, India, Bangladesh and Pakistan), YAS Holding LLC (Middle East and North Africa), Abdi Ibrahim (Turkey), Kamada Ltd. (Israel), Mega Labs, Stein, Libbs, Tuteur and Saval (Latin America) and Lotus Pharmaceuticals Co., Ltd. (Thailand, Vietnam, Philippines, and South Korea). Each commercial partnership covers a unique set of product(s) and territories. Except as specifically set forth therein, Alvotech disclaims responsibility for the content of periodic filings, disclosures and other reports made available by its partners. For more information, please visit www.alvotech.com. None of the information on the Alvotech website shall be deemed part of this press release.

Forward-Looking Statements

Certain statements in this communication may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements generally relate to future events or the future financial operating performance of Alvotech and may include, for example, Alvotech's expectations regarding competitive advantages, business prospects and opportunities including pipeline product development, future plans and intentions, results, level of activities, performance, goals or achievements or other future events, regulatory review and interactions, the satisfactory responses to the FDA's inspection findings and resolution of other deficiencies conveyed following the inspection of Alvotech's manufacturing site, the potential approval and commercial launch of its product candidates, the timing of regulatory approval and market launches, and the estimated size of the total addressable market of Alvotech's pipeline products. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expect", "intend", "will", "estimate", "anticipate", "believe", "predict", "potential", "aim" or "continue", or the negatives of these terms or variations of them or similar terminology. Such forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by Alvotech and its management, are inherently uncertain and are inherently subject to risks, variability, and contingencies, many of which are beyond Alvotech's control. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (1) the outcome of any legal proceedings that may be instituted against Alvotech or others following the business combination between Alvotech Holdings S.A., Oaktree Acquisition Corp. II and Alvotech; (2) the ability to maintain stock exchange listing standards; (3) changes in applicable laws or regulations; (4) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (5) Alvotech's estimates of expenses and profitability; (6) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (7) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (8) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (9) the ability of Alvotech or its partners to enroll and retain patients in clinical studies;

(10) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (11) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (12) Alvotech's ability to obtain and maintain regulatory approval or authorizations of its products, including the timing or likelihood of expansion into additional markets or geographies; (13) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (14) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (15) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (16) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (17) the potential impact of the ongoing COVID-19 pandemic on the FDA's review timelines, including its ability to complete timely inspection of manufacturing sites; (18) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, war in Ukraine and global geopolitical tension, and the ongoing and evolving COVID-19 pandemic on the Company's business, financial position, strategy and anticipated milestones; and (19) other risks and uncertainties set forth in the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in documents that Alvotech may from time to time file or furnish with the SEC. There may be additional risks that Alvotech does not presently know or that Alvotech currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. Nothing in this communication should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. Alvotech does not undertake any duty to update these forward-looking statements or to inform the recipient of any matters of which any of them becomes aware of which may affect any matter referred to in this communication. Alvotech disclaims any and all liability for any loss or damage (whether foreseeable or not) suffered or incurred by any person or entity as a result of anything contained or omitted from this communication and such liability is expressly disclaimed. The recipient agrees that it shall not seek to sue or otherwise hold Alvotech or any of its directors, officers, employees, affiliates, agents, advisors, or representatives liable in any respect for the provision of this communication, the information contained in this communication, or the omission of any information from this communication.

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