# 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 February 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**

**European Medicines Agency (EMA) Confirms Acceptance of Application for AVT04, a Proposed Biosimilar to Stelara® (ustekinumab)**

On February 9, 2023, Alvotech announced that the European Medicines Agency (the "EMA") has accepted a Marketing Authorization Application for AVT04, Alvotech's proposed biosimilar to Stelara® (ustekinumab). Alvotech and STADA anticipate that the EMA could recommend approving a marketing authorization for AVT04 as soon as in the second half of 2023. A copy of the press release is attached hereto as Exhibit 99.1.

**Forward Looking Statements**

Certain statements in this Report on Form 6-K (the "Report") 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 and may include, for example, Alvotech's expectations regarding regulatory review and interactions, the timing of the review of the marketing authorization application, and the potential recommendation for AVT04 by the EMA. 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) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (8) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (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 Report 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 Report. 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 Report 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 Report, the information contained in this Report, or the omission of any information from this Report.

**INCORPORATION BY REFERENCE**

The Company hereby incorporates by reference the information contained in the body of this Report on Form 6-K into the Company's registration statements on Form S-8 (File No. 333-266881) of Alvotech 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.

## EXHIBIT INDEX

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release dated February 9, 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: February 9, 2023

By: /s/ Tanya Zharov
Name: Tanya Zharov
Title: General Counsel

**Press release**

**EMA Confirms Acceptance of Application for AVT04, a Proposed Biosimilar to Stelara® (ustekinumab)**

- Partners Alvotech and STADA have marketing authorization application (MAA) for ustekinumab accepted for filing by the European Medicines Agency (EMA)
- EMA opinion on AVT04 could come as soon as the second half of 2023
- Reference product Stelara® (ustekinumab) is prescribed to treat a variety of inflammatory conditions

**Reykjavik, Iceland & Bad Vilbel, Germany –February 9, 2023** – Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, and global pharmaceutical company STADA Arzneimittel (STADA) today announced that the European Medicines Agency (EMA) has accepted a Marketing Authorization Application for AVT04, Alvotech's proposed biosimilar to Stelara® (ustekinumab). The companies anticipate that the EMA could recommend approving a marketing authorization for AVT04 as soon as in the second half of 2023.

"We are pleased to be able to move closer to making AVT04 available to patients in Europe," said Joseph McClellan, Chief Scientific Officer of Alvotech. "Our goal is to meet an increasing need for broader access to affordable biologic medicines and Alvotech's end-to-end biosimilars platform is designed to support the development and manufacture of multiple products simultaneously."

"The EMA's acceptance for filing marks a key milestone in making an additional treatment option for inflammatory conditions available to patients and physicians in Europe," commented STADA's Head of Specialty, Bryan Kim. "Authorization for ustekinumab would add to STADA's extensive range of six approved biosimilars in Europe, a portfolio that includes a high-concentration, citrate-free of adalimumab brought to market through our strategic partnership with Alvotech."

In November 2019, Alvotech and STADA announced a strategic partnership to commercialize eight biosimilar candidates developed by Alvotech in Europe. As of December 2022, the companies had launched marketing and sales of the first biosimilar in the partnership, high-concentration adalimumab, in 16 countries in Europe.

In May 2022, Alvotech announced that a confirmatory clinical, safety and efficacy study for AVT04 had met its primary endpoint, in demonstrating therapeutic equivalence between Alvotech's biosimilar candidate and the reference product in patients with moderate to severe chronic plaque-type psoriasis. Earlier in May 2022, Alvotech also announced positive top-line results from a pharmacokinetic (PK) similarity study for AVT04.

* Stelara® is a registered trademark of Johnson & Johnson

**About AVT04 (ustekinumab)**

AVT04 is a monoclonal antibody and a biosimilar candidate to Stelara® (ustekinumab). Ustekinumab binds to two cytokines, IL-12 and IL-23, that are involved in inflammatory and immune responses [1]. AVT04 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

[1] https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf

**About STADA Arzneimittel AG**

STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of generics, specialty pharma and non-prescription consumer healthcare products. Worldwide, STADA Arzneimittel AG sells its products in approximately 120 countries. In financial year 2021, STADA achieved group sales of EUR 3,249.5 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 776.5 million. As of 31 December 2021, STADA employed 12,520 people worldwide.

Executive Board: Peter Goldschmidt (CEO) / Simone Berger / Miguel Pagan Fernandez / Boris Döbler
Chairman of the Supervisory Board: Dr. Günter von Au

**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), 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**

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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) changes in applicable laws or regulations; (3) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (4) Alvotech’s estimates of expenses and profitability; (5) Alvotech’s ability to develop, manufacture and commercialize the products and product candidates in its pipeline, including AVT04; (6) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (7) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (8) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (9) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (10) the ability of Alvotech’s partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (11) Alvotech’s ability to obtain and maintain regulatory approval or authorizations of its products, including AVT04, including the timing or likelihood of expansion into additional markets or geographies; (12) the success of Alvotech’s current and future collaborations, joint ventures, partnerships or licensing arrangements, including the partnership with STADA; (13) Alvotech’s ability, and that of its commercial partners, to execute their commercialization strategy for approved products, including AVT04; (14) Alvotech’s ability to manufacture sufficient commercial supply of its approved products, including AVT04; (15) the outcome of ongoing and future litigation regarding Alvotech’s products and product candidates; (16) 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; and (17) 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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