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 August 2022

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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

Press Release

On August 25, 2022, Alvotech announced the initiation of a confirmatory patient study for its product candidate AVT03.

This Report on Form 6-K, including Exhibit 99.1 hereto, shall be deemed to be incorporated by reference into the registration statement on Form S-8 (File No. 333-266881) of Alvotech and to be a part thereof from the date on which this report is furnished, to the extent not superseded by documents or reports subsequently filed or furnished.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated August 25, 2022.

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: August 25, 2022

By: /s/ Tanya Zharov
Name: Tanya Zharov
Title: Deputy Chief Executive Officer

Alvotech Initiates Confirmatory Patient Study for AVT03, a Proposed Biosimilar for Prolia® and Xgeva®

- *Alvotech has now entered four biosimilar candidates into confirmatory patient studies*
- *Combined sales of Prolia® and Xgeva® (denosumab) which are used to treat bone diseases were nearly $5.3 billion in 2021*

REYKJAVIK, ICELAND (August 25, 2022) – Alvotech (NASDAQ: ALVO), a global biotech company specialized in the development and manufacture of biosimilar medicines for patients worldwide, announced today the initiation of a confirmatory patient study for AVT03 (denosumab), a biosimilar candidate to Prolia® and Xgeva®. The objective of the study is to demonstrate clinical similarity of AVT03 to Prolia® in terms of efficacy, safety, immunogenicity, and pharmacokinetics in postmenopausal women with osteoporosis. The results from this trial will be used to support additional indications for AVT03 to XGeva® based on extrapolation.

Prolia® (denosumab) is indicated for the treatment of osteoporosis in postmenopausal women and for bone loss in adult men and women at increased risk of fracture. Xgeva® (denosumab), which is the same biologic in a different presentation, is indicated for prevention of skeletal-related events such as pathological fractures in adults with advanced malignancies involving bone. It is also indicated for the treatment of giant cell tumor in bone. In 2021, combined net revenues worldwide from sales of Prolia® and Xgeva® were nearly US$5.3 billion.

“We are proud to be able to initiate the confirmatory patient study for AVT03, adding another important milestone in the development of our biosimilars portfolio. Alvotech’s growing biosimilars pipeline shows our commitment to improving people’s lives globally by increasing access to cost-effective biologic medicines,” said Mark Levick, CEO of Alvotech.

The AVT03-GL-C01 multicenter study is of randomized double-blind parallel design, with repeat dosing and 2 arms. Approximately 476 volunteers, postmenopausal women 50 years or older diagnosed with osteoporosis, will be randomly assigned between the two arms. Each participant will receive three doses of either AVT03 or Prolia, at six-month intervals. The primary outcome measure will be to demonstrate clinical similarity of AVT03 and Prolia® in terms of change from baseline in markers for bone mass density (BMD). While the primary endpoint will be measured at 12 months, all participants will be followed until an end of study visit after 18 months from the initial dose.

Alvotech’s current biosimilars portfolio targets autoimmune disease, eye disorders, bone disease, respiratory disease, and cancer. A biosimilar to Humira® (adalimumab) is already approved in Europe (Hukyndra®) and Canada (Simlandi®), and three biosimilar candidates including AVT03 have entered or completed confirmatory patient studies. The start of a pharmacokinetic study for AVT03 in healthy adult subjects was previously announced in July 2022.

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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.

About AVT03 (denosumab)

AVT03 is a human monoclonal antibody and a biosimilar candidate to Prolia® and Xgeva® (denosumab). Denosumab targets and binds with high affinity and specificity to the RANK ligand membrane protein, preventing the RANK ligand/RANK interaction from occurring, resulting in reduced osteoclast numbers and function, thereby decreasing bone resorption and cancer-induced bone destruction. AVT03 is an investigational product and has not received regulatory approval in any country. Biosimiliarity has not been established by regulatory authorities and is not claimed.

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 1955, 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, expected patient enrollment, the potential approval and commercial launch of its product candidates, the timing of the

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announcement of clinical study results, the commencement of patient studies, regulatory approvals 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" 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 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 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 product candidates, 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; (13) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (14) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (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

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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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