**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 June 2025**

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 [ X ]  Form 40-F [ ]

**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, 333-273262, and 333-275111 and 333-281684) 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Form S-8 (File No. 333-266881) and to be a part thereof from the date on which this Report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 June 25, 2025, Alvotech issued a press release announcing the positive topline results from a confirmatory efficacy study comparing AVT23 a proposed biosimilar to Xolair® (omalizumab), with the reference biologic. A copy of the Press Release is furnished herewith as exhibit 99.1.

**EXHIBIT INDEX**

| Exhibit Number | Description |
| --- | --- |
| 99.1 | Press Release dated June 25, 2025 |

## 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**
(Registrant)

Date: June 25, 2025

/s/ Tanya Zharov
Tanya Zharov
General Counsel

**Positive Top Line Results from Confirmatory Efficacy Study for Proposed Biosimilar to Xolair® (omalizumab)**

REYKJAVIK, Iceland and PISCATAWAY, N.J. and LONDON, June 25, 2025 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacturing of biosimilar medicines for patients worldwide, Kashiv Biosciences LLC ("Kashiv"), a fully integrated biopharmaceutical company headquartered in New Jersey, US, and Advanz Pharma Holdco Limited ("Advanz Pharma"), a UK-headquartered global pharmaceutical company with a strategic focus on specialty, hospital, and rare disease medicines, today announced positive topline results from a confirmatory efficacy study comparing AVT23 (ADL-018), a proposed biosimilar to Xolair® (omalizumab), with the reference biologic.

The randomized, double-blind, multicenter study assessed the efficacy, safety, and immunogenicity of AVT23 compared to Xolair® in patients with Chronic Spontaneous Urticaria (CSU), who remained symptomatic despite treatment with H1 antihistamines. The study met its primary endpoint, with data demonstrating equivalence of therapeutic endpoints and comparable safety between the biosimilar candidate and the reference biologic. Participants received subcutaneous doses of either 150 mg or 300 mg every four weeks over a 24-week period. A total of 600 patients were enrolled, and efficacy and safety were evaluated in 400 patients who received the confirmatory dose of 300 mg. The primary efficacy measure was the change from baseline in the weekly Itch Severity Score (ISS7) at Week 12 between the treatment groups of ADL-018 and reference product.

"The positive results from this confirmatory patient study represent an important step in the development of the Xolair® biosimilar candidate. We look forward to working with our partners to increase global patient access to this important medicine," said Joseph McClellan, Chief Scientific Officer of Alvotech.

"This marks a positive advancement for Kashiv's growing biosimilar pipeline in addition to its current portfolio of Releuko® and Fylnetra®. We look forward to collaborating with regulatory authorities to make this treatment available to patients," said Dr. Sandeep Athalye, Chief Executive Officer at Kashiv BioSciences, "We remain focused on delivering cost-effective, high-quality therapies to improve patient outcomes globally, working with commercial partners such as Alvotech and Advanz Pharma."

"The successful confirmatory efficacy results for the proposed biosimilar to XOLAIR® mark an important milestone in Advanz Pharma's ambition to expand patient access to specialty medicines across our core geographies, Europe, Canada, and Australia." said Nick Warwick, Chief Medical Officer at Advanz Pharma.

The UK Medicines and Healthcare Products Regulatory Agency (MHRA) has already validated and accepted the marketing authorization application (MAA) for AVT23 earlier this year, and the filing of an MAA with the European Medicines Agency (EMA) is expected before the end of the year.

**About AVT23**
AVT23 is a proposed biosimilar to Xolair® (omalizumab). Omalizumab is a humanized monoclonal antibody that targets free immunoglobulin E (IgE). Xolair®, which contains omalizumab, is indicated for severe persistent allergic asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), and IgE-mediated food allergy [1]. AVT23 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.

Alvotech partnered with Kashiv BioSciences for the development of the proposed Xolair® biosimilar, which is referred to as AVT23 by Alvotech and as ADL-018 by Kashiv Biosciences.

**Use of trademarks**
Xolair® is a registered trademark of Novartis AG.

**Sources**
[1] MHRA Product Information for Xolair®

**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. Two biosimilars, to Humira® (adalimumab) and Stelara® (ustekinumab) are already approved and marketed in multiple global markets. The current development pipeline includes nine disclosed 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), Dr. Reddy's (EEA, UK and US), Biogaran (FR), 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 https://www.alvotech.com. None of the information on the Alvotech website shall be deemed part of this press release.

For more information, please visit our investor portal, and our website or follow us on social media on LinkedIn, Facebook, Instagram, and YouTube.

**Alvotech 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 submissions, review and interactions, the potential approval and commercial launch of its product candidates, the timing of regulatory approval, and market launches. 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 ability get marketing approval for AVT23 in the UK and other jurisdictions; (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 impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, conflicts in Ukraine, the Middle East and other global geopolitical tension, on the Company's business, financial position, strategy and anticipated milestones; and (18) 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.

**About Advanz Pharma**

Partner of choice in specialty, hospital, and rare disease medicines. Advanz Pharma is a global pharmaceutical company with the purpose to improve patients' lives by providing and enhancing the specialty, hospital, and rare disease medicines they depend on. Our headquarters are in London, UK. We have commercial sales in more than 90 countries globally and have a direct commercial presence in more than 20 countries, including key countries in Europe, the US, Canada, and Australia, a Centre of Excellence in Mumbai, India, as well as an established global distribution and commercialization partner network. Advanz Pharma's product portfolio and pipeline comprises innovative medicines, biosimilars & specialty generics and originator brands. Our products cover a broad range of therapeutic areas, including hepatology, rheumatology, gastroenterology, anti-infectives, critical care, endocrinology, oncology, CNS, and, more broadly, rare disease medicines. Our ambition is to be a partner of choice for the commercialization of specialty, hospital, and rare disease medicines in Europe, Canada, and Australia. In line with our ambition, we are partnering with biopharma and development companies to bring medicines to patients. We can only achieve this due to our dedicated and highly qualified employees, acting in line with our company values of entrepreneurship, speed, and integrity.

**Advanz Pharma Forward Looking Statements**

Certain statements in this press release are forward-looking statements. These statements may be identified by words such as "anticipate", "expectation", "belief', "estimate", "plan", "target", "project", "will", "may", "should" or "forecast" and similar expressions, or by their context. Although Advanz Pharma believes that these assumptions were reasonable when made, by their

nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial consequences of the plans and events described herein. Actual results may differ from those set forth in the forward-looking statements as a result of various factors (including, but not limited to, future global economic conditions, changed market conditions affecting the industry, intense competition in the markets in which Advanz Pharma operates, costs of compliance with applicable laws, regulations and standards, diverse political, legal, economic and other conditions affecting Advanz Pharma's markets, and other factors beyond the control of Advanz Pharma. Neither Advanz Pharma nor any of its directors, officers, employees, advisors, or any other person is under any obligation to update or keep current the information contained in this press release or revise any forward-looking statements, whether as a result of new information, future events or otherwise. You should not place undue reliance on forward-looking statements, which speak of the date of this press release. Statements contained in this press release regarding past trends or events should not be taken as a representation that such trends or events will continue in the future. No obligation is assumed to update any forward-looking statements. The information contained in this press release is provided as at the date of this document and is subject to change without notice.

**About Kashiv BioSciences:**
Kashiv BioSciences, LLC is a vertically integrated biopharmaceutical company with numerous commercial and advanced clinical-stage assets and is among the few U.S.-based companies to both manufacture and receive marketing authorization for multiple biosimilars. Kashiv BioSciences, LLC in the USA, and its subsidiaries in India (together "Kashiv BioSciences") operate together with robust infrastructure and highly skilled teams that provide global R&D, clinical, manufacturing, regulatory, and IP capabilities. We believe our people, partners, and shared purpose fuel our work to advance patient care and access to important medicines.

**CONTACTS**

**Alvotech Investor Relations and Global Communications**
Benedikt Stefansson, VP
alvotech.ir@alvotech.com

**Advanz Pharma Global Corporate Communications**
Courtney Baines
courtney.baines@advanzpharma.com

**Kashiv Biosciences**
Dr. Paras Vasanani
paras.vasanani@kashivbio.com
https://www.kashivbiosciences.com/