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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

_____, Individually and on behalf of all others
similarly situated,

Plaintiff,

v.

ALVOTECH, and ROBERT WESSMAN,

Defendants.

Case No:

**CLASS ACTION COMPLAINT FOR
VIOLATIONS OF THE FEDERAL
SECURITIES LAWS**

JURY TRIAL DEMANDED

Plaintiff ____ (“Plaintiff”), individually and on behalf of all other persons similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, among other things, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants’ public documents, public filings, wire and press releases published by and regarding Alvotech (“Alvotech” or the “Company”), and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a class action on behalf of persons or entities who purchased or otherwise acquired publicly traded Alvotech securities between July 29, 2025 and November 12, 2025, inclusive (the “Class Period”). Plaintiff seeks to recover compensable damages caused by Defendant’s violations of the federal securities laws under the Securities Exchange Act of 1934 (the “Exchange Act”).¹

JURISDICTION AND VENUE

2. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act (15 U.S.C. §78aa).

4. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)) as the alleged misstatements entered and the subsequent damages took place in this judicial district.

5. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

¹ Unless otherwise stated all emphasis is added and internal citations are omitted.

PARTIES

6. Plaintiff ____, as set forth in the accompanying certification, incorporated by reference herein, purchased Alvotech securities during the Class Period and was economically damaged thereby.

7. Defendant Alvotech describes itself as a “global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide.”

8. Pertinent to this action is AVT05, which Alvotech describes as follows:

AVT05 is a biosimilar candidate for Simponi[®] and Simponi Aria[®] (golimumab). Golimumab is a monoclonal antibody that inhibits tumor necrosis factor alpha (TNF alpha). Elevated TNF alpha levels have been implicated in the pathophysiology of several chronic inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis [2]. AVT05 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.

9. Alvotech is incorporated in Luxembourg. Its head office is at 9, rue de Bitbourg L-1273, Luxembourg. Its operational headquarters are located at Saemundargata 15-19 102 Reykjavik, Iceland. Alvotech common stock trades on the Nasdaq Stock Market LLC (“NASDAQ”) under the ticker symbol “ALVO”.

10. Defendant Robert Wessman served as the Company’s Chief Executive Officer (“CEO”) and Chairman at all relevant times.

11. Defendant Robert Wessman is collectively referred to herein as the “Individual Defendant.”

12. The Individual Defendant:

- (a) directly participated in the management of the Company;
- (b) was directly involved in the day-to-day operations of the Company at the highest levels;

- (c) was privy to confidential proprietary information concerning the Company and its business and operations;
- (d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;
- (e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;
- (f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or
- (g) approved or ratified these statements in violation of the federal securities laws.

13. Alvotech is liable for the acts of the Individual Defendant and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of the Individual Defendant's employment.

14. The scienter of the Individual Defendant and other employees and agents of the Company is similarly imputed to the Company under *respondeat superior* and agency principles.

15. Alvotech and the Individual Defendant are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Materially False and Misleading Statements Issued During the Class Period

16. On July 28, 2025, after market hours, Alvotech filed with the SEC a current report on Form 6-K. It included the following statement:

From June 26, 2025 to July 4, 2025, the U.S. Food and Drug Administration (“*FDA*”), as an ordinary course of business, conducted a Pre-Approval Inspection at Alvotech’s manufacturing facility in Reykjavik, Iceland, for three Biologic License Applications (“*BLA*”) for AVT03, AVT05, and AVT06 and a Prior Approval Supplement to an approved BLA for AVT02, all of which that are currently under review by FDA. The inspection occurred at Alvotech’s manufacturing facility in Reykjavik, Iceland, from June 26 to July 4, 2025. At the conclusion of the inspection FDA inspection team issued a report to Alvotech’s management, which contains the team’s inspectional observations, a so-called “Form 483”. ***The observations relate to deficiencies in certain manufacturing operations and controls, instances of certain quality procedures not being followed, deficiencies in some documentation practices, laboratory controls and materials management procedures.*** Alvotech intends to fully address all observational topics identified.

Some of these observations relate to fact-specific historical occurrences, which have already been addressed by Alvotech, or other topics that have already been fully addressed since identified by FDA. Alvotech has provided a detailed response to FDA on July 25, 2025, as required. Alvotech will continue to work to ensure that its responses are satisfactory to FDA, to enable approval of the pending BLAs. Following the receipt of Alvotech's detailed response and plan of action, FDA can follow-up with additional questions, recommendations, or provide classification of the inspection.

17. The statement in ¶ 16 was materially false and misleading at the time it was made because Alvotech understated the seriousness of the FDA’s conclusions. Specifically, by stating that some of the FDA’s observations related to “historical occurrences” that had already been addressed, or other topics that had been fully addressed, Alvotech materially understated the gravity of the matter and the FDAs conclusions regarding deficiencies at Alvotech’s manufacturing facility in Reykjavik, Iceland.

18. The statement contained in ¶ 16 was materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company’s business, operations, and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) Alvotech materially understated the regulatory challenges facing it due to deficiencies at its manufacturing facility in Reykjavik, Iceland; and (2) as a result, Defendants’

statements about its business, operations, and prospects, were materially false and misleading and/or lacked a reasonable basis at all times.

THE TRUTH BEGINS TO EMERGE

19. On November 2, 2025, Alvotech issued a press release entitled “Alvotech Provides Update on the Status of U.S. Biologics License for AVT05.”

20. The press release stated, in part, the following:

[Alvotech announces that] the U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) for Alvotech’s Biologics License Application (BLA) for AVT05, in a prefilled syringe and autoinjector presentations, a biosimilar candidate to Simponi® (golimumab).

The CRL noted that certain deficiencies, which were conveyed following the FDA’s pre-license inspection of Alvotech’s Reykjavik manufacturing facility that concluded in July 2025, must be satisfactorily resolved before this BLA for AVT05 can be approved. The FDA did not identify any other deficiencies with the application. The facility remains FDA approved to manufacture and continues supplying currently commercialized products.

Sales of Simponi in the U.S. in the first half of 2025 were less than \$300 million, according to data published by IQVIA. Currently, there are no FDA approvals for a biosimilar to Simponi.

21. The press release quoted Defendant Wessman as stating the following:

As previously discussed, following the inspection of our facility, Alvotech submitted a comprehensive response to the FDA detailing our Corrective and Preventive Action (CAPA) plan. While we are disappointed in receiving the CRL, we expect to resolve any outstanding issues and will continue to work with the FDA to bring this first-to-market biosimilar to patients in the U.S.

22. The press release stated the following regarding the financial impact of this failure:

Following the receipt of the CRL, Alvotech has reevaluated its outlook for 2025. Total revenues in 2025 are now expected to be \$570-\$600 million and adjusted EBITDA \$130-\$150 million, ***lower than previously provided.*** The lowered adjusted EBITDA outlook is primarily driven by expected continuation of investments related to resolving certain facility issues, which also require a temporary slowdown in production. These investments, however, also serve to support Alvotech’s future growth plans and new product launches.

23. On this news, the price of Alvotech stock fell \$2.62 per share, or 34.24%, to close at \$5.03 on November 3, 2025, damaging investors. The next day, it fell a further \$0.20, or 3.97%, to close at \$4.83 on November 4, 2025.

24. On November 13, 2025, before the market opened, Alvotech held its Q3 2025 earnings call (the “Q3 Call”)

25. The Q3 2025 earnings call, more than four months after the statement on July 28, 2025 that materially downplayed the significance of the FDA’s findings, included the following statement from Joseph McClellan, who had been appointed Chief Scientific & Technical Officer in large part to fix the issues at the Reykjaving facility, in which he revealed the number of corrections that Alvotech had made in response to the FDA’s inspection:

This is Joe McClellan, Chief Operating Officer for Alvotech. We have been in a situation where we have done a significant number of improvements since the inspection has concluded. The observations were not repeat observations. Let me say it clearly. There were no repeat observations in the deficiencies identified in the Form 483 from the FDA at the conclusion of the inspection.

And so it's a number of things that we have to improve about the facility associated with some of our aspects associated with manufacturing, control of our facility, documentation, investigations. ***We have committed to the FDA to complete more than 180 different changes to address all of their observations plus more so that we will not be in the situation again.*** In doing this, we have now completed 93% of these commitments and we have communicated them to the FDA. ***We're in the process of completing additional actions that we will continue to keep the FDA updated on.***

26. The Q3 Call included the following exchange between an analyst from UBS and Defendant Wessman, in which the analyst questioned the strategic value of Alvotech keeping the Reykjavik facility, in light of the issues, signaling doubts about Alvotech’s viability:

Analyst: Got it. And just as a follow-up. So I know this Form 483, you have 10 observations. And even for Humira back a while ago, I think you ultimately climbed up to 18. Just taking a step back on the manufacturing facility, ***if this has been a little bit of a challenge, has that made you think about the strategic value of keeping the manufacturing in Iceland?***

I'm just trying to understand, is there something that is driven by less of an availability of pharma talent or anything of that regard, and whether if you would not have it at that location or at some other place, then it might ultimately solve the problem in the long run.

Defendant Wessman: Yes. Thank you for the question. Robert Wessman here, CEO. Overall, I mean, the concept and the vision and the strategy around the business is to keep everything in-house, both R&D and manufacturing. We think creating a platform like we have is extremely important. We can say that in U.S., we are around 18 months into being a commercial company, if you will. We have gone through 3 FDA inspections over the 18 months. And the first two, which was early '24, was only one 483. And then late last year, we had a general GMP inspection, which we only got 2 minor 483s.

So overall, I would say it was very disappointing to get this CRL and unexpected. But the company has continued to grow and strengthen further the quality systems, and we have full intention to absolutely stay and be best-in-class when it comes to GMP and quality. And I mean, that's reflected. We have gone through successfully 5 EMA inspections. We have gone through at least 4 inspections from different global health authorities and now 2 successful FDA inspections. [. . .]

27. On this news, Alvotech stock fell \$0.08 per share, or 1.4%, to close at \$5.52 on November 13, 2025.

28. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common shares, Plaintiff and the other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

29. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants who acquired Alvotech securities publicly traded on the NASDAQ during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

30. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds, if not thousands of members in the proposed Class.

31. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

32. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

33. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the Exchange Act was violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business and financial condition of the Company;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- whether the Defendants caused the Company to issue false and misleading filings during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false filings;
- whether the prices of the Company's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

34. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

35. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- the Company's securities met the requirements for listing, and were listed and actively traded on the NASDAQ, an efficient market;
- as a public issuer, the Company filed public reports;
- the Company communicated with public investors via established market communication mechanisms, including through the regular dissemination of press releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;
- the Company's securities were liquid and traded with moderate to heavy volume during the Class Period; and

- the Company was followed by a number of securities analysts employed by major brokerage firms who wrote reports that were widely distributed and publicly available.

36. Based on the foregoing, the market for the Company securities promptly digested current information regarding the Company from all publicly available sources and reflected such information in the prices of the common units, and Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

37. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information as detailed above.

COUNT I
For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder
Against All Defendants

38. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

39. This Count asserted against Defendants is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

40. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

41. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of the Company's securities during the Class Period.

42. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

43. Individual Defendants, who are or were senior executives and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other Company's personnel to members of the investing public, including Plaintiff and the Class.

44. As a result of the foregoing, the market price of the Company's securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of the Company's securities during the Class Period in purchasing the Company's securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.

45. Had Plaintiff and the other members of the Class been aware that the market price of the Company's securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased the Company's securities at the artificially inflated prices that they did, or at all.

46. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

47. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchase of the Company's securities during the Class Period.

COUNT II
Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants

48. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

49. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the

conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about the Company's misstatement of revenue and profit and false financial statements.

50. As officers of a public business, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

51. Because of their positions of control and authority as senior executives and/or directors, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period concerning the Company's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Company securities.

52. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, on behalf of himself and the Class, prays for judgment and relief as follows:

(a) declaring this action to be a proper class action, designating plaintiff as Lead Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and designating plaintiff's counsel as Lead Counsel;

(b) awarding damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, together with interest thereon;

(c) awarding plaintiff and the Class reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) awarding plaintiff and other members of the Class such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated:

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