



Alvotech Reports Financial Results for First Nine Months of 2023 and Provides a Business Update

November 28, 2023

- *Product revenue for the nine months of 2023 increased to \$29.8 million, compared to \$11.1 million for the same period in 2022*
- *Marketing authorization was received for AVT04 in Canada and Japan, the first for a biosimilar to Stelara[®] (ustekinumab)*
- *The European Medicines Agency proposed market authorization for AVT04 in the 30 member states of the European Economic Area, pending a final decision by the European Commission*
- *Approvability of AVT02 and AVT04 in the U.S. now pending satisfactory US Food and Drug Administration (FDA) inspection of Alvotech's facility in Iceland, currently expected on January 10 – 19, 2024*
- *Management will conduct a business update conference call and live webcast on Wednesday November 29, 2023, at 8:00 am ET (13:00 pm GMT)*

REYKJAVIK, Iceland, Nov. 28, 2023 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO, or the "Company"), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, today reported unaudited financial results for the first nine months of 2023 and provided a summary of recent corporate highlights.

"We continue to celebrate global biosimilar first, with approvals of AVT04, our biosimilar to Stelara[®], in Japan and Canada and a positive CHMP opinion in Europe, also the first for an ustekinumab biosimilar. We look forward to bringing our second product to global markets. We also continued to strengthen our pipeline with a new development and commercialization partnership for AVT23, a biosimilar candidate to Xolair[®], which has already entered into a confirmatory patient study," said Robert Wessman, Chairman and CEO of Alvotech. "A forthcoming FDA reinspection, scheduled for January 2024, sets the stage for potential approval of AVT02 in the U.S. by the BsUFA date in late February 2024. AVT02 is well positioned to be the first interchangeable high-concentration biosimilar to Humira[®] in the U.S. market. A satisfactory FDA inspection should also pave the way for approval of AVT04 in the U.S. by the end of April 2024, well in advance of the license entry date in February of 2025."

Recent Highlights

Alvotech and Fuji Pharma announced marketing approval in Japan for AVT04, a biosimilar to Stelara[®] (ustekinumab). This was the first approval of a biosimilar to Stelara in global markets.

Alvotech and JAMP Pharma also announced the receipt of a marketing authorization in Canada for AVT04. This is the first biosimilar to Stelara which receives marketing authorization in Canada, and the second approved biosimilar developed under the exclusive commercialization partnership between Alvotech and JAMP Pharma.

Alvotech and STADA Arzneimittel announced that the Committee for Medicinal Products for Human Use (CHMP) within the European Medicines Agency (EMA) adopted a positive opinion for AVT04. This is the first positive opinion issued by the EMA for a biosimilar to Stelara. Marketing authorization, which is pending final approval from the European Commission, would be valid across all 27 European Union (EU) member states, as well as in Iceland, Liechtenstein, and Norway.

Alvotech announced that the US Food and Drug Administration (FDA) accepted a resubmitted Biologics License Application (BLA) for AVT02, with a Biosimilar User Fee Act (BsUFA) goal date of February 24, 2024. Approval is pending FDA reinspection of Alvotech's facility, which is scheduled to take place on January 10-19, 2024.

Alvotech resubmitted BLA for AVT04, has also been accepted by the FDA, with a BsUFA goal date of April 16, 2024. Approval of AVT04 is also subject to a satisfactory outcome of the expected FDA facility reinspection in January 2024. According to a settlement agreement reached with Johnson & Johnson in June 2023, the U.S. license entry date for AVT04 is February 21, 2025.

Alvotech entered into an exclusive licensing agreement with Kashiv Biosciences for the development and commercialization of AVT23 a biosimilar candidate for Xolair[®] (omalizumab). Under the agreement, Kashiv will develop and manufacture AVT23, while Alvotech will leverage its global partnerships and market expertise for commercialization. Initiation of a confirmatory patient study has been announced by Kashiv, that will compare AVT23 and Xolair in terms of efficacy, safety, tolerability, and immunogenicity.

Financial Results for First Nine Months of 2023

Cash position and sources of liquidity: As of September 30, 2023, the Company had cash and cash equivalents of \$68.3 million, excluding \$25.2 million of restricted cash. In addition, the Company had borrowings of \$912.1 million, including \$13.6 million of current portion of borrowings, as of September 30, 2023. Gross proceeds of \$140 million from the private placement of convertible bonds, including Teva Pharmaceutical's subscription for \$40 million in a separate transaction, have been received during the third quarter 2023.

Product Revenue: Product revenue was \$29.8 million for the nine months ended September 30, 2023, compared to \$11.1 million for the same nine months of 2022. Revenue for the nine months ended September 30, 2023, consisted of product revenue from sales of AVT02 in select European countries and Canada.

License and Other Revenue: License and other revenue was \$8.2 million for the nine months ended September 30, 2023, compared to \$48.1 million for the same nine months of 2022. The decrease of \$39.9 million was primarily attributable to the recognition of a \$34.7 million research and development milestone during the same period in the prior year, due to the completion of the AVT04 main clinical program. The remainder of the decrease is principally due to the timing of development milestones and licensing arrangements.

Cost of product revenue: Cost of product revenue was \$104.4 million for the nine months ended September 30, 2023, compared to \$35.4 million for the same nine months of 2022, as a result of the successful launch of AVT02 in select European countries and Canada. Cost of product revenue for the quarter is disproportionate relative to product revenue due to the timing of new launches and elevated production-related charges, resulting in higher costs than revenues recognized for the period. The Company expects this relationship to normalize with increased production from the scaling and expansion of new or recent launches. The Company estimates that the anticipated increase in sales volumes will result in greater absorption of fixed manufacturing costs. Prior to the recognition of cost of product revenues, costs from pre-commercial manufacturing activities were reported as R&D expenses.

Research and development (R&D) expenses: R&D expenses were \$152.8 million for the nine months ended September 30, 2023, compared to \$133.1 million for the same nine months of 2022. The increase was primarily driven by a one-time charge of \$18.5 million relating to the termination of the co-development agreement with Biosana for AVT23, and a \$30.9 million increase in direct program expenses mainly from three biosimilar candidates, AVT03, AVT05, and AVT06, that entered clinical development in late 2022 and early 2023. These increases were partially offset by a decrease of \$28.3 million primarily related to programs that have completed clinical phase (i.e., AVT02 and AVT04).

General and administrative (G&A) expenses: G&A expenses were \$58.6 million for the nine months ended September 30, 2023, compared to \$156.5 million for the same nine months of 2022. The decrease in G&A expenses was primarily attributable to a \$83.4 million non-cash share listing expense, \$21.0 million of transaction costs recognized as a result of the Business Combination, and \$10.6 million of non-recurring IP-related legal expenses incurred during the nine months ended September 30, 2022. This decrease was partially offset by a \$9.3 million net increase in other general administrative expenses due to incremental costs from operating as a public company. Lastly, the Company recognized \$9.4 million in G&A expenses for share-based payments, resulting from the granting of Restricted Share Units (RSUs) during the nine months ended September 30, 2023.

Finance income: Finance income was \$46.4 million for the nine months ended September 30, 2023, compared to \$97.3 million for the same nine months of 2022. The change was primarily attributable to a decrease in the fair value of the derivative financial liabilities, resulting from a decrease in the price of Alvotech's ordinary shares.

Finance costs: Finance costs were \$107.8 million for the nine months ended September 30, 2023, compared to \$69.2 million for the same nine months of 2022. The increase was primarily attributable to interest charged on additional borrowings and convertible bonds issued during the nine months of 2023.

Exchange rate differences: Exchange rate differences resulted in a gain of \$0.9 million for the nine months ended September 30, 2023, compared to a gain of \$13.6 million for the same nine months of 2022. The decrease was primarily driven by the impact of the exchange rate on financial assets and liabilities denominated in Icelandic Krona and Euros.

Income tax benefit: Income tax benefit was \$67.1 million for the nine months ended September 30, 2023, compared to \$14.8 million for the same nine months of 2022. The increase was primarily driven by \$27.9 million deferred tax credit corresponding to an increase in operating losses, and a \$27.6 million favorable foreign currency impact due to strengthening of the Icelandic Krona against the U.S. dollar, increasing the U.S. dollar value of tax loss carry-forwards expected to be utilized against future taxable profits.

Loss for the Period: Net loss was \$275.2 million, or (\$1.21) per share on a basic and diluted basis, for the nine months ended September 30, 2023, as compared to net loss of \$193.1 million, or (\$1.00) per share on a basic and diluted basis, for the same nine months of 2022.

Business Update Conference Call

Alvotech will conduct a business update conference call and live webcast on Wednesday, November 29 at 8:00 am ET (13:00 GMT).

A live webcast of the call will be available on Alvotech's website in the Investors Section of the Company's website (<https://investors.alvotech.com>) under "News and Events – Events and Presentations", where you will also be able to find a replay of the webcast, following the call for 90 days.

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 AVT04 (ustekinumab)

AVT04 is a monoclonal antibody and a biosimilar to Stelara® (ustekinumab). Ustekinumab binds to two cytokines, IL-12 and IL-23, that are involved in inflammatory and immune responses [1]. AVT04 has received market authorization in Japan and Canada and has been proposed for approval by the European Medicines Authority. Dossiers are also under review in multiple countries globally.

About AVT23 (omalizumab)

AVT23 is a proposed biosimilar to Xolair® (omalizumab). Omalizumab is a humanized monoclonal antibody that targets free IgE, reducing the amount of free IgE that is available to trigger the allergic cascade [2]. AVT23 is an investigational compound 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>

[2] https://www.ema.europa.eu/en/documents/product-information/xolair-epar-product-information_en.pdf

Use of trademarks

Humira is a registered trademark of AbbVie Inc. Stelara is a registered trademark of Johnson & Johnson Inc. Xolair is a registered trademark of Novartis AG.

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 submissions, review and interactions, including the resubmission of BLAs for AVT02 and AVT04, a potential reinspection of Alvotech's manufacturing facility, 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, including for AVT04, 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 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 raise substantial additional funding, which may not be available on acceptable terms or at all; (3) the ability to maintain stock exchange listing standards; (4) changes in applicable laws or regulations; (5) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (6) Alvotech's estimates of expenses and profitability; (7) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (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 respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (10) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (11) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (12) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (13) 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; (14) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (15) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (16) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (17) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (18) 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; (19) 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 (20) 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.

CONTACTS

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Unaudited Condensed Consolidated Interim Statements of Profit or Loss and Other Comprehensive Income or Loss

**Nine months
ended**

**Nine months
ended**

| | 30 September 2023 | 30 September 2022 |
|--|-------------------------|-------------------------|
| <i>USD in thousands, except for per share amounts</i> | | |
| Product revenue | 29,800 | 11,060 |
| License and other revenue | 8,244 | 48,111 |
| Other income | 56 | 197 |
| Cost of product revenue | (104,437) | (35,362) |
| Research and development expenses | (152,813) | (133,140) |
| General and administrative expenses | (58,558) | (156,520) |
| Operating loss | <u>(277,708)</u> | <u>(265,654)</u> |
| Share of net loss of joint venture | (3,983) | (1,732) |
| Finance income | 46,383 | 97,299 |
| Finance costs | (107,826) | (69,200) |
| Exchange rate differences | 884 | 13,643 |
| Gain on extinguishment of financial liabilities | - | 17,800 |
| Non-operating profit / (loss) | <u>(64,542)</u> | <u>57,810</u> |
| Loss before taxes | <u>(342,250)</u> | <u>(207,844)</u> |
| Income tax benefit | 67,076 | 14,771 |
| Loss for the period | <u><u>(275,174)</u></u> | <u><u>(193,073)</u></u> |
| Other comprehensive loss | | |
| <i>Item that will be reclassified to profit or loss in subsequent periods:</i> | | |
| Exchange rate differences on translation of foreign operations | <u>(2,648)</u> | <u>(8,852)</u> |
| Total comprehensive loss | <u><u>(277,822)</u></u> | <u><u>(201,925)</u></u> |
| Loss per share | | |
| Basic and diluted loss for the period per share | <u>(1.21)</u> | <u>(1.00)</u> |

Unaudited Condensed Consolidated Interim Statement of Financial Position

| | 30 September 2023 | 31 December 2022 |
|---------------------------------|----------------------|---------------------|
| <i>USD in thousands</i> | | |
| Non-current assets | | |
| Property, plant and equipment | 235,091 | 220,594 |
| Right-of-use assets | 108,371 | 47,501 |
| Goodwill | 11,555 | 11,643 |
| Other intangible assets | 20,283 | 25,652 |
| Contract assets | 8,111 | 3,286 |
| Investment in joint venture | 42,035 | 48,568 |
| Other long-term assets | 1,957 | 5,780 |
| Restricted cash | 25,187 | 25,187 |
| Deferred tax assets | 277,838 | 209,496 |
| Total non-current assets | <u>730,428</u> | <u>597,707</u> |
| Current assets | | |
| Inventories | 81,995 | 71,470 |
| Trade receivables | 21,945 | 32,972 |
| Contract assets | 18,514 | 25,370 |
| Other current assets | 36,031 | 32,949 |

| | | |
|----------------------------------|----------------|----------------|
| Receivables from related parties | 1,591 | 1,548 |
| Cash and cash equivalents | 68,315 | 66,427 |
| Total current assets | 228,391 | 230,736 |
| Total assets | 958,819 | 828,443 |

Unaudited Condensed Consolidated Interim Statement of Financial Position

| <i>USD in thousands</i> | 30 September 2023 | 31 December 2022 |
|--|------------------------------|-----------------------------|
| Equity | | |
| Share capital | 2,271 | 2,126 |
| Share premium | 1,224,844 | 1,058,432 |
| Other reserves | 45,411 | 30,582 |
| Translation reserve | (4,090) | (1,442) |
| Accumulated deficit | (1,929,288) | (1,654,114) |
| Total equity | (660,852) | (564,416) |
| Non-current liabilities | | |
| Borrowings | 898,483 | 744,654 |
| Derivative financial liabilities | 359,861 | 380,232 |
| Other long-term liability to related party | 7,440 | 7,440 |
| Lease liabilities | 94,375 | 35,369 |
| Long-term incentive plan | - | 544 |
| Contract liabilities | 72,695 | 57,017 |
| Deferred tax liability | 63 | 309 |
| Total non-current liabilities | 1,432,917 | 1,225,565 |
| Current liabilities | | |
| Trade and other payables | 52,662 | 49,188 |
| Lease liabilities | 8,579 | 5,163 |
| Current maturities of borrowings | 13,594 | 19,916 |
| Liabilities to related parties | 1,189 | 1,131 |
| Contract liabilities | 53,419 | 36,915 |
| Taxes payable | 1,721 | 934 |
| Other current liabilities | 55,590 | 54,047 |
| Total current liabilities | 186,754 | 167,294 |
| Total liabilities | 1,619,671 | 1,392,859 |
| Total equity and liabilities | 958,819 | 828,443 |

Unaudited Condensed Consolidated Interim Statements of Cash Flows

| <i>USD in thousands</i> | Nine months ended 30 September 2023 | Nine months ended 30 September 2022 |
|---|--|--|
| Cash flows from operating activities | | |
| Loss for the period | (275,174) | (193,073) |
| Adjustments for non-cash items: | | |
| Gain on extinguishment of SARs liability | - | (4,803) |
| Share listing expense | - | 83,411 |

| | | |
|---|------------------|------------------|
| Share-based payment expense | 15,199 | 5,686 |
| Depreciation and amortization | 17,485 | 15,084 |
| Impairment of other intangible assets | - | 2,765 |
| Loss on disposal of property, plant and equipment | 323 | - |
| Change in allowance for receivables | 18,500 | - |
| Share of net loss of joint venture | 3,983 | 1,732 |
| Finance income | (46,383) | (97,299) |
| Finance costs | 107,826 | 69,200 |
| Gain on extinguishment of financial liabilities | - | (17,800) |
| Exchange rate difference | (884) | (13,643) |
| Income tax benefit | (67,076) | (14,771) |
| Operating cash flow before movement in working capital | (226,201) | (163,511) |
| Increase in inventories | (10,525) | (28,401) |
| (Increase) / decrease in trade receivables | 11,027 | 4,437 |
| Increase in net liabilities with related parties | 15 | 1,188 |
| (Increase) / decrease in contract assets | 2,031 | (8,286) |
| Increase in other assets | (15) | (10,297) |
| Increase in trade and other payables | (566) | 9,884 |
| Increase / (decrease) in contract liabilities | 32,182 | (10,340) |
| Increase / (decrease) in other liabilities | (21,737) | (29,214) |
| Cash used in operations | (213,789) | (234,540) |
| Interest received | 46 | 14 |
| Interest paid | (30,582) | (13,072) |
| Income tax paid | (697) | (416) |
| Net cash used in operating activities | (245,022) | (248,014) |
| Cash flows from investing activities | | |
| Acquisition of property, plant and equipment | (29,440) | (28,942) |
| Disposal of property, plant and equipment | 133 | 379 |
| Acquisition of intangible assets | (6,571) | (9,591) |
| Restricted cash in connection with the amended bond agreement | - | (14,914) |
| Net cash used in investing activities | (35,878) | (53,068) |
| Cash flows from financing activities | | |
| Repayments of borrowings | (97,538) | (2,206) |
| Repayments of principal portion of lease liabilities | (5,838) | (6,990) |
| Proceeds from new borrowings | 244,908 | 16,537 |
| Gross proceeds from the private placement equity offering fee | 136,877 | - |
| Gross private placement equity offering fee paid | (4,141) | - |
| Proceeds from warrants | 6,390 | - |
| Gross proceeds from the PIPE Financing | - | 174,930 |
| Gross PIPE Financing fees paid | - | (5,561) |
| Proceeds from the Capital Reorganization | - | 9,827 |
| Proceeds from loans from related parties | - | 110,000 |
| Net cash generated from financing activities | 280,658 | 296,537 |
| Decrease in cash and cash equivalents | (242) | (4,545) |
| Cash and cash equivalents at the beginning of the period | 66,427 | 17,556 |
| Effect of movements in exchange rates on cash held | 2,130 | (167) |
| Cash and cash equivalents at the end of the period | 68,315 | 12,844 |