



Alvotech Reports Financial Results for First Nine Months of 2022 And Provides Business Update

November 16, 2022

- Revenue for first nine months of 2022 increased to \$59.2 million, compared to \$2.0 million for the same period in 2021
- Discussions with U.S. FDA progressed regarding both biologic license applications for AVT02 (adalimumab); aiming to launch in the U.S., if approved, on July 1, 2023; additional regulatory approvals granted in major markets
- Continued pipeline progression with submission of marketing applications for AVT04, biosimilar candidate to Stelara®, in major markets including the U.S. and EU
- Management to conduct a business update conference call and live webcast on Wednesday, November 16, 2022 at 8:00 am ET (13:00 pm GMT)

REYKJAVIK, Iceland, Nov. 15, 2022 (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 2022 and provided a summary of recent corporate highlights.

"Submission of new regulatory applications, further approvals and expanded commercial partnerships demonstrate strong progress of our strategy and continued commitment to our vision for the biosimilars market," said founder and Executive Chairman of Alvotech, Robert Wessman. "We are engaging with the FDA to resolve outstanding issues regarding manufacturing site inspection status and anticipate meeting our launch date of July 1, 2023 for our proposed biosimilar to Humira® in the U.S., with the potential to be the first high-concentration, interchangeable biosimilar."

Pipeline and Partnership Highlights

Presented AVT02 switching study data at American College of Rheumatology Conference 2022

Alvotech presented two posters and held an Ignite Talk outlining data from a switching study conducted to investigate the pharmacokinetics (PK), immunogenicity, efficacy and safety in patients undergoing repeated switches between Humira® and AVT02. The results of the switching study, which demonstrate bioequivalence of repeated switches between administration of Humira® and AVT02 to administration of Humira® without switching, were included in Alvotech's interchangeable Biologics License Application, which was [accepted for filing by the FDA in February 2022](#).

Reported update on initial AVT02 Biologics License Application: Alvotech received communication in September 2022 from the U.S. Food and Drug Administration (FDA) noting certain deficiencies related to the March 2022 inspection of Alvotech's manufacturing facility in Reykjavik, Iceland, and stated that satisfactory resolution of the deficiencies is required before FDA may approve this BLA. Alvotech progressed discussions with the FDA in addressing outstanding issues.

Expanded exclusive partnership with JAMP Pharma: Alvotech has expanded its exclusive partnership with JAMP Pharma covering the Canadian market to commercialize biosimilars developed and manufactured by Alvotech, by adding two biosimilar candidates from Alvotech's pipeline: AVT16, a biosimilar for an immunology product, and AVT33, a biosimilar for an oncology product.

Application submitted for marketing approval of first biosimilar candidate in Japan: Alvotech's commercialization partner Fuji Pharma Co., Ltd. submitted an application to the Japanese Ministry of Health, Labor and Welfare for marketing approval of AVT04, biosimilar to Stelara® (ustekinumab), developed under the companies' exclusive commercialization partnership.

Increased access to adalimumab for patients in Switzerland: Alvotech and STADA announced the launch of Hukyndra® (adalimumab), a biosimilar to Humira® in Switzerland. Hukyndra® has already launched in multiple European markets. STADA is supporting launches in individual countries through tailored educational materials as well as dedicated patient support programs.

Gained approval for Ciptunec™ and Aralicip™ (adalimumab) in Australia: Alvotech's commercialization partner, Cipla Limited's wholly owned subsidiary Cipla Limited Australia, received marketing approval in Australia for Alvotech's AVT02 (adalimumab) biosimilar to Humira® as Ciptunec™/Aralicip™.

Gained approval for Simlandi (adalimumab) in Saudi Arabia: Alvotech's AVT02 (adalimumab) biosimilar to Humira®, received marketing approval in Saudi Arabia as Simlandi™ (adalimumab). Alvotech's exclusive commercialization partner in Saudi Arabia is YAS Holding LLC and its wholly owned subsidiary Bioventure.

Corporate Highlights

Appointed Sarah Tanksley as Chief Quality Officer: Alvotech appointed Sarah Tanksley as Chief Quality Officer, effective October 14, 2022. Ms. Tanksley has 20 years of experience within the U.S. National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA), and as an industry consultant.

Financial Results for First Nine Months of 2022

Cash position

As of September 30, 2022, the Company had cash and cash equivalents of \$12.8 million. In addition, the Company had borrowings of \$518.6 million, including \$75.0 million of current portion of borrowings, as of September 30, 2022.

Revenue

Revenue was \$59.2 million for the nine months ended September 30, 2022, compared to \$2.0 million for the same nine months of 2021. Revenue for the nine months ended September 30, 2022 consisted of \$11.1 million of product revenue from sales of AVT02 in selected European countries and Canada, and \$48.1 million of license and other revenue from milestone payments related to the AVT04 main clinical program and the AVT05 clinical trial application.

Cost of product revenue

Cost of product revenue was \$35.4 million for the nine months ended September 30, 2022. These costs were primarily a result of the successful launch of AVT02 in select European countries and Canada during the nine months ended September 30, 2022. These costs included both variable and fixed manufacturing expenses associated with commercial manufacturing, resulting in higher costs than revenues recognized for the period. The Company expects this to normalize as it increases in scale and expands on existing and new product launches, which will result in increased absorption of fixed manufacturing costs. Prior to recognition of cost of product revenue, these costs were reported as research and development expenses as pre-commercial manufacturing activity.

Research and development (R&D) expenses

R&D expenses were \$133.1 million for the nine months ended September 30, 2022, compared to \$146.6 million for the same nine months of 2021. The decrease was primarily driven by manufacturing costs that were previously recognized as R&D expense, but are now being recognized as cost of product revenue in conjunction with the Company's first commercial launch, partly offset by increase in direct program expenses. Increase in direct program expenses was driven by AVT05 and AVT03 entering into clinical development, while AVT02 and AVT04 related spending decreased as the clinical activities for these programs wind down.

General and administrative (G&A) expenses

G&A expenses were \$156.5 million for the nine months ended September 30, 2022, compared to \$106.3 million for the same nine months of 2021. The increase in G&A expenses was primarily attributable to the \$83.4 million non-cash share listing expense and an increase of \$16.2 million of transaction costs recognized as a result of the business combination with Oaktree Acquisition Corp. II in June 2022, and the listing application process for the Nasdaq Main Market in Iceland. In addition, there were incremental costs associated with beginning operations as a public company. These expenses were partially offset by a \$55.4 million decrease in expense related to the long-term incentive plan.

Finance income

Finance income was \$97.3 million for the nine months ended September 30, 2022. This 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 \$69.2 million for the nine months ended September 30, 2022, compared to \$157.4 million for the same nine months of 2021. The decrease in finance costs was primarily attributable to the extinguishment of the convertible bonds and shareholder loans during the year ended December 31, 2021. The derivative liabilities associated with the convertible bonds and loans resulted in \$72.0 million of finance costs recognized during the nine months ended September 30, 2021, due to the change in fair value. There was \$31.8 million of interest expense recognized on the extinguished convertible shareholder loans during the nine months ended September 30, 2021. The decreases related to the extinguished liabilities were partially offset by \$7.4 million of expense recognized for the special put option and consent fee paid to bondholders, and a \$6.5 million loss on the remeasurement of bonds during the nine months ended September 30, 2022.

Exchange rate differences

Exchange rate differences resulted in a gain of \$13.6 million for the nine months ended September 30, 2022, compared to a gain of \$3.2 million for the same nine months of 2021. The increase was primarily driven by the impact of the exchange rate to financial assets and liabilities denominated in Icelandic Krona.

Gain on extinguishment of financial liabilities

Alvotech recognized a gain on extinguishment of financial liabilities of \$17.8 million during the nine months ended September 30, 2022, compared to a gain of \$2.6 million for the same nine months of 2021. The gain recognized in 2022 relates to the settlement of related party loans with shares, while the amount in 2021 relates to the substantial modification to the terms and conditions of the convertible bonds and other related, concurrent transactions.

Income tax benefit

Income tax benefit was \$14.8 million for the nine months ended September 30, 2022, compared to \$48.0 million for the same nine months of 2021. The decrease was primarily driven by a \$15.8 million lower tax credit on net operating losses, for which Alvotech expects will be fully utilized against future taxable profits, and a foreign currency impact of \$17.3 million due to weakening of the Icelandic Krona against the U.S. dollar which decreased the U.S. dollar value of tax loss carry-forwards expected to be utilized against future taxable profits.

Net Loss

Net loss was 193.1 million, or (\$1.00) per share on a basic and diluted basis, for the nine months ended September 30, 2022, as compared to net loss of \$355.3 million, or (\$3.48) per share on a basic and diluted basis, for the same nine months of 2021.

Business Update Conference Call

Alvotech will conduct a business update conference call and live webcast on Wednesday, November 16, at 8:00 am ET (1:00 pm GMT).

A live webcast of the call will be available on Alvotech's website in the Investors Section of the Company's website 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.

In order to participate in the conference call, please register in advance using the link on Alvotech's Investor Relations website under [News and Events – Events and Presentations](#), to obtain a local or toll-free phone number and your personal pin.

About AVT02 (adalimumab)

AVT02 is a monoclonal antibody that is being evaluated for biosimilarity and interchangeability to Humira® (adalimumab), which inhibits tumor necrosis factor (TNF). AVT02 has been approved in the EU, Norway, Iceland, Lichtenstein, the UK and Switzerland (Hukyndra®); Canada and Saudi Arabia (Simlandi®); and Australia (Ciptunec™ and Aralicip™). AVT02 dossiers are under review in multiple countries, including in the United States

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. Abnormal regulation of these cytokines has been associated with immune mediated diseases, such as psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. 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.

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

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 or operating performance of Alvotech and may include, for example, Alvotech's expectations regarding future growth, results of operations, performance, future capital and other expenditures including the development of critical infrastructure for the global healthcare markets, 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, the re-inspection of Alvotech's manufacturing site, the potential approval, including for AVT02 and AVT04 by the FDA and other regulatory agencies and commercial launch of its product candidates, the timing of the announcement of clinical study results, the commencement of patient studies, regulatory applications, 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 raise substantial additional funding, which may not be available on acceptable terms or at all; (3) the ability to maintain stock exchange listing standards or meet requirements for listing on the Nasdaq Main Market in Iceland; (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 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 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. 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CONTACTS

Alvotech Investor Relations and Global Communication

Benedikt Stefansson, [alvotech.ir\[at\]alvotech.com](mailto:alvotech.ir[at]alvotech.com)

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

	Nine months ended 30 September 2022	Nine months ended 30 September 2021
<i>USD in thousands, except for per share amounts</i>		
Product revenue	11,060	-
License and other revenue	48,111	2,008
Other income	197	911
Cost of product revenue	(35,362)	-
Research and development expenses	(133,140)	(146,605)
General and administrative expenses	(156,520)	(106,304)
Operating loss	(265,654)	(249,990)
Share of net loss of joint venture	(1,732)	(1,674)
Finance income	97,299	7
Finance costs	(69,200)	(157,355)
Exchange rate differences	13,643	3,234
Gain on extinguishment of financial liabilities	17,800	2,561
Non-operating profit / (loss)	57,810	(153,227)
Loss before taxes	(207,844)	(403,217)
Income tax benefit	14,771	47,955
Loss for the period	(193,073)	(355,262)
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	(8,852)	(429)
Total comprehensive loss	(201,925)	(355,691)
Loss per share		
Basic and diluted loss for the period per share	(1.00)	(3.48)

Unaudited Condensed Consolidated Interim Statement of Financial Position

	30 September 2022	31 December 2021
<i>USD in thousands</i>		
Non-current assets		
Property, plant and equipment	94,614	78,530
Right-of-use assets	134,709	126,801
Goodwill	10,656	12,367
Other intangible assets	22,915	21,509
Contract assets	2,719	1,479
Investment in joint venture	47,683	55,307
Other long-term assets	5,200	1,663
Restricted cash	25,001	10,087
Deferred tax assets	185,956	170,418
Total non-current assets	529,453	478,161

Current assets		
Inventories	67,459	39,058
Trade receivables	24,959	29,396
Contract assets	25,005	17,959
Other current assets	22,210	14,736
Receivables from related parties	1,196	1,111
Cash and cash equivalents	12,844	17,556
Total current assets	<u>153,673</u>	<u>119,816</u>
Total assets	<u><u>683,126</u></u>	<u><u>597,977</u></u>

Unaudited Condensed Consolidated Interim Statement of Financial Position

<i>USD in thousands</i>	30 September 2022	31 December 2021
Equity		
Share capital	2,126	135
Share premium	1,058,432	1,000,118
Translation reserve	(4,183)	4,669
Accumulated deficit	(1,333,607)	(1,140,534)
Total equity	<u>(277,232)</u>	<u>(135,612)</u>
Non-current liabilities		
Borrowings	443,643	398,140
Derivative financial liabilities	151,442	-
Other long-term liability to related party	7,440	7,440
Lease liabilities	110,090	114,845
Long-term incentive plan	4,568	56,334
Contract liabilities	40,309	44,844
Deferred tax liability	385	150
Total non-current liabilities	<u>757,877</u>	<u>621,753</u>
Current liabilities		
Trade and other payables	36,441	28,587
Lease liabilities	8,034	7,295
Current maturities of borrowings	74,986	2,771
Liabilities to related parties	4,333	638
Contract liabilities	23,887	29,692
Taxes payable	996	841
Other current liabilities	53,804	42,012
Total current liabilities	<u>202,481</u>	<u>111,836</u>
Total liabilities	<u>960,358</u>	<u>733,589</u>
Total equity and liabilities	<u><u>683,126</u></u>	<u><u>597,977</u></u>

Unaudited Condensed Consolidated Interim Statements of Cash Flows

<i>USD in thousands</i>	Nine months ended 30 September 2022	Nine months ended 30 September 2021
Cash flows from operating activities		
Loss for the period	(193,073)	(355,262)

Adjustments for non-cash items:		
Gain on extinguishment of SARs liability	(4,803)	-
Share listing expense	83,411	-
Long-term incentive plan	5,686	61,075
Depreciation and amortization	15,084	13,610
Impairment of property, plant and equipment	-	2,155
Impairment of other intangible assets	2,765	3,993
Share of net loss of joint venture	1,732	1,674
Finance income	(97,299)	(7)
Finance costs	69,200	157,355
Gain on extinguishment of financial liabilities	(17,800)	(2,561)
Exchange rate difference	(13,643)	(3,234)
Income tax benefit	(14,771)	(47,955)
Operating cash flow before movement in working capital	(163,511)	(169,157)
Increase in inventories	(28,401)	(11,994)
(Increase) / decrease in trade receivables	4,437	(5,381)
Increase in net liabilities with related parties	1,188	1,455
(Increase) / decrease in contract assets	(8,286)	21,455
Increase in other assets	(10,297)	(6,409)
Increase in trade and other payables	9,884	11,433
Increase / (decrease) in contract liabilities	(10,340)	23,967
Increase / (decrease) in other liabilities	(29,214)	707
Cash used in operations	(234,540)	(133,924)
Interest received	14	4
Interest paid	(13,072)	(23,166)
Income tax paid	(416)	(326)
Net cash used in operating activities	(248,014)	(157,412)
Cash flows from investing activities		
Acquisition of property, plant and equipment	(28,942)	(6,876)
Disposal of property, plant and equipment	379	-
Acquisition of intangible assets	(9,591)	(3,023)
Restricted cash in connection with the amended bond agreement	(14,914)	-
Net cash used in investing activities	(53,068)	(9,899)
Cash flows from financing activities		
Repayments of borrowings	(2,206)	(36,754)
Repayments of principal portion of lease liabilities	(6,990)	(4,818)
Proceeds from the Capital Reorganization	9,827	-
Gross proceeds from the PIPE Financing	174,930	-
Gross PIPE Financing fees paid	(5,561)	-
Proceeds from loans from related parties	110,000	-
Proceeds from new borrowings	16,537	114,282
Net proceeds on issue of equity shares	-	66,850
Net cash generated from financing activities	296,537	139,560
Decrease in cash and cash equivalents	(4,545)	(27,751)
Cash and cash equivalents at the beginning of the period	17,556	31,689
Effect of movements in exchange rates on cash held	(167)	48
Cash and cash equivalents at the end of the period	12,844	3,986