Alvotech Reports Financial Results for the First Nine Months of 2024

November 13, 2024

- *Total Revenues in the first nine months of 2024 increased by $300 million compared to same period in 2023, to $339 million, with Q3 revenues contributing $103 million*

- *Product revenues in the first nine months of 2024 increased over four-fold compared to the same period last year, to $128 million, with Q3 product revenues contributing $62 million*

- *License and other revenues for the first nine months of 2024 increased by $203 from the same period last year, to $211 million, with Q3 license and other revenues contributing $41 million*

- *Adjusted EBITDA was $87 million in the first nine months of 2024, compared to negative ($225) million for the same period last year, with Q3 adjusted EBITDA contributing $23 million*

- *Marketing applications were accepted in Europe for biosimilar candidates to Prolia®/Xgeva® (denosumab) and Simponi (golimumab) and Alvotech initiated a confirmatory clinical study for AVT16, a biosimilar candidate to Entyvio® (vedolizumab)*

- *Alvotech will conduct a business update conference call and live webcast on Thursday, November 14, 2024, at 8:00 am ET (13:00 GMT)*

REYKJAVIK, Iceland, Nov. 13, 2024 (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 2024 and provided a summary of recent corporate highlights.

"We are delighted by the results in the quarter and the first nine months of 2024. The third quarter marked our second consecutive quarter with positive adjusted EBITDA and operating profit. Not only did we see growth in product revenue compared to the previous quarter, but we also experienced a more than doubling of product gross margins, primarily due to improved utilization and scale at our manufacturing site," said Robert Wessman, Chairman and CEO of Alvotech. "We are also pleased with the steady progress of our pipeline, which included multiple filing acceptances in Europe and the initiation of our confirmatory clinical study for AVT16, our proposed biosimilar to Entyvio. The continued execution of our research and development activities not only contributes to our topline through milestone revenues but also provides further opportunities for the company to grow and diversify in the future."

Product development highlights

Alvotech announced that the European Medicines Agency (EMA) accepted a Marketing Authorization Application (MAA) for AVT03, a proposed biosimilar to Prolia® and Xgeva® (denosumab) and an MAA for AVT05, a proposed biosimilar to Simponi® (golimumab). For European markets, Alvotech has partnership agreements for commercialization of AVT03 with STADA and Dr. Reddy's Laboratories and for AVT05 with Advanz Pharma.

Alvotech announced the initiation of a confirmatory patient study for AVT16, a proposed biosimilar to Entyvio® (vedolizumab). Entyvio, which generated approximately $5.4 billion in global sales in the twelve months until June 30, 2024 [1], is used to treat ulcerative colitis and Crohn's disease [2].

Alvotech and Teva Pharmaceuticals announced that the U.S. FDA has approved a new presentation of SELARSDI™ (ustekinumab-aekn), a biosimilar to Stelara® (ustekinumab), in a 130 mg/26 mL single-dose vial for intravenous infusion. This approval also expands SELARSDI's label to include treatment for adults with Crohn's disease and ulcerative colitis, aligning it with the reference product's indications. The U.S. launch of SELARSDI is expected in February 2025.

Summary of the Financial Results for First Nine Months of 2024

Cash position and sources of liquidity: As of September 30, 2024, the Company had cash and cash equivalents of $118.3 million. In addition, the Company had borrowings of $1,028.2 million, including $22.2 million of current portion of borrowings.

Product Revenue: Product revenue was $128.0 million for the nine months ended September 30, 2024, compared to $29.8 million for the same nine months of 2023. Revenue for the nine months ended September 30, 2024, consisted of product revenue from sales of AVT02 in select European countries and Canada, launch of AVT02 in the U.S., and launch of AVT04 in Canada, Japan and select European markets.

License and Other Revenue: License and other revenue was $210.5 million for the nine months ended September 30, 2024, compared to $8.2 million for the same nine months of 2023. The license and other revenue of $210.5 million was primarily attributable to the recognition of a $6.6 million research and development milestone due to the approval of AVT04 in Europe, $16.8 million relative to research and development milestone due to the commencement of a clinical phase for the AVT16 program, $22.3 million due to the MAA submission for AVT03 and AVT06, and $95.6 million due to the Confirmatory Efficacy and Safety (CES) trial completion of AVT03 and AVT05. This also included $41.1 million of performance milestone relative to the product launch of AVT04 in Japan and Europe, the achievement of sales target of AVT02 in Europe and Canada, and the product launch of AVT02 in the U.S., and a net milestone revenue of $26.4 million for the execution of out-license contracts during the nine months ended September 30, 2024.

Cost of product revenue: Cost of product revenue was $105.0 million for the nine months ended September 30, 2024, compared to $104.4 million for the same nine months of 2023, as a result of sales in the period, including the launch of AVT02 in the U.S., AVT04 in Canada, Japan and select European countries tempered by lower production-related charges and lower costs associated with FDA inspection readiness.

Research and development (R&D) expenses: R&D expenses were $131.1 million for the nine months ended September 30, 2024, compared to $152.8 million for the same nine months of 2023. The decrease 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 recognized during the nine months of 2023, a decrease of $4.3 million primarily related to programs which have completed clinical phase (i.e., AVT02 and AVT04 programs), a decrease of $6.0 million related to programs for which the clinical phase is substantially completed (i.e. AVT03, AVT05, and AVT06), and overall lower headcount and other R&D expenses of $11.4 million, partially offset by a $17.4 million increase in direct program expenses mainly due to AVT16 that is in clinical phase.

General and administrative (G&A) expenses: G&A expenses were $46.4 million for the nine months ended September 30, 2024, compared to $58.6 million for the same nine months of 2023. The decrease in G&A expenses was primarily attributable to $6.6 million in lower third-party services, lower insurance premiums and less headcount, coupled with a $4.6 million decrease in expenses for share-based payments.

Operating profit: Operating profit was $56.2 million for the nine months ended September 30, 2024, compared to ($277.7) million for the same nine months of 2023. The increase of $333.9 million was primarily attributable to the sharp increase in total revenues due to a combination of expansion of our product launches and milestones recognition for advancing our product through our pipeline and achieving contractual sales targets. This is coupled with a decrease in operating expenses driven by continuing efforts by the Company to scale and rationalize operations.

Share of net loss of joint venture and loss on interest in joint venture: In June 2024, Alvotech sold its share in the joint venture for gross proceeds of $18.0 million (less $1.3 million in transaction costs). The sale resulted in a net loss of $3.0 million during the nine months ended 30 September 2024.

Finance income: Finance income was $79.1 million for the nine months ended September 30, 2024, compared to $46.4 million for the same nine months of 2023. Finance income for the nine months ended September 30, 2024, was primarily attributable to the change in fair value of the Tranche A Conversion Feature of the 2022 Convertible bonds impacted by the bond holders exercising their right to conversion into ordinary shares on the last scheduled conversion date prior to maturity, which was July 1, 2024. The Finance income for the nine months ended September 30, 2023, was mainly attributable to a favorable change in fair value of the Predecessors Earn Out shares.

Finance costs: Finance costs were $237.7 million for the nine months ended September 30, 2024, compared to $107.8 million for the same nine months of 2023. The Finance costs for the nine months ended September 30, 2024, were primarily comprised of a $107.3 million change in fair value of the Predecessors Earn Out shares, which was negatively impacted by the increase in the Company's share price during that period, and by interest charges on outstanding debts of $115.0 million.

Exchange rate differences: Exchange rate differences resulted in a gain of $1.7 million for the nine months ended September 30, 2024, compared to a gain of $0.9 million for the same nine months of 2023. The change was primarily driven by the movements in the exchange rate of the dollar against other currencies, predominantly Icelandic krona and euros.

Loss on extinguishment of financial liabilities: On June 7, 2024, the Company entered into a $965.0 million Facility, maturing in July 2029, that was funded in July 2024. Upon the closing of the Facility, the Company was required to settle its existing debt obligations. In parallel, the Company announced that all holders of the Tranche A and some holders of the Tranche B of the 2022 Convertible Bonds exercised their right to conversion into ordinary shares at the fixed conversion price of $10.00 per share on the last scheduled conversion date prior to maturity, which is July 1, 2024. Similarly, some holders of the Aztiq Convertible Bonds decided to exercise similar conversion right into ordinary shares at the same conversion price. A loss on extinguishment of financial liabilities of $69.0 million related to the refinancing of existing debt obligations, including the conversion of the 2022 Convertible Bonds and Aztiq Convertible Bonds, was recorded during the nine months ended September 30, 2024.

Income tax benefit: Income tax benefit was $8.2 million for the nine months ended September 30, 2024, compared to a benefit of $67.1 million for the same nine months of 2023. The decrease in benefit was mainly driven by a decrease of $61.1 million in deferred tax credit corresponding to lower operating losses and a $4.2 million decrease in foreign currency impact on the strengthening of the Icelandic Krona against the U.S. Dollar, increasing the U.S. Dollar value of Icelandic tax loss carry-forwards that Alvotech expects to utilize against future taxable profits. The decrease in income tax benefit is partly offset by an increase in other permanent differences of approximately $7.0 million.

Loss for the Period: Reported net loss was $164.9 million, or ($0.63) per share on a basic and diluted basis, for the nine months ended September 30, 2024, compared to a reported net loss of $275.2 million, or ($1.21) per share on a basic and diluted basis, for the same nine months of 2023. As mentioned above, the net loss for the period is heavily impacted by the non-cash fair value charges associated with our derivative liabilities and the impact of the refinancing of the existing debt obligations.

Business Update Conference Call

Alvotech will conduct a business update conference call and live webcast on Thursday, November 14, at 8:00 am ET (13:00 pm GMT). Registration for the conference call and access to the live webcast is found on https://investors.alvotech.com/events/event-details/q3-2024-earnings, 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 has been approved as a biosimilar to Humira® (adalimumab) in over 50 countries globally, including the U.S., Europe, Canada, Australia, Egypt, Saudi Arabia and South Africa. It is currently marketed in the U.S. as SIMLANDI and under private label (adalimumab-ryvk), in Europe as HUKYNDRA, in Canada as SIMLANDI and in Australia as ADALACIP. Dossiers are also under review in multiple countries globally.

About AVT03

AVT03 is a human monoclonal antibody and a biosimilar candidate to Prolia® and Xgeva® (denosumab). Denosumab targets and binds with high affinity and specificity to the RANK ligand membrane protein, preventing the RANK ligand/RANK interaction from occurring, resulting in reduced osteoclast numbers and function, thereby decreasing bone resorption and cancer-induced bone destruction [3]. AVT03 is an investigational product and has not received regulatory approval in any country. Biosimiliarity has not been established by regulatory authorities and is not claimed.

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 [4]. AVT04 has been launched in Canada as JAMTEKI, in the EEA as UZPRUVO, and in Japan as USTEKINUMAB BS (F). It has been approved in the U.S. as SELARSDI (ustekinumab-aekn). Dossiers are also under review in multiple countries globally.

About AVT06/AVT29

AVT06/AVT29 is a recombinant fusion protein and a biosimilar candidate to Eylea® (aflibercept) 2 mg and 8 mg dose, which binds vascular endothelial growth factors (VEGF), inhibiting the binding and activation of VEGF receptors, neovascularization, and vascular permeability [5]. AVT06/AVT29 are investigational products and have not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

About AVT16

AVT16 is a human monoclonal antibody and a biosimilar candidate to Entyvio® (vedolizumab). AVT16 is an investigational product and has not received regulatory approval in any country. Biosimiliarity has not been established by regulatory authorities and is not claimed.

Sources

[1] IQVIA
[2] Entyvio product information
[3] Prolia product information
[4] Uzpruvo product information
[5] Eylea product information

Use of trademarks

Humira is a registered trademark of AbbVie Inc. Stelara is a registered trademark of Johnson & Johnson Inc. Prolia and Xgeva are registered trademarks of Amgen Inc. Elyea is a registered trademark of Regeneron Pharmaceuticals Inc. and Bayer AG. Entyvio is a registered trademark of Millenium Pharmaceuticals Inc.

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 has launched two biosimilars. 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 www.alvotech.com. None of the information on the Alvotech website shall be deemed part of this press release.

Please visit our investor portal, and our website or follow us on social media on LinkedIn, Facebook, Instagram, X 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 to raise substantial additional funding, which may not be available on acceptable terms or at all; (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.

ALVOTECH INVESTOR RELATIONS AND GLOBAL COMMUNICATIONS
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Unaudited Condensed Consolidated Interim Statements of Profit or Loss and Other Comprehensive Income or Loss

USD in thousands, except for per share amounts	**Nine months ended 30 September 2024**	**Nine months ended 30 September 2023**
Product revenue	128,018	29,800
License and other revenue	210,459	8,244
Other income	160	56
Cost of product revenue	(104,979)	(104,437)
Research and development expenses	(131,050)	(152,813)
General and administrative expenses	(46,435)	(58,558)
Operating profit / (loss)	56,173	(277,708)
Share of net loss of joint venture	—	(3,983)
Loss on sale of investment in joint venture	(2,970)	—
Finance income	79,079	46,383
Finance costs	(237,683)	(107,826)
Exchange rate differences	1,657	884
Loss on extinguishment of financial liabilities	(69,378)	—
Non-operating loss	(229,295)	(64,542)
Loss before taxes	(173,122)	(342,250)
Income tax benefit	8,225	67,076
Loss for the period	(164,897)	(275,174)
Other comprehensive (loss)		
Item that will be reclassified to profit or loss in subsequent periods:		
Exchange rate differences on translation of foreign operations	1,347	(2,648)
Total comprehensive loss	(163,550)	(277,822)
Loss per share		
Basic and diluted loss for the year per share	(0.63)	(1.21)

Unaudited Condensed Consolidated Interim Statements of Financial Position
USD in thousands

Non-current assets	**30 September 2024**	**30 September 2023**
Property, plant and equipment	255,838	236,779
Right-of-use assets	153,044	119,802
Goodwill	12,201	12,058
Other intangible assets	20,538	19,076
Contract assets	28,828	10,856
Interest in joint venture	—	18,494
Other long-term assets	9,524	2,244

Restricted cash	—	26,132
Deferred tax assets	320,369	309,807
Total non-current assets	800,342	755,248
Current assets		
Inventories	125,014	74,433
Trade receivables	77,420	41,292
Contract assets	68,128	35,193
Other current assets	43,729	31,871
Receivables from related parties	41	896
Cash and cash equivalents	118,274	11,157
Total current assets	432,606	194,842
Total assets	1,232,948	950,090

Unaudited Condensed Consolidated Interim Statements of Financial Position

USD in thousands

Equity	**30 September 2024**	**30 September 2023**
Share capital	2,825	2,279
Share premium	2,007,784	1,229,690
Other reserves	16,607	42,911
Translation reserve	(181)	(1,528)
Accumulated deficit	(2,370,742)	(2,205,845)
Total equity	(343,707)	(932,493)
Non-current liabilities		
Borrowings	1,005,940	922,134
Derivative financial liabilities	182,361	520,553
Lease liabilities	140,762	105,632
Contract liabilities	85,502	73,261
Deferred tax liability	1,541	53
Total non-current liabilities	1,416,106	1,621,633
Current liabilities		
Trade and other payables	57,720	80,563
Lease liabilities	11,584	9,683
Current maturities of borrowings	22,217	38,025
Liabilities to related parties	1,387	9,851
Contract liabilities	16,024	59,183
Taxes payable	1,106	925
Other current liabilities	50,511	62,720
Total current liabilities	160,549	260,950
Total liabilities	1,576,655	1,882,583
Total equity and liabilities	1,232,948	950,090

Unaudited Condensed Consolidated Interim Statements of Cash Flows

USD thousands **Cash flows from operating activities**	**Nine months ended 30 September 2024**	**Nine months ended 30 September 2023**
Loss for the period	(164,897)	(275,174)
Adjustments for non-cash items:		
Depreciation and amortization	23,146	17,485
Change in allowance for receivables	—	18,500
Change in inventory reserves	(3,531)	—
Share-based payments	7,881	15,199
Loss on disposal of property, plant and equipment	184	323
Loss on sale of interest in joint venture	2,970	—
Share of net loss of joint venture	—	3,983
Finance income	(79,079)	(46,383)
Finance costs	237,683	107,826
Exchange rate difference	(1,657)	(884)
Loss on extinguishment of financial liabilities	69,378	—
Income tax benefit	(8,225)	(67,076)

Operating cash flow before movement in working capital	83,853	(226,201)
Increase in inventories	(47,050)	(10,525)
(Increase) / decrease in trade receivables	(36,128)	11,027
(Decrease) / increase in liabilities with related parties	(8,367)	15
(Increase) / decrease in contract assets	(50,907)	2,031
Increase in other assets	(9,853)	(15)
Decrease in trade and other payables	(27,937)	(566)
(Decrease) / increase in contract liabilities	(30,474)	32,182
Decrease in other liabilities	(18,721)	(21,737)
Cash used in operations	(145,584)	(213,789)
Interest received	97	46
Interest paid	(51,583)	(30,582)
Income tax paid	(571)	(697)
Net cash used in operating activities	(197,641)	(245,022)
Cash flows from investing activities		
Acquisition of property, plant and equipment	(24,091)	(29,440)
Disposal of property, plant and equipment	—	133
Acquisition of intangible assets	(1,857)	(6,571)
Restricted cash in connection with debt extinguishment	26,132	—
Proceeds from the sale in joint venture	12,000	—
Net cash generated from (used in) investing activities	12,184	(35,878)
Cash flows from financing activities		
Repayments of borrowings	(745,448)	(97,538)
Repayments of principal portion of lease liabilities	(7,669)	(5,838)
Proceeds from new borrowings	900,805	244,908
Transaction cost from new borrowings	(4,236)	—
Gross proceeds from equity offering	150,451	136,877
Fees from equity offering	(5,812)	(4,141)
Proceeds from warrants	4,843	6,390
Stock options exercised	76	—
Net cash generated from financing activities	293,010	280,658
Increase / (decrease) in cash and cash equivalents	107,553	(242)
Cash and cash equivalents at the beginning of the year	11,157	66,427
Effect of movements in exchange rates on cash held	(436)	2,130
Cash and cash equivalents at the end of the period	118,274	68,315